独立行政法人医薬品医療機器総合機構

平成 30 年度アジア諸国
医薬品・医療機器規制
情報収集・分析事業

調査報告書

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第 1 章　調査概要

1.1 調査の背景と目的

医薬品ならびに医療機器は人々の生命に関わる製品であり、適切かつ高度な規制が求められる。その一方で、近年、医薬品ならびに医療機器は世界規模で開発・製造・流通されるようになり、各国の薬事規制機関は、自国のみではその役割を全うすることが難しく、他国の薬事規制機関との密接な協力・連携が求められている。

日本の薬事規制機関である独立行政法人医薬品医療機器総合機構（Pharmaceuticals and Medical Devices Agency、 以下「PMDA」とする。）は、世界各国の薬事規制機関との連携や国際会議等での国際調和等の国際活動に尽力し、世界各国ならびに近隣のアジア諸国の薬事規制を牽引し、世界の保健水準の向上に貢献している。PMDA は 2016 年 4 月に、アジア諸国に対して日本の薬事規制の理解を促すことを目的に、薬事規制に関するアジア諸国の規制当局の人材の育成機関「アジア医薬品・医療機器トレーニングセンター」を設置し、国内および海外で研修等を実施している。

同センターにおいて効果的な研修等の企画・立案および実施をするためには、研修の対象となる国・地域での最新の薬事規制に関する情報を収集・分析する必要がある。今回、同センターによる研修等が予定されているバングラデシュ人民共和国について、最新の薬事規制に関する基礎情報の収集・分析業務を実施した。

1.2 調査対象国の概況

本調査の対象国は、バングラデシュ人民共和国（以下、「バングラデシュ」とする。）である。バングラデシュの一般概況および保健医療概況を以下に記述する。

1.2.1 バングラデシュの一般概況

南アジアに位置するバングラデシュは、国土の大部分がガンジス川をはじめとした大河の三角州地帯にある。同国は西、北、東方をインドに囲まれ、東南部はミャンマーと国境を接する。南部はベンガル湾に面しており、湿地帯が多い。また、国土面積（14 万 7 千㎢）は日本の約 4 割であるのに対して、人口は約 1 億 6000 万人と人口密度が非常に高い国である[1]。バングラデシュは堅調な経済成長を続けているが、一人当たりの国民総所得（2017 年）は USD1,470[2]であり、世界銀行の所得階層別分類では低中所得国[3]に分類されている。

1.2.2 バングラデシュの保健医療概況

主な保健指標を表 1-1 に示す。バングラデシュの平均寿命（出生時の平均余命）は、男性は 71 歳、女性は 74 歳である。母子保健指標はいずれも改善傾向にあり、バングラデシ

[1] 「世界の医療事情　バングラデシュ ｜ 外務省」（https://www.mofa.go.jp/mofaj/toko/medi/asia/bangla.html.、2018 年 10 月 2 日閲覧）

[2] 世界銀行 Altras Method を使用。世界銀行 Web サイト（https://data.worldbank.org/indicator/NY.GNP.PCAP.CD?locations=BD、2018 年 12 月 9 日閲覧）

[3] 一人当たりの国民総所得が USD996 から USD3,895 までに該当する国が、低中所得国に分類される（https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups）

ュが属する南アジア地域[4]の平均と比較しても良好な数値である。

表 1-1：主な保健指標

指標	年	男性	女性	南アジア地域
平均寿命（出生時の平均余命）*1	2016	71.1 歳	74.4 歳	-
健康寿命 注 1）*1	2016	-	-	63.3 歳
新生児死亡率（対千出生）*2	2016	20 人		28 人
乳幼児死亡率（対千出生）*2	2016	28 人		39 人
5 歳未満児死亡率（対千出生）*2	2016	34 人		48 人
妊産婦死亡率（対 10 万出生）*2	2016	-	176 人	182 人

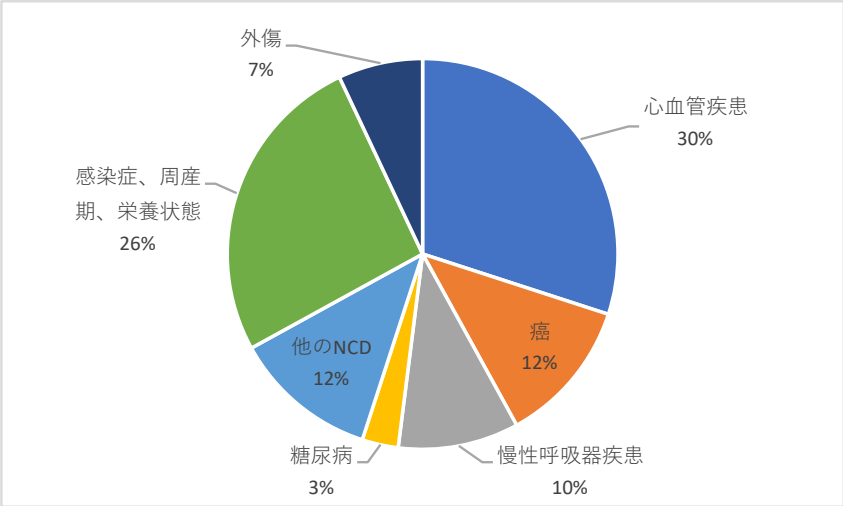
注 1）人の寿命において、「健康上の問題で日常生活に制限されることなく生活できる期間」

出典：*1：World Health Statistics 2018, World Health Organization

***2：The State of the World's Children 2017 (unicef)**

バングラデシュの死亡要因（2016 年）を図 1-1 に示す。死亡要因は、心血管疾患が全体の 30%を占め、第 1 位となっている。次いで癌が 12%と第 2 位の死亡要因となっている。死亡要因の 67%が非感染性疾患によるものと推定される。

また、非感染性疾患の主要なリスク要因を表 1-2 に示す。日本の状況と比較するとバングラデシュの 15 歳以上の人口に占める喫煙者は男性が 44%と高い（日本は男性 32%、女性 9%）。また、18 歳以上の人口に占める高血圧の患者の割合が男女共に 20%程度（日本は男性 30%、女性 24%）、18 歳以上の人口に占める肥満の割合が男性は 2%で女性は 5%であり、女性の方の割合が高い（日本は男性 5%、女性 4%）。



出典：World Health Organization Noncommunicable Diseases (NCD) Country Profiles, 2018

図 1-1：バングラデシュの死亡要因（2016 年）

[4] 南アジア地域に属するのは、アフガニスタン、バングラデシュ、ブータン、インド、モルディブ、ネパール、パキスタン、スリランカである（The State of the World's Children 2017、UNICEF）。

表 1-2：非感染性疾患の主要なリスク要因

指標	年	バングラデシュ		日本	
		男性	女性	男性	女性
15 歳以上の人口に占める喫煙者の割合	2016	44%	1%	32%	9%
18 歳以上の人口に占める高血圧[注1）]患者の割合	2015	22%	20%	30%	24%
18 歳以上の人口に占める肥満[注2）]の割合	2016	2%	5%	5%	4%

注 1）収縮期血圧（SBP）140mmHg 以上、または拡張期血圧（DBP）90mmHg 以上を高血圧と定義。

注 2）BMI 値が 30kg/㎡以上と定義。

出典：World Health Organization Noncommunicable Diseases (NCD) Country Profiles, 2018

1.3 調査項目

本調査の調査項目は、表 1-3 のとおりである。

表 1-3：調査項目

No	調査項目
1	医薬品および医療機器の定義および分類
2	医薬品および医療機器の承認等（認証を含む。）に関する規制（承認制度、申請資料の信頼性保証の仕組みを含む。）の内容、およびその動向
3	医薬品および医療機器の市販後の安全対策（副作用情報の収集・分析・医療現場への情報提供の方法（含む添付文書改訂）や体制、不良品の回収、偽造品等）に関する規制の内容、およびその動向
4	医薬品および医療機器の製造・品質管理に関する規制（GMP、QMS、薬局方等）の内容、およびその動向
5	医薬品および医療機器の非臨床試験の実施方法等に関する規制（GLP 等）の内容、およびその動向
6	医薬品および医療機器の臨床試験（治験）の実施方法等に関する規制（GCP 等）の内容、およびその動向
7	医薬品および医療機器の副作用等の被害救済に関する制度の内容、およびその動向
8	医薬品・医療機器の販売規制（医師の処方せんの必要性、入手可能な店舗および交付者に関する規制）に関する制度の内容、およびその動向
9	医薬品および医療機器の開発方針、必要な試験の内容、試験計画等に関する相談の仕組み、その内容および動向
10	規制当局の審査、調査等のパフォーマンス（組織体制、人員等を含む）
11	外国規制当局の基準および評価結果への依拠（承認審査や調査結果の同等性認定、簡略承認審査プロセス、参照薬局方、相互承認協定等）に関する制度の内容、およびその動向
12	政府での規制改革の取組の有無、およびその内容
13	産業界から規制当局に対する要望の有無、およびその内容

1.4 調査手法

インターネットで公開されている関連の文献等の調査を行った後、バングラデシュの医薬品・医療機器規制について知見を有する日本国内および在バングラデシュの有識者（規制当局関係者を含む）に対するヒアリング調査を実施した。

第 2 章　バングラデシュにおける薬事の規制当局および法規制

2.1 バングラデシュにおける薬事の規制当局

バングラデシュにおける薬事規制を所管するのは保健家族福祉省の医薬品管理総局（The Directorate General of Drug Administration、以下「DGDA」とする）である。1976 年に保健家族福祉省の保健サービス総局（The Directorate General of Health Services）の傘下に設立された医薬品管理局（The Directorate of Drug Administration）が、2010 年に現在の総局（Directorate General）に昇格している[5]。DGDA は、全ての薬事（原材料および梱包資材の調達、医薬品の製造・輸入、輸出、販売、価格設定など）に関する規制と監督に関連する業務を実施する[6]。

2.2 薬事関連の法規制

バングラデシュにおける主要な薬事関連の法律は、（1）医薬品法 1940 およびその改正（医薬品規則 1945 および医薬品規則 1946）、（2）医薬品（統制）令 1982 およびその改正（医薬品（統制）改正令 1984 および医薬品 （統制）改正令 2006）である。 バングラデシュにおける医薬品の規制に係る法規等のこれまでの整備状況を以下に示す[7]。

1940 年	医薬品法 1940 制定（Drug Act (XXIII of 1940)）
1945 年	医薬品規則 1945 制定（Drug Rule 1945 (under the Drug Act 1940)
1946 年	医薬品規則 1946 制定（Bengal Drugs Rules 1946）
1982 年	医薬品（統制）令 1982 制定（Drugs (Control) Ordinance1982）
	医薬品（統制）改正令公布（Drugs (Control) (Amendment) Ordinance 1982）
	国家医薬品政策 1982 策定（National Drug Policy 1982）
1984 年	医薬品（統制）改正令公布（Drugs (Control) (Amendment) Ordinance 1984）
2001 年	国民医薬品集第 1 版発行（First edition of the national formulary）
2003 年	国民医薬品集第 2 版発行（Second edition of the national formulary）
2005 年	国家医薬品政策 2005 策定（National Drug Policy 2005）
2006 年	医薬品（統制）改正令公布（Drug (Control) Ordinance Amendment Act 2006）
	国民医薬品集第 3 版発行（Third edition of the national formulary）
2015 年	国民医薬品集第 4 版発行（Fourth edition of the national formulary）
2016 年	国家医薬品政策 2016 策定（National Drug Policy 2016）

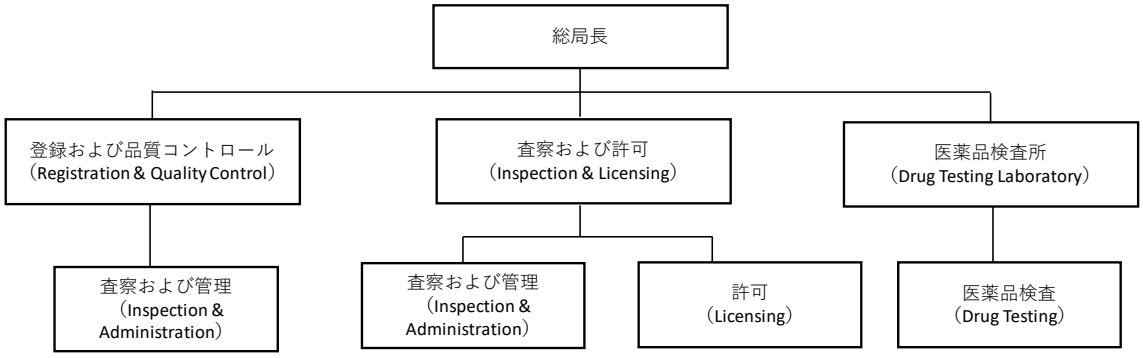
[5] Nwokike, J., H. L. Choi. 2012. Assessment of the Regulatory Systems and Capacity of the Directorate General for Drug Administration in Bangladesh. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health（ http://apps.who.int/medicinedocs/en/d/Js21824en/、2018 年 8 月 15 日閲覧）

[6] DGDA の Web サイト（http://www.dgda.gov.bd/index.php/downloads/background、2018 年 12 月 11 日閲覧）

[7] Nwokike, J., H. L. Choi. 2012[5] を基に筆者作成

2.3 規制当局の組織および役割

規制当局である DGDA は、登録および品質コントロールの担当部署（Registration & Quality Control）、査察および許可の担当部署（Inspection & Licensing）、医薬品検査所（Drug Testing Laboratory）のほか、国内に 55 の地域事務所[6]を有している。



出典：DGDA の Web サイトで提供されている組織図を基に筆者作成

図 2-1：DGDA 組織図

2018 年 12 月時点において、DGDA はバングラデシュ国内の 858 の製薬会社（アロパシー薬 271 社、アーユルヴェーダ薬 205 社、ウナニ薬 271 社、ハーブ薬（herbal drug）32 社、ホメオパシー薬 79 社[8]）の監督および規制をしている。DGDA 総局長に任命された当該局内の担当責任者（the chief of Directorate）が、医薬品の製造、販売、輸入、輸出の許可証を発行する権限（Licensing Authority：LA）を有している。また、全ての職員は「医薬品査察官」としての役割を担っている[6]。

DGDA の主な機能は、以下のとおりである[9]。

- 医薬品の全システムに関わる新規プロジェクトの提案の評価
- 医薬品製造許可証の発行と更新
- 医薬品の小売および卸売の許可証の発行と更新
- 医薬品の登録と更新
- 医薬品の公定価格の設定と認可
- 製薬施設の査察
- 原材料および梱包材の輸入のブロックリスト[10]の承認
- 完成医薬品の輸入承認
- 医薬品安全性監視
- 麻薬裁判、およびその他の裁判における訴訟の起訴
- 輸出許可、自由販売証明書（Free Sales Certificate）、GMP（Good Manufacturing Practices）証明書および医薬品の発売証明書（Certificate for Pharmaceutical Products）の発行

[8] アロパシーとは従来の西洋医学を指し、アーユルヴェーダ、ウナニ、ホメオパシーはそれぞれ代替医療の名称である。

[9] DGDA の Web サイト（http://www.dgda.gov.bd/index.php/downloads/directorate-info、2018 年 8 月 8 日閲覧）

[10] 輸入する原材料および梱包材の詳細

また、DGDA には計 10 の技術委員会がある。委員会名とその役割等について、下表に示す[5]。

表 2-1：DGDA の技術委員会*

委員会名	役割／機能	消費者団体の参加有無	会議開催の頻度
医薬品諮問委員会（Drug Advisory Committee）	DGDA に対して政策、運営に関する提言	無	必要に応じて
医薬品起訴当局（Drug Appellate Authority）	起訴	無	必要に応じて
医薬品統制委員会（Drug Control Committee）	医薬品登録承認	無	年に 1～2 回
医薬品技術小委員会（Drug Technical Sub-Committee）	DCC に対する助言	無	年に 1～2 回
医薬品価格委員会(Drug Pricing Committee)	価格設定	有	毎月
医薬品価格技術小委員会（Drug Pricing Technical Sub-Committee）	価格設定	無	毎月
製造プロジェクト評価委員会（Manufacturing Project Evaluation Committee）	新製薬所設立に関する提案書の評価	無	3～4 カ月ごと
輸入常任委員会（Standing Committee for Import）	輸入	無	5～6 カ月ごと
ハーブ薬諮問委員会（Herbal Drug Advisory Committee）	ハーブ薬に関する技術的助言	無	N/A
薬物有害反応諮問委員会（Adverse Drug Reaction Advisory Committee）	医薬品の安全	無	過去 5 年間の開催なし

* 参照文献の報告書発行当時（2012 年）の状況。薬物有害反応諮問委員会は、医薬品安全性監視システムガイドラインでは、四半期に 1 回開催される（後述）。

出典：Nwokike, J., H. L. Choi. 2012[5] を基に筆者作成。

第 3 章　医薬品に関する規制

3.1 定義・分類

3.1.1 医薬品の定義

「医薬品法 1940[11]」及び「医薬品（統制）令 1982[12]」では、医薬品（drugs）の定義を以下のように定めている。

1. ヒトまたは動物の内的または外的使用のための全ての医薬品（medicines）、ならびにヒトまたは動物の疾病の治療、緩和または予防に使用することを意図した全ての物質（all substances）、アーユルヴェーダ、ウナニ、ホメオパシーまたはバイオケミカルシステム医学（biochemic system of medicine）に従って使用する物質。
2. 診断、中絶および避妊物質、外科結紮糸、縫合糸、包帯、脱脂綿、バクテリオファージ、絆創膏、ゼラチンカプセルおよび消毒溶液。
3. 人体の構造または機能に影響を及ぼすことを目的としている、またはヒトまたは動物の病気を引き起こす害虫または昆虫の駆除に使用されることを目的とした物質（食品以外）。
4. 英国薬局方（the British Pharmacopoeia）、英国医薬品コーデックス（the British Pharmaceutical Codex）、米国薬局方（the United States Pharmacopoeia）、米国国民医薬品集（the National Formulary of the United States）、国際薬局方（the International Pharmacopoeia）のいずれかにモノグラフとして記載されている物質、単独または任意の物質と組み合わされたものでアーユルヴェーダ、ウナニ、ホメオパシーまたはバイオケミカルシステム医学で使用される物質で前項 1、2 および 3 に記載されるいずれかの目的で使用される物質。
5. 官報の通知などにより、政府が「医薬品」であると定めるその他の物質。

3.1.2 医薬品の分類

DGDA の Web サイトでは、登録医薬品をアロパシー薬、アーユルヴェーダ薬、ウナニ薬、ハーブ薬、ホメオパシーおよびバイオケミカル薬の 5 分類として、それぞれの登録医薬品を掲載している（表 3-1 参照）。

表 3-1：登録医薬品数

医薬品分類	登録数
アロパシー薬	29,376
アーユルヴェーダ薬	3,998
ウナニ薬	6,207
ハーブ薬	524
ホメオパシーおよびバイオケミカル薬	2,400

出典：DGDA の Web サイト

（http://www.dgda.gov.bd、2018 年 12 月 9 日閲覧時の数値）

[11] 医薬品法 1940（http://www.dgda.gov.bd/index.php/laws-and-policies/83-drug-act-1940、2018 年 8 月 8 日閲覧）
[12] 医薬品（統制）令 1982（http://bdlaws.minlaw.gov.bd/print_sections_all.php?id=623、2018 年 8 月 8 日閲覧）

また、医薬品の取扱いに関しては、処方せんが必要な処方せん薬と処方せんが不要な一般市販薬（Over the Counter：OTC）に分類される。

3.2 承認等に関する規制

3.2.1 医薬品の承認、登録

医薬品の承認、登録に関しては、1982 年に制定、公布された医薬品（統制）令（Drug (Control) Ordinance, 1982）で、次のように定めている[12]。

- いかなる種類の医薬品も、ライセンス機関に登録されていない限り、販売用に製造、輸入、流通させることはできない。
- 認可当局は、医薬品統制委員会によって登録が妥当である旨の勧告がなされない限り、医薬品を登録してはならない。
- 登録は、認可当局によって指定された条件で許可されなければならない。
- 登録は、早期に取り消されない限り 5 年間有効である。

2016 年に策定された国家医薬品政策 2016 では、（1）登録薬の選択、（2）登録基準、（3）輸入品の登録申請に関して、主に次のような政策を掲げている[13]。

(1) 登録薬の選択

- 異なる剤形で製造される全ての医薬品、および輸入、流通、販売または使用される全ての医薬品は、医薬品統制委員会の勧告に基づき、認可当局によって登録される。また、医薬品統制委員会が定期的に会合を開催することにより、救命に関わる新薬をより迅速に入手できるようにする。
- 医薬品統制委員会の機能は、適用される全ての医薬品および医療機器の安全性、有効性および有用性の評価を通じて、現地製造または輸入の可否を勧告することである。

(2) 登録基準

- 登録は確立された手順に従って行われ、医薬品統制委員会の妥当勧告なしに新薬は承認されない。
- 適切な製造設備と品質保証管理がなければ医薬品の製造を承認しない。高技術を要する医薬品（high-tech drugs）や、生産のために異なる製造設備と専用施設を必要とするものは、WHO の GMP ガイドラインに従って、製造に必要な設備が満たされなければ登録できない。
- 治療に必須でない限り、アロパシー薬の組み合わせ製品の登録は原則推奨しない。組み合わせ製品の誤用の可能性については特別な配慮をする。アロパシー薬の登録の際、米国食品医薬品局（United States Food and Drug Administration：US-FDA）、医薬品およびヘルスケア製品規制機関（Medicines and Health Care Products Regulatory Agency：MHRA）、または英国国民医薬品集（British National Formulary：BNF）で

[13] National Drug Policy-2016（http://www.dgda.gov.bd/index.php/laws-and-policies/261-national-drug-policy-2016-english-version、2018 年 8 月 8 日閲覧）

認可されているか確認する。必要に応じて、既存の組み合わせ製品の登録を再評価する。

このほか、アーユルヴェーダ、ウナニ、ハーブ、ホメオパシー、バイオケミカルなどの代替医療の医薬品の登録基準に関する記載がある。

(3) 輸入登録

- バングラデシュに登録されている外国製医薬品は、ライセンス機関からの承認を受けて輸入することができる。輸入製品の登録申請のためには、生物学的同等性試験および臨床試験の情報を提出しなければならない。輸入医薬品の登録については、新たに発明された救命効果が高い薬が優先される。米国、英国、ドイツ、フランス、スイス、日本、オーストラリアのうち、少なくとも 1 カ国にて同名の医薬品が販売登録されている必要があり、輸入医薬品は上記のいずれかの国の製造現場（または工場）から入手されなければならない。
- 魚や家畜用の医薬品の輸入許可には、欧州連合（EU）諸国、米国、スイス、カナダ、オーストラリア、日本、韓国、シンガポールのいずれかの国から発行された自由販売証明書（Free Sale Certificate）を提出する必要があり、また、当該国で登録されたブランド名と同一名で登録される。
- 輸入された医薬品や原材料が GMP の準拠の下に製造されているかを確認するために有効な証明書の提出を求め、必要に応じて製造施設の検査を要求する。GMP ガイドラインとチェックリストに従って、医薬品輸出国の医薬品製造現場での検証と認証が行われる。
- ハーブおよびホメオパシー 、バイオケミカルシステムに使用する医薬品は、医薬品統制委員会の勧告に基づき、DGDA の輸入登録が必要である。ウナニやアーユルヴェーダの必須医薬品は、国内で生産されないものに限っては輸入の対象として考慮する。
- 重大な副作用の可能性が認められている特定の医薬品は、他の代替薬が存在しない場合に、承認された用法・用量に則り限定量を輸入することを認める。

3.2.2 承認手続き

バングラデシュでは、2011 年から 2018 年にかけてアメリカ合衆国国際開発庁（United States Agency for International Development : USAID）による「医薬品およびサービスへのアクセス向上プログラム（Systems for Improved Access to Pharmaceuticals and Services）、以下「SIAPS プログラム」とする）」 が実施され、保健家族福祉省に対して質の高い医薬品と有効な医薬品サービスの可用性の向上を目的とした技術支援が提供された。同 SIAPS プログラムにより、審査および医薬品承認プロセスの標準化と合理化、ならびに承認オンライン登録システムの導入が進められた。また、SIAPS プログラムにおいて DGDA 職員に対して研修も実施されている。詳細は、以下のとおりである 。

(1) コモン・テクニカル・ドキュメント（CTD）の採用

SIAPS プログラムにより、医薬品の承認申請のための国際共通化資料であるコモン・テクニカル・ドキュメント（CTD）のガイドラインが 2017 年 5 月に DGDA から発行されている[14]。CTD の構成は、1) 申請書等行政情報および添付文書に関する情報、2) 品質に関する概括資料、3) 品質に関する文書、4) 非臨床試験報告書、5) 臨床試験報告書の 5 つのモジュールで構成されるが、同ガイドラインでは、モジュール 1 から 3 の様式の説明に限定されている。その理由は、モジュール 4（非臨床試験報告書）は、バングラデシュでは大半の製品が非臨床試験を必要としないジェネリック医薬品であることから該当しないとし、またモジュール 5（臨床試験報告書）は、国際標準の採用は複雑であるとの理由から現時点では要求しないこととしている。但し、ガイドラインでは、医薬品原薬（APIs）については、モジュール 5 として生物学的同等性試験データ/報告書の提出により臨床試験報告書の提出を免除できる可能性があるとしている。

(2) 公式テンプレートの作成

SIAPS プログラムの支援の下、申請手続きに関連する文書および製品登録時の技術審査のための各種テンプレートが作成されている[15]。

1) 申請手続きに関連する文書

- 書類受領の通知（Acknowledgment letter）
  本通知には、審査が完了する予定日が示される。後述するオンライン登録システムでプロセスが完全に自動化されてからは、オンライン提出後に自動的に発行される。
- 書類スクリーニングの結果、不備があることを知らせる通知（Dossier screening deficiency letter）
  不足している情報または文書が記載される。さらなる評価のために再提出の期日が申請者に示される。
- 書類内容の審査の結果、不備があることを知らせる通知（Review deficiency letter）
  欠陥する内容について記載され、さらなる評価のために期日までに必要な情報を提供するよう申請者に示される。
- 医薬品販売の承認通知（Drug marketing authorization letter）
  安全性、有効性、品質に関する評価後に発行する製品のマーケティング、また

[14] Guidelines for the Submission of Bangladesh Common Technical Document: General Guidelines, Module 1, Module 2 (Quality Overall Summary) And Module 3 (Quality), DGDA, May 2017（http://www.dgda.gov.bd/index.php/publications/52-guidelines1-for-the-submission-of-bangladesh-common-technical-document、2018 年 8 月 15 日閲覧）

[15] Aimiuwu, J. 2016. Improving the Process of Medicines Registration in Bangladesh: Adoption of the Common Technical Document Format and Implementation of Pharmadex to Automate the Registration of Medicines. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.（ http://siapsprogram.org/publication/improving-the-process-of-medicines-registration-in-bangladesh-adoption-of-the-common-technical-document-format-and-implementation-of-pharmadex-to-automate-the-registration-of-medicines/、2018 年 8 月 15 日閲覧）

は自由販売を認可する公式文書（DGDA が発行）。以下の内容が記載される。

- ✓ 製品名、医薬品製剤、単位投与量当たりの量的処方（賦形剤を含む）、保存期間、保管条件、および包装特性など、認可の基準となる情報。
- ✓ 医療従事者および一般市民向けの製品情報、販売分類、認可保有者の名前と住所、および認可の有効期間。

- 申請却下の通知（Rejection notification letter）

2） 技術審査のためのテンプレート

Good Review Practice（GRP）のプロセスを促進するために、以下の目的でテンプレートが作成されている。

- 書類のスクリーニング
- 管理およびラベリング情報の評価
- 製品の品質の評価

(3) オンライン医薬品登録システムの導入

医薬品の登録プロセスの効率性の向上を目的に、SIAPS プログラムの支援により DGDA は「Pharmadex[16]」を使ったオンライン医薬品登録システムを導入し、2016 年 9 月よりパイロット運用を実施し、2017年5月に本格的な運用を開始している[17]。但し、一部の製品（心血管系疾患の医薬品）のみで、全製品に対しての運用には至っておらず、徐々に全製品への運用拡大を図ることとしている[18]。

Pharmadex は、規制当局と主要な関係機関間で規制情報の管理、文書化、配布、共有を容易にする Web ベースの統合情報ソリューションで、規制当局は、Pharmadex を通してオンラインによる製薬会社からの医薬品の登録申請受付、医薬品の登録、ライセンス付与、修正、検査の管理などを行うことができる。主な機能は、以下のとおりである。

- オンライン申請および規制対象の業界および消費者との情報共有
- 製品登録、ライセンス、販売前後の検査から品質管理、医薬品安全性監視の管理
- 文書の保管、文書化、管理、検索
- 医薬品国際一般名称、解剖学的治療化学分類法、国際医学用語（Medical Dictionary for Regulatory Activities）などの標準的な用語および辞書の提供
- 製品承認履歴、承認書、および認可済み製品情報へのアクセス

申請者および DGDA の双方に対するユーザーマニュアルが DGDA の Web サイトで提供されている。

[16] http://pharmadexbd.org/（2018 年 8 月 15 日閲覧）

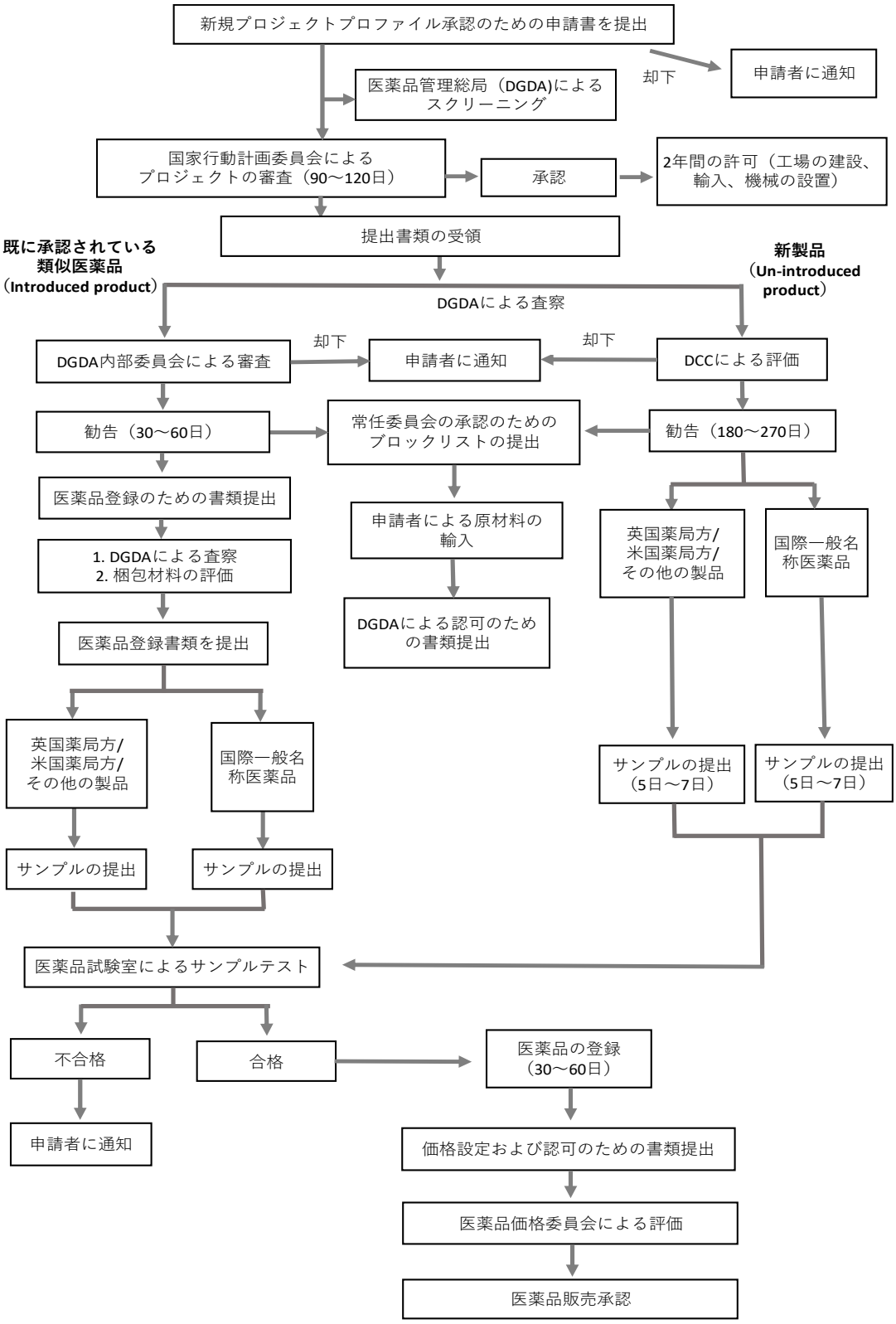
[17] Abdullah M, Zahedul I, Azad SN, Liza Talukder L, Khaled M. (2018). SIAPS Bangladesh End of Project Report. This report is submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health（http://siapsprogram.org/publication/siaps-bangladesh-end-of-project-report/、2018 年 8 月 15 日閲覧）

[18] 有識者へのヒアリングによる。

図 3-1：Pharmadex のフロントページ [16]

USAID の SIAPS プログラムの報告書によると、申請書のスクリーニングに約 60 日間、新薬の申請書の審査には 180 日から 360 日間要するとしている [5]。また、有識者へのヒアリングによると、新薬の場合、医薬品技術小委員会（Drug Technical Sub-Committee）と医薬品統制委員会（Drug Control Committee）の開催頻度（年に 1～3 回）等により異なるが、DCC 通過後、諸手続きで 74～126 日間（労働日）を要するとのことである [18]。具体的には、製法承認で 1～1.5 カ月、製品登録で 1～2 カ月、薬価承認に 1～2 週間、市販許可に 1 週間程度の時間を要するとのことである [18]。

審査手続きのフローは、次頁の図 3-2 のとおりである。



出典：Assessment of the Regulatory Systems and Capacity of the Directorate General for Drug Administration in Bangladesh[5] および DGDA のヒアリングを基に、筆者作成

図 3-2：審査手続きのフローチャート

また、医薬品の登録（製造に係るライセンス料を含む）に係る主な手数料を表 3-2 に示す（その他の詳細な手数料は添付資料 3 を参照）[19]。

表 3-2：医薬品の登録に係る主な手数料一覧

項目	適用細目	手数料の金額（タカ[20]）
医薬品製造ライセンス料（新規）	1. アロパシー薬	
	(1) 生物学的	1,00,000
	(2) 非生物学的	50,000
	2. ウナニ、アーユルヴェーダ、ホメオパシー、バイオケミカルおよびハーブ	10,000
医薬品製造ライセンス料（更新）	1. アロパシー薬	
	(1) 生物学的	30,000
	(2) 非生物学的	15,000
	2. ウナニ、アーユルヴェーダ、ホメオパシー、バイオケミカルおよびハーブ	5,000
サンプル分析料	1. アロパシー薬	
	(1) 米国薬局方／英国薬局方	30,000
	(2) INN／その他	15,000
	2. ウナニ、アーユルヴェーダ、ホメオパシー、バイオケミカルおよびハーブ	5,000
新規登録料	1. アロパシー薬	10,000
	2. ウナニ、アーユルヴェーダ、ホメオパシー、バイオケミカルおよびハーブ	2,000
登録更新料（5 年ごと）	1. アロパシー薬	10,000
	2. ウナニ、アーユルヴェーダ、ホメオパシー、バイオケミカルおよびハーブ	1,000
工程評価料	1. アロパシー薬	5,000
	2. ウナニ、アーユルヴェーダ、ホメオパシー、バイオケミカルおよびハーブ	500
製造ライセンスの所有権変更手数料	1. アロパシー薬	
	(1) 生物学的	200,000
	(2) 非生物学的	100,000
	2. ウナニ、アーユルヴェーダ、ホメオパシー、バイオケミカルおよびハーブ	50,000

出典：2013 年 5 月 16 日付の DGDA の通達文書

[19] 2013 年 5 月 16 日付の DGDA の通達。ベンガル語の通達文書を仮英訳。

[20] バングラデシュの通貨単位。1 タカ=1.34 円（2018 年 12 月 9 日、https://www.oanda.com/lang/ja/currency/converter/）

3.3 市販後の安全対策に関する規制

医薬品法 1940 および医薬品規則 1946 に査察官（Inspectors）と査察官の権限、査察の手順に関する記述がある。

2016 年に策定された「国家医薬品政策」では、「偽造、有害、未登録、基準以下、不正表示の医薬品および医療機器の製造、販売および流通は禁じられ、そのような行為を犯した者には罰則が科される」としている。また、副作用に関しても、「全ての関係者に不利な薬物事象についての正確な情報を提供するという動機付けを通して、市販後医薬品安全性監視および薬物有害反応の適切なモニタリングを確実なものにする」としている[21]。医薬品安全性監視システムおよび偽造品や基準以下の市販後の医薬品の監視について以下に記述する。

3.3.1 医薬品安全性監視システム

バングラデシュでは、医薬品安全性監視システムを 1996 年に導入し、保健家族福祉省は 1997 年に薬物有害反応の評価、分析、提言を行う薬物有害反応諮問委員会を結成している[22]。しかし、人員と財源の不足により十分に機能していなかった。保健家族福祉省は、2013 年に国家医薬品安全性監視プログラムを活性化させるため、前述の SIAPS プログラムの技術支援により DGDA に薬物有害反応モニタリング室（Adverse Drug Reaction Monitoring Cell）を設立するとともに、国家医薬品安全性監視システムおよび関連する活動実施のための基本的な枠組みを示す「医薬品安全性監視（Pharmacovigilance：PV）システム」のガイドラインを 2018 年に発行している[23]。また、薬物有害反応モニタリング室および薬物有害反応諮問委員会に対して、それぞれ有害事象の報告の手続きに関する標準作業手順書（Standard Operating Procedures、以下「SOP」とする）を作成している 。

ガイドラインで示されている医薬品安全性監視システムの枠組みについて、以下に記述する。

(1) モニタリングの対象

バングラデシュの医薬品安全性監視システムの対象となるのは、以下の医療製品である。

- 従来の（アロパシー）医薬品
- ワクチン
- 医療機器
- 生物学的製剤
- 血液製剤
- 代替医療薬（アーユルヴェーダ、ウナニ、ハーブ、ホメオパシー、バイオケミカル）

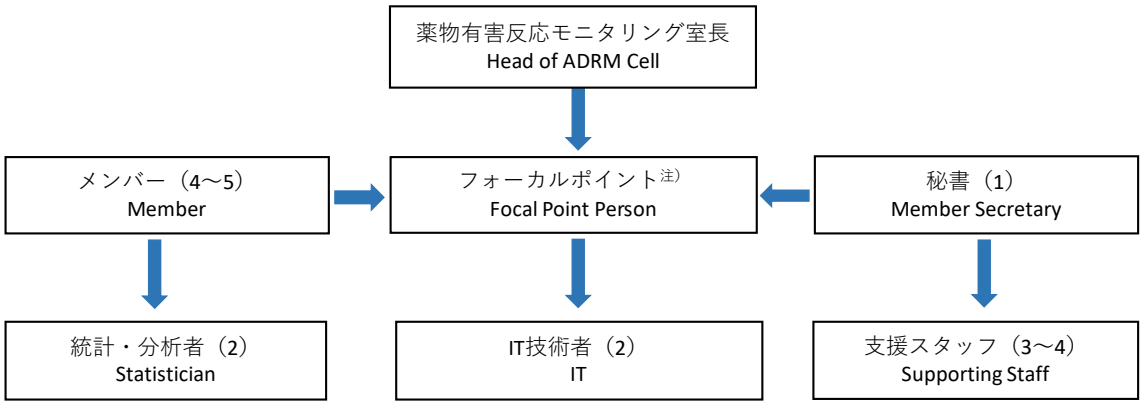
[21] 国家医薬品政策 2016（英語版）

[22] DGDA の Web サイト（http://www.dgda.gov.bd/index.php/2013-03-31-04-35-57/adrm-reaction-monitoring、2018 年 8 月 30 日閲覧）

[23] National Guideline on the Pharmacovigilance System in Bangladesh, DGDA。同ガイドラインには、①有害事象諮問委員会の構成メンバー、②有害事象の分類、③有害事象の報告フォーム、④ワクチンの副反応の報告フォーム、⑤WHO の因果関係評価基準、⑥Naranjo 有害事象因果関係判定アルゴリズム、⑦薬物有害反応重症度評価尺度の資料が添付されている。

(2) モニタリングの体制

薬物有害反応モニタリング室は、国家医薬品モニタリングセンターとして機能している。薬物有害反応モニタリング室の組織図は図 3-3 のとおりである。



注）関係者や委員会との定期的な会合の調整と連絡を担当。

出典：National Guideline on the Pharmacovigilance System in Bangladesh[23] を基に筆者作成

図 3-3：薬物有害反応モニタリング室の組織図

また、保健福祉家族省は、薬物有害反応報告システムの強化のために、薬物有害反応の評価、分析、提言を行う独立組織として薬物有害反応諮問委員会（Adverse Drug Reaction Advisory Committee）を結成した。同委員会とその中の技術小委員会が薬物有害反応等に関する報告書を検証・評価する。薬物有害反応諮問委員会は、DGDA の総局長を議長とし、臨床医、医科大学病院の研究者、バングラデシュ医師会の代表、バングラデシュ製薬協会の代表、バングラデシュ消費者団体の代表、医薬品に係る専門家など 17 名で構成される [23]。

(3) 監視（Surveillance）の種類および報告方法

ガイドラインでは、監視は下記の 3 種類が定められている。

① 受動的監視（Passive Surveillance）
② アクティブ監視（Active Surveillance）
③ 製薬業者およびマーケティング免許保有者による監視プログラム

受動的監視は、薬物有害反応が生じた際に、医療従事者や患者、消費者から自発的に薬物有害反応モニタリング室に報告されるもので、バングラデシュで最も主要な方法である。DGDA は、Web サイト上で薬物有害反応の疑いが認められる場合には報告するよう呼びかけるとともに、報告様式と記載方法について掲載している。また、同サイトからオンラインで報告できる仕組みも整備されている（図 3-4 参照）。

出典：DGDA の Web サイト（http://www.dgda.gov.bd/index.php/2013-03-31-04-35-57/adrm-entry-form、2018 年 8 月 23 日閲覧）

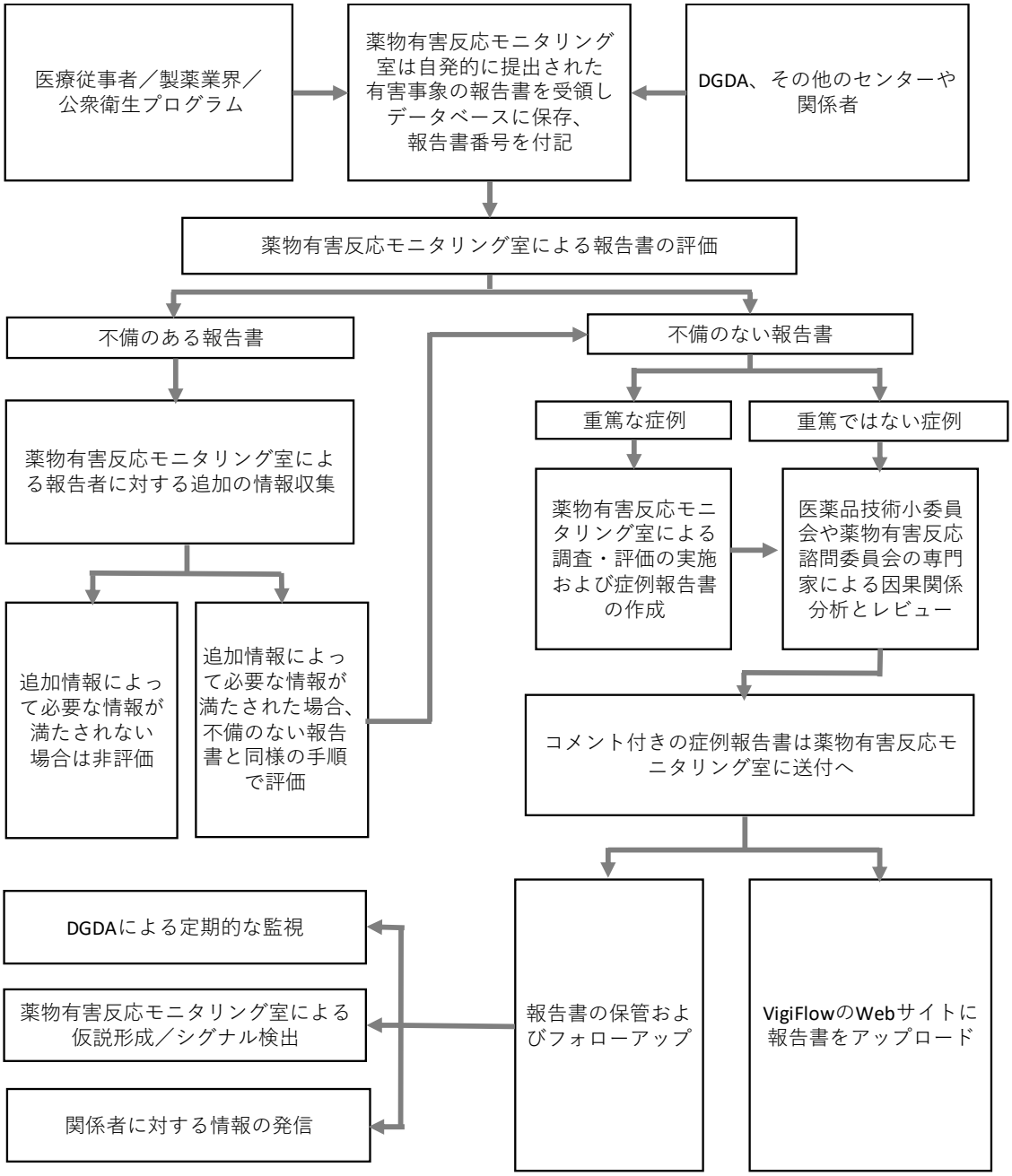
図 3-4：疑いのある有害事情報告エントリー画面

報告するタイミングについては、重篤な有害事象（死亡、生命を脅かす状態、障害、先天性異常、入院、または毒性による治療の変更）の場合には、発生後速やかに薬物有害反応モニタリング室、またはフォーカルポイント[24]に報告することとし、報告様式に記載の上、24 時間から 48 時間以内に薬物有害反応モニタリング室に提出されることとしている。

また、薬物有害反応モニタリング室への報告以降の流れは、下記および図 3-5 のとおりである。

① 薬物有害反応モニタリング室において、報告書に番号が付記される。
② 報告書の内容を確認し、不備がある場合には、薬物有害反応モニタリング室が直接報告者に聞き取り調査を行う。
③ 薬物有害反応モニタリング室は、死亡など重篤な有害事象については速やかに症例報告書を作成する。
④ 四半期に 1 度開催される薬物有害反応諮問委員会により、報告書の内容が分析された後、提言がまとめられる。

[24] SIAPS Bangladesh End of Project Report（USAID、2018）によると、30 の病院と 30 の製薬会社がフォーカルポイントとして指定されている。（http://siapsprogram.org/publication/siaps-bangladesh-end-of-project-report/、2018 年 8 月 15 日閲覧）



出典：National Guideline on the Pharmacovigilance System in Bagladesh を基に筆者作成

図 3-5：有害事象が起こった際の報告フロー

また、バングラデシュにおける医薬品の製造・販売業者は、医薬品の登録・承認後、継続的に安全性を監視する必要があり、登録・承認から最初の 2 年間は半年ごとに、またその後 2 年間は 1 年に 1 回、安全性に関する報告書の提出が義務付けられている [23]。

(4) 医療機関や消費者に対する情報提供

薬物有害反応モニタリング室は、有害事象が発生した際の緊急時だけではなく、定期的に医療従事者と消費者に対して医薬品等の安全性に関する情報を提供する責任があるとさ

れている。薬物有害反応モニタリング室は、薬物有害反応の発生シグナルが発信されると、3 週間以内に医療従事者と消費者に情報提供し、ラベル、パッケージ、パッケージに挿入する製品情報に必要な変更を確実に行うこととされている。また、薬物有害反応モニタリング室を通じて、下記の方法により情報が提供される[23]。

- 重大、または以前に知られていない安全性への懸念が発生した場合、医療機関に対して通知
- ニュースレター（半年に 1 回）などによる広報
- 国民医薬品集（National Drug Formulary）は、リスクや推奨される使用方法など医薬品に関する新しい情報を反映するために、2〜3 年ごとに改訂、更新
- 医薬品の登録情報の改訂、更新

上記の通知、広報物は DGDA の Web サイト[25]にもアップロードされて閲覧可能としている[23]。

(5) 実施状況

2014 年、バングラデシュは 120 番目の WHO の国際医薬品モニタリングプログラムのメンバーに登録されている[26]。

当初、DGDA は、20 の私立病院、および SIAPS プログラムから支援を受けた 13 の製薬会社に医薬品モニタリングプログラムを導入した。導入当時、スクエア・ホスピタル・リミテッド（SHL）に雇用されていた全ての医師と看護師に医薬品モニタリングに関するオリエンテーションが実施された。現在は、医薬品モニタリングのフォーカルポイントとして指定されている 30 の病院と 30 の製薬会社は、DGDA の下で医薬品モニタリングの定点監視サイトとして指定されている。2017 年 4 月現在、1,800 件以上の副作用の報告がなされ、 これらのうち 393 件の報告は薬物有害反応モニタリング室によってレビューされ、WHO の VigiFlow データベースにアップロードされた[26]。

3.3.2 市販後監視（Post Marketing Surveillance：PMS）

バングラデシュでは、大半の医療製品、特にジェネリック医薬品が海外で製造されているため、小売および卸売の薬局などで販売される製品の品質および安全性の問題に規制当局が取り組むことは非常に重要であるとしている。国内には、偽造品、基準以下の医薬品が多く流通しているため、これらの製品を監視し、違法、または安全ではない製品が市場に流通することを禁ずることが DGDA の責務であるとしている[27]。

DGDA は、市販後または臨床試験後の医薬品監視の標準手順書（SOP）を作成している。

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[25] DGDA の Web サイト上の薬物有害反応モニタリングニュースのページ（http://www.dgda.gov.bd/index.php/2013-03-31-04-35-57/adrm-news）WHO の UPPSALA の報告書が掲載されている（2018 年 10 月 15 日閲覧）

[26] Abdullah M, Zahedul I, Azad SN, Liza Talukder L, Khaled M. (2018). SIAPS Bangladesh End of Project Report. This report is submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.（http://siapsprogram.org/publication/siaps-bangladesh-end-of-project-report/、2018 年 8 月 15 日閲覧）

[27] Standard Procedure for Inspection of Retail and Wholesale Pharmacy (Post-Marketing Surveillance)（ http://siapsprogram.org/publication/standard-procedure-for-inspection-of-retail-and-wholesale-pharmacy-post-marketing-surveillance/、2018 年 8 月 16 日閲覧）

DGDA 職員を対象に作成された SOP は、小売および卸売の薬局で入手可能な医薬品（伝統的な補完代替医療、ワクチン、および生物学的製剤を含む医薬品）に対して PMS を実施するために、査察、サンプル採取と提出、PMS 活動の管理など必要な手順が示されている [27]。SOP には、査察官の権限、査察官の任務、査察プロセス、サンプリング方法、報告書の作成に関する手順・内容が示されている。

また、PMS で採取された医薬品は、医薬品検査所で品質検査が行われる。2013 年は、PMS の目的で 3,540 件の検査が実施されている[28]。

3.4 製造・品質管理に関する規制

バングラデシュにおける製造・品質管理として、Good Manufacturing Practice（GMP）の実施内容および医薬品検査所による品質検査について、以下に記述する。

3.4.1 Good Manufacturing Practice（GMP）

医薬品（統制）令 1982 では、全ての医薬品製造者は WHO の GMP 基準を遵守し、そのような優良事例に従わない製造業者は製造許可証を取り消すと規定されている。

DGDA は、各医薬品製造施設に製造許可証を発行する。新規製造施設への製造許可証の発行に当たっては、DGDA による GMP 査察に合格する必要がある。製造許可証は 2 年間有効で、バングラデシュで合法的に医薬品を製造するためには 2 年ごとに許可証の更新が必要である。更新の際にも、WHO の GMP 基準の継続的な遵守を保証するために GMP 査察を実施することが義務付けられている[29]。

バングラデシュの医薬品の製造許可証には下記の 2 種類がある [29]。

- 生物学的製剤の製造許可証
- 非生物学的製剤の製造許可証

また、バングラデシュの企業が医薬品を輸出するためには、「国際間で流通する医薬品の品質に関する WHO 証明制度（Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce）」の証明書が必要である。この証明書は、特別な（追加的な）GMP 査察後に DGDA によって発行される [29]。尚、医薬品の製造に使用される少量の原材料および先発医薬品（reference standards）を製薬会社が輸入する場合は、DGDA の承認の下、GMP 遵守は輸入業者によって保証されなければならない [21]。

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[28] Kim, E M. 2014. Rapid Assessment Report on the Capacity of Drug Testing Laboratory of DGDA of Bangladesh. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health（ http://siapsprogram.org/publication/rapid-assessment-of-the-capacity-of-drug-testing-laboratory-of-the-dgda-of-bangladesh/、2018 年 8 月 16 日閲覧）

[29] Anisfeld, M. H., Kim, E.M., Aimiuwu, J., Thumm M., 2015. Assessment of the Good Manufacturing Practices (GMP) Inspection Program of the Bangladesh Directorate General of Drug Administration. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health（http://apps.who.int/medicinedocs/en/d/Js22111en/、2018 年 8 月 15 日閲覧）

前述の SIAPS プログラムでは、2012 年および 2015 年に DGDA の GMP の実施状況について調査し、報告書を取りまとめている。報告書に記載されている「製造許可証の発行プロセス」および GMP の実施状況と課題について当該報告書から一部抜粋したものを以下に記述する[5, 29]。

バングラデシュにおける製造許可証の発行プロセス[5]

① DGDA と製造プロジェクト評価委員会が製造サイトを査察した後、同委員会による評価のためのプロジェクト概略が提出される。

② 製造許可証の申請書が提出される。申請には、最初に製造する品目の構成が記載される。製造工程は、製造施設の査察後に医薬品統制委員会によって評価される。既に承認されている医薬品に類似した品目は、DGDA の内部委員会によって評価される。医薬品国際一般名称（INN）の製品では、ブロックリストの品目の承認には、試験と分析のために少量のサンプルの提出が必要である。

③ 包装および販促用資料が提出される。DGDA の職員は、提出された資料の内容を確認し、必要に応じて製造現場を再度査察する。

④ この段階で許可証の発行は可能で、製造者は DGDA が承認した価格を使用する条件で製品を登録することができる。

⑤ 輸入常任委員会による事前承認のために、ブロックリストが提出される。

⑥ 医薬品検査所による試験および分析のために最初の商用バッチのサンプルが提出されるとともに、商品の希望価格が提示される。基礎的医療に挙げられた医薬品 117 品目の価格は、価格委員会によって決定される必要がある。他の全ての医薬品は、DGDA が承認する価格を使用する。

DGDA では、GMP 査察官の資格要件を薬剤師としている。通常、3 人の DGDA スタッフのチームによって実施される。DGDA の査察は、一貫した方法で実施できておらず、文書化、フォローアップするための包括的なガイドライン、標準作業手順（SOP）、品質管理システムは存在しない。DGDA の中央事務所の査察官は、製造現場での GMP 査察の実施に加え医薬品登録のための書類審査の責任を担う。地域事務所（6 つの事業所）の査察官は製薬会社、流通業者、薬局の査察を行っている。

同報告書の中での DGDA への聞き取り調査では、「製品の輸出に関心があり、GMP 証明書が必要な製薬会社の要請により、GMP 査察（full GMP inspections）が実施され、その数は登録されている 277 社のうち約 40 から 50 社を占める」としている。

同報告書では、DGDA による GMP の課題として次の事項を指摘している。

- *GMP 査察官のための研修プログラムは確立されておらず、研修プログラムの有効性を保証する品質保証メカニズムがない。*
- *DGDA には、WHO ガイダンス（最新版は 2012 年）に基づいた品質マニュアル（QM）があるが、GMP 査察実務やスタッフ研修の実務に関する内容は含まれていない。*

- *バングラデシュの企業は、DGDA によって「大」、「中」、「小」と区分されている。この分類は、DGDA のGMP 査察の頻度、実施時間の長さ（日数の条件）に反映されていない。例えば、過去に製品リコールや有害薬物事象の経験がある企業や前回の査察で重大な欠陥が認められた企業に対する査察の頻度を増やすなどの基準を設けるべきである。*
- *GMP 査察の標準的な査察テンプレート、またはチェックリストがなく、GMP の査察が標準化されていない。*
- *査察は一日（8 時間）要するものが、実際には3 時間から4 時間で終了している。また、複数（報告書では 6 施設）の製造オペレーションを 1 日の査察だけで実施するため、十分な査察が実施できていない。*
- *DGDA には、査察データを保存するためのコンピュータシステムはなく、査察データは、手書きの紙ベースの報告書であることが多い。*

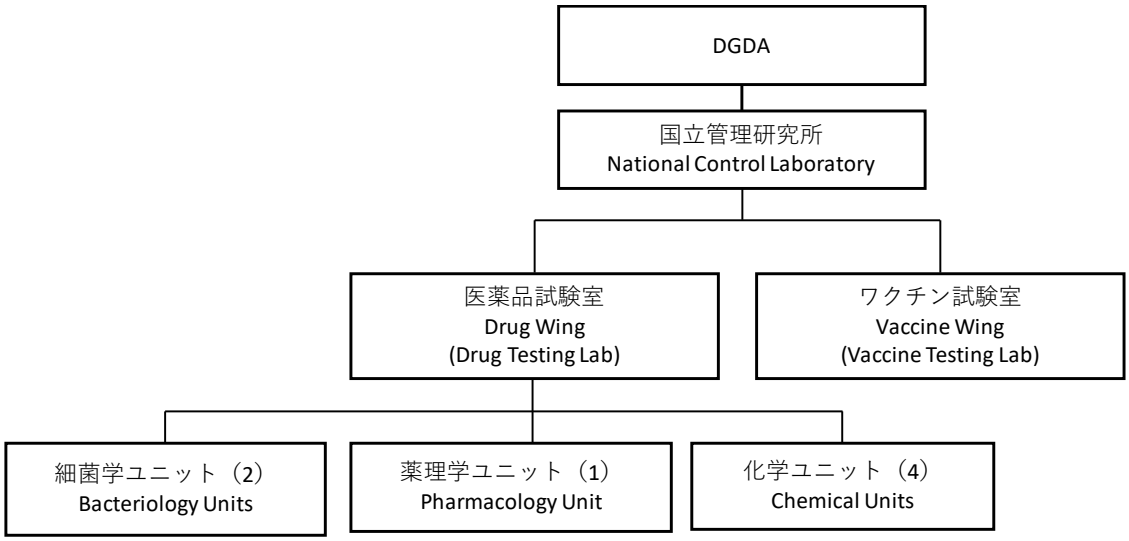
上記課題に基づき、同報告書では、査察官の業務分掌の作成、研修プログラムの作成および実施、ガイドライン・SOP の作成に加え、バングラデシュ製薬協会（Bangladesh Association of Pharmaceutical Industries：BAPI）の同意を得て、医薬品査察協定および医薬品査察協同スキーム（PIC/S）への加盟申請が推奨されると提言している [29]。

国家医薬品政策 2016 では、GMP ガイドラインと関連する問題の理解を深めるためにDGDA の査察官の 国内外での研修の受講や PIC/S の加盟の必要性が謳われている。

3.4.2 医薬品検査所による品質検査

DGDA の傘下には国立品質管理研究所（National Control Laboratory）があり、医薬品の登録前および市販後の品質評価を行っている。国立品質管理研究所は、ダッカとチッタゴンの 2 カ所にあり、それぞれ医薬品のサンプル検査を行う医薬品検査所（Drug Testing Laboratory）とワクチンおよび生物学的製剤の品質検査を行うワクチン検査所の二部門に分かれている 。尚、医薬品検査所は登録前および市販後の医薬品の品質検査に加え、郡や他の政府機関などからの検査依頼も受け付けている [28]。

医薬品検査所は、細菌学（2 ユニット）、薬理学（1 ユニット）、化学（4 ユニット）の計 7 ユニットで構成されている（組織図は、図 3-6 を参照）。医薬品のサンプルは、医薬品の種類と検査依頼数によって各ユニットに割り振られる。SIAPS プログラムでは、2014 年 8 月に医薬品検査所の実態調査を実施している。その調査報告書によると、医薬品検査所は、有効成分の事前承認サンプル試験を実施しておらず、完成した医薬品のみについてサンプルテストを実施している。2011 年から 2013 年の 3 年間の実績では、全体の 70%が市販後の医薬品サンプルの検査である。SIAPS プログラムによる調査当時の医薬品登録プロセスでは、医薬品検査所の結果が出る前に、書類審査に問題がなければ医薬品が登録される流れになっていた。そのため、品質に問題がある医薬品が市場に流出する恐れがあったとしている [28]。但し、現在では、上記プロセスは見直されているとのことである（前述の図 3-2 を参照）[18]。SIAPS の報告書によると、2011 年から 2013 年までの事前承認のためのサンプルの平均サンプリングテスト不合格率は、13.13%と報告されている [28]。



出典：Assessment of the Good Manufacturing Practices (GMP) Inspection Program of the Bangladesh Directorate General of Drug Administration[28]を基に筆者作成

図 3-6：医薬品検査所の組織図

上記の問題は、サンプル検査の依頼数の増加に対応できるだけの医薬品検査室のキャパシティが不足していたことによるが、WHOにより施設・機材の整備が進み、依頼数における検査実績は2013年に4,531件（依頼数の83%）で、2011年（依頼数の80%）と2012年（依頼数の65.4%）と比較すると増加傾向にある。

また、国家医薬品政策2016では、国内の全ての管区で国立品質管理研究所の支所を段階的に設立するとしている。現在、クルナ管区（Khulna）、ラジシャヒ管区（Rajshahi）、バリサル管区（Barisal）、ロンプール管区（Rangpur）、シレット管区（Sylhet）の5つの管区での設立が計画されている[18]。この設立に当たっては、前述のSIAPSプログラムの次のフェーズで支援対象になる予定とのことだが、具体的な時期などは明らかではない[18]。

また、2018年8月に国立品質管理研究所の品質マニュアル改訂第4版が発行されている。本マニュアルには、国際規格「ISO/IEC 17025[30]」の要件に満たす内容とし、不均衡（imparity）、機密性（confidentiality）、構造要件（structural requirements）、リソース要件（resource requirements）、プロセス要件（process requirements）、管理システム要件（management system requirements）、計量トレーサビリティ（metrological traceability）、検査所の安全性（laboratory safety）に関する基準が記載されている。

3.4.3 薬局方等

国民医薬品集の第4版（Bangladesh National Formulary 2015）が発行されており、2018年12月現在、第5版（Bangladesh National Formulary 2018）が作成中である。国民医薬品集には、医薬品に関する適応、禁忌、副作用、用量用法などが収載されている。なお、一般的に医薬品の性状や製造方法など規格基準を示す薬局方については、バングラデシュ独自で

[30] 試験および校正を行う試験所の能力に関する一般要求事項

は発行しておらず、米国および英国の薬局方を参照しているとのことである[18]。

3.5 非臨床試験の実施方法等に関する規制

前述のとおり、非臨床試験を必要としないジェネリック医薬品が大半を占めるバングラデシュは、非臨床試験に関する独自のガイドラインを有していない。新薬の承認申請のための書類に関する手引書[31]では、非臨床および臨床試験の要件は、関連のWHO-TRSに準拠するとしている。

但し、バイオシミラー製品については、2018 年に個別のガイドラインが発行されている。バイオシミラー製品に関する非臨床試験の実施方法等に関する規制について、以下に記述する。

3.5.1 バイオシミラー製品に関するガイドラインおよび非臨床試験の実施方法等の規制

バイオシミラー製品については、2018年に新たに登録に関するガイドライン（Guidelines for Registration of Biosimilar Products 2018）が発行されており、非臨床試験と臨床試験を必要とする。当該ガイドラインは、WHO、欧州医薬品庁、韓国の規制当局のガイドラインなどが参照され、内容の調和が図られている[32]。

当該ガイドラインは、以下の 11 章で構成される。

- 第 1 章：序章
- 第 2 章：ガイドラインの対象（Scope）
- 第 3 章：一般的な考慮事項
- 第 4 章：定義
- 第 5 章：基準製品の選択
- 第 6 章：品質評価
- 第 7 章：非臨床評価
- 第 8 章：臨床評価
- 第 9 章：医薬品安全性監視
- 第 10 章：処方情報とラベル
- 第 11 章：DGDA の役割と責任

このほか、添付資料として、以下の資料が添付されている。

- 輸入されたバルク医薬品[33]で製造されたバイオシミラー製品の登録プロセス・フロー
- 国内で開発されたバイオシミラー製品の登録プロセス・フロー
- 輸入されたバイオシミラー製品の登録プロセス・フロー

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[31] Guidance for Industry Requirements for permission of New Drug Approval, DGDA (2010)（http://www.dgda.gov.bd/index.php/2013-03-31-05-16-29/guidance-documents/15-guidance-for-industry 、 2018 年 8 月 15 日閲覧）

[32] Guidelines for Registration of Biosimilar Products, DGDA (2018)（http://www.dgda.gov.bd/index.php/2013-03-31-05-16-29/guidance-documents/437-guideline-for-registration-of-biosimilar-product、2018 年 8 月 15 日閲覧）

[33] 最終包装工程を除く全ての製造工程を終了している製品

- 物理化学的および生物学的特性の要件
- バイオシミラー製造用一般機器リスト
- 品質管理のための一般的な機器リスト
- 人材の専門分野
- 様式 9（輸入許可申請に伴う事業の形態）

当該ガイドラインではバイオシミラー製品に関する非臨床試験として下記の事項が記載されている。

- 試験管内試験（in vitro studies）
- 動物試験（in vivo studies）
  - 臨床応用に関連する生物学的/薬力学的活性
  - 非臨床毒性（関連する種における少なくとも 1 回の反復投与毒性試験での決定で毒物動態測定を含む）
  - 局所耐性試験
  - その他の毒物学的研究

3.6 臨床試験（治験）の実施方法等に関する規制

臨床試験の標準的なオペレーションシステムの構築について、規制当局（DGDA）において検討中である。現在、発行されているガイドラインについて、以下に記述する。

3.6.1 臨床試験に関するガイドライン

バングラデシュでは、臨床試験に関するガイドライン（Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products Bangladesh）を発行している。当該ガイドラインの作成に当たって、技術委員会が結成され、ICH の GCP ガイドライン（E6）、WHO の GCP ガイドライン（TRS 850、付属書 3）、マレーシアの GCP ガイドライン、汎アメリカ保健機構（PAHO）の GCP ガイドライン、インドの GCP ガイドライン（附属書 Y）が参照され、大半の内容は ICH の GCP ガイドライン（E6）に沿ったものとしている。

当該ガイドラインは、以下の 8 章で構成される。

- 第 1 章：用語集
- 第 2 章：バングラデシュ GCP の原則
- 第 3 章：審査委員会/独立倫理委員会（Institutional Review Board／Independent Ethics Committee）
- 第 4 章：DGDA の役割
- 第 5 章：治験者（Investigator）
- 第 6 章：治験依頼者（Sponsor）
- 第 7 章：臨床試験プロトコルおよびプロトコル改正
- 第 8 章：治験者概要書（Investigator’s Brochure）

このほか、ガイドラインには添付資料として、①インフォームドコンセントのテンプレート、②臨床試験を実施するための要件（チェックリスト）、③生物学的同等性試験の規制要件、④バイオワクチンの臨床試験の規制要件が巻末に添付されている。

3.6.2 生物学的同等性試験の規制概要

バングラデシュでは、大半がジェネリック医薬品のため、生物学的同等性試験の需要が高く、より重要であると考えられる。以下には、当該ガイドラインの添付資料の一部として記載されている生物学的同等性試験の規制要件の概要を記述する。

(1) 標準的な研究デザイン

2つの製剤の比較には、無作為化された群に対する2期にわたる2系列の単回用量クロスオーバー試験が推奨される。第 2 期の開始時には、全ての被験者における薬物血中濃度が生物学的定量の下限を下回るのに十分なウォッシュアウト（wash out）期間を設ける必要がある。通常、消失半減期の 5 倍以上の期間が必要である。単回投与後の生物学的同等性を決定するための研究では、分析されるパラメータはAUC（0-t）およびCmaxである。

これらのパラメータについては、試験製品と基準製品の比率の 90%信頼区間は 80.00～125.00%内でなければならない。さらなる詳細は、欧州医薬品庁（European Medicines Agency）のガイドライン「THE INVESTIGATION OF BIOEQUIVALENCE（CPMP / EWP / QWP / 1401/98 Rev. 1 / Corr）」、およびアメリカ食品医薬品局（Food and Drug Administration; FDA）のガイドライン（Guidance for industry: Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA）の参照が推奨される。

(2) 規制手続き

企業／治験依頼者が生物学的同等性試験を実施する場合、開発部門とは異なる臨床部門（separated clinical unit）での実施、または医薬品開発受託機関（Contract Research Organization：CRO）で実施されなければならず、DGDAによる事前承認が必要である。まず、臨床部門またはCROが試験プロトコルを準備する。治験依頼者は内容を見直し、プロトコルを審査委員会/独立倫理委員会（IRB / IEC）に提出する。その後、プロトコルはIRB / IECによって確認され、承認または却下の決定が下される。また、必要に応じて、プロトコルはバージョン番号を維持して変更することが可能である。承認後、治験依頼者/ CROは承認されたプロトコルと共に必要な情報をDGDAへ提出する。

DGDAは、プロトコル、研究場所の登録およびGMP適合性の状況を確認し、生物学的同等性試験実施の承認を与える。研究期間中、DGDA はリスク分析に応じて研究サイトを監査する。死亡または深刻な副作用については、IRB、DGDA および治験依頼者に通知する必要がある。安全性が懸念される場合は、試験を中止し、必要に応じて適切な補償を行う。試験が成功裏に完了した後、添付書類を含む全ての研究報告書は最終承認のために DGDA に提出される。DGDA の臨床試験担当部署は、最終承認のために報告書の内容を確認する。

DGDA に治験開始前および治験中に提出する書類は以下のとおりである[34]。

1) 治験開始前

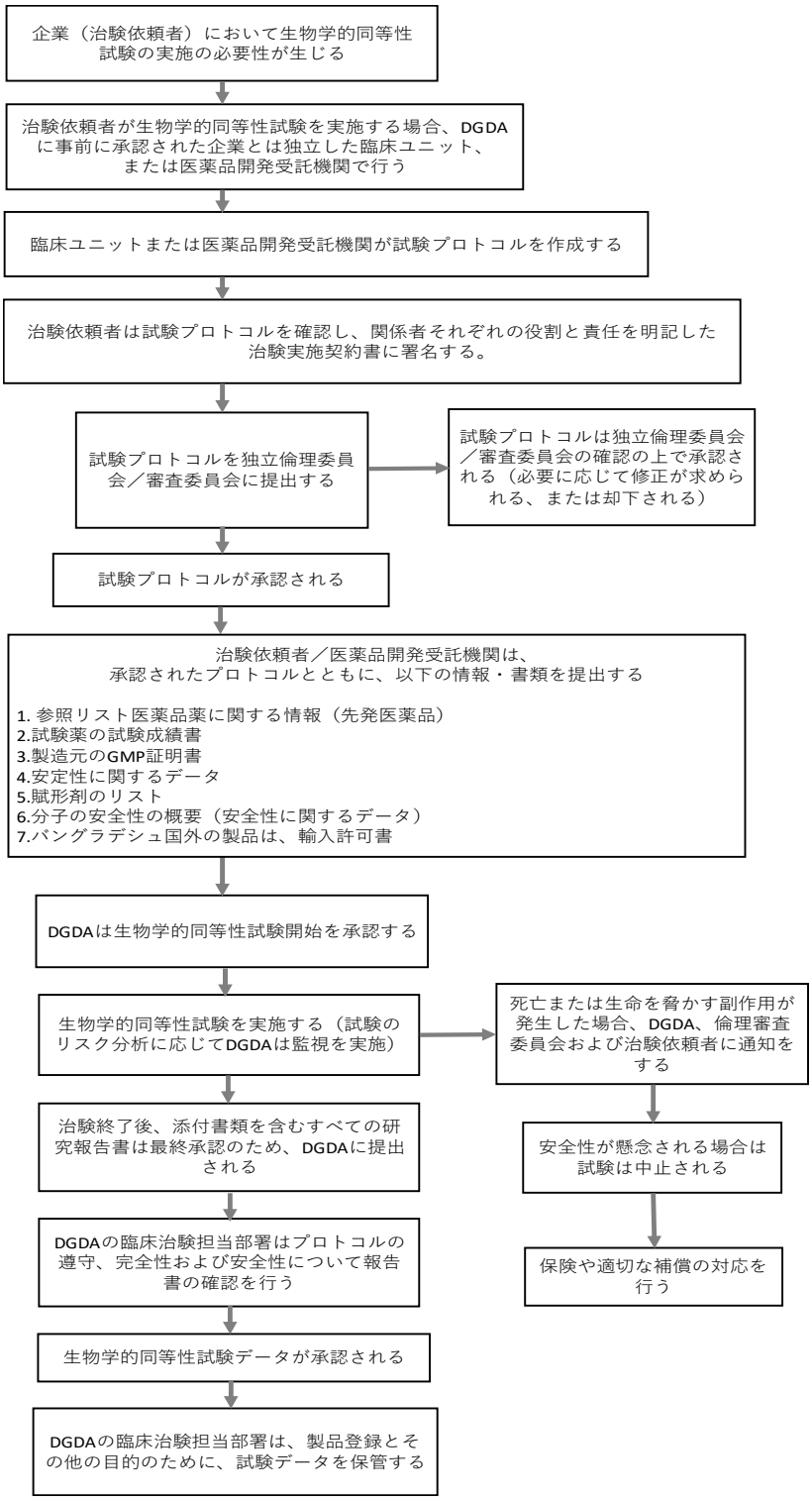
- BMRC／IRB／IEC に承認されたプロトコル
- 治験薬概要書
- インフォームドコンセント
- 治験依頼者、CRO、治験センター、治験統括責任者間で署名された同意書
- 治験統括責任者およびその他治験者（associates）の経歴書
- 治験薬の分析証明書
- 治験実施資金の詳細
- 症例報告書（Case Record Form）
- 各作業の SOP
- GCP 研修修了書（治験統括責任者およびチームメンバー）

2) 治験実施中

- 研究プロトコルにおける修正点
- 新しい治験者の経歴書（必要に応じて）
- 新しい製品バッチが使用されている場合、治験薬の分析証明
- 重篤な有害作用

生物学的同等性試験の治験に係る手続きの一連の流れを図 3-7 に示す。

[34] Documents submitted to DGDA for clinical trial （ http://www.dgda.gov.bd/index.php/2013-03-31-05-16-29/registered-medical-device-list-4/299-documents-submitted-to-dgda-for-clinical-trial、2018 年 8 月 15 日閲覧）



出典：Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products Bangladesh[35]を基に筆者作成

図 3-7：生物学的同等性試験の治験に係る手続きフロー

[35] Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products Bangladesh (2015)（http://www.dgda.gov.bd/index.php/2013-03-31-05-16-29/registered-medical-device-list-4/129-good-clinical-practice-gcp-guidelines、2018 年 8 月 15 日閲覧）

3.6.3 バイオシミラー製品の臨床試験の実施方法等の規制

バイオシミラー製品に関しては、前述のとおり別途ガイドライン [32] が作成されている。バイオシミラー製品に関する臨床試験として下記の事項が記載されている。

- 薬物動態（PK）試験
- 薬力学（PD）試験
- 確認的 PK / PD 試験
- 有効性試験
- 安全性
- 免疫原性
- 他の臨床適応への外挿

3.6.4 臨床試験の査察に関するガイダンス[36]

DGDA では、臨床試験前、実施中、実施後に、定期的または特定の事由により査察を実施するとしている。査察は、臨床試験サイトおよび治験依頼者／医薬品開発受託機関に対して実施される。2011 年には、査察実施者に対して実施方法を取りまとめたガイダンスを作成している。ガイダンスによる査察を実施する際の対象選定の基準例としては次の事項が挙げられている。

- 研究の性質
- 臨床試験データに基づく規制決定
- データの不規則性
- 苦情
- 被験者の脆弱性
- 特定のサイトに登録された被験者の数を含む治験数

このほか、ガイダンスには治験依頼者／医薬品開発受託機関に対するインタビュー内容、治験サイトでの確認事項が示されている。

3.6.5 医薬品開発受託機関（CRO）

バングラデシュで登録されている医薬品開発受託機関は、表 3-3 のとおり 7 機関である。

表 3-3：バングラデシュ国内の医薬品開発受託機関

No.	機関名	承認日
1	M/s. Khwaza Yunus Ali Medical College & Hospital	2016 年 2 月 25 日
2	M/s. Clinical Research Organization Ltd.	2016 年 3 月 23 日
3	International Centre for Diarrhoeal Disease Research, Bangladesh	2016 年 4 月 5 日
4	Filaria and General Hospital.	2016 年 8 月 2 日
5	M/S. Beximco Bioequivalence Center.	2017 年 6 月 1 日
6	M/s. Projahnmo Research Foundation	2018 年 3 月 19 日
7	Eminence Associates for Social Development	2018 年 5 月 10 日

出典：DGDA の Web サイトで公開されている資料を基に筆者作成

[36] Guidance on Clinical Trial Inspection, DGDA (2011) （http://www.dgda.gov.bd/index.php/2013-03-31-05-16-29/registered-medical-device-list-4/16-on-clinical-trial-inspection、2018 年 8 月 15 日閲覧）

3.7 副作用等の被害救済に関する制度

日本の「医薬品副作用被害救済制度」のように、医薬品を適正に使用したにもかかわらず、その副作用により入院治療が必要になるほど重篤な健康被害が生じた場合に、医療費や年金などの給付を行う公的な制度[37]は、バングラデシュでは整備されていない[18]。

尚、過失による死亡が認められるものについて、バングラデシュでは、刑法の 304 条 A「過失による死亡」[38]が医療の法システムに適用されるが、法的制度による最終判決までには時間がかかり、実際には実行されていないのが現状である[18]。

3.8 販売規制に関する制度

医薬品の流通・販売には免許取得が必要で、2 カ所以上の施設で医薬品を保管、販売する場合には、それぞれ許可申請が必要となる。許可証の有効期間は発行日から 2 年間である[39]。2016 年に策定された「国家医薬品政策」では、「医薬品の合理的使用を確保するために、登録医師から発行された処方せんなしに医薬品の販売および流通を禁止する」とし、その上で、「先進国のシステムに合わせて一般用医薬品（Over-the-Counter：OTC）の一覧を発行する」としている。また、一般用医薬品（OTC）については、DGDA の Web サイトで OTC 薬の一覧を公表している[40]。

DGDA の Web サイトによると、101,917 の医薬品販売店が登録されており、アロパシー、アーユルヴェーダ、ウナニ、ハーブ、ホメオパシー・バイオケミカルの各小売薬局（Retail Pharmacy）、ならびに卸売薬局（Wholesale Pharmacy）が種別ごとに Web サイトに掲載され、各薬局の許可証の有効期間が公開されている[41]。また、バングラデシュでは、模倣品、偽造品、基準以下の医薬品の販売防止の強化を目的に合同ドナー技術支援基金（The Joint Donor Technical Assistance Fund）の資金の下、英国国際開発省（Department for International Development：DFID）と Management Science for Health[42]（MSH）の技術支援によりバングラデシュモデル薬局イニシアティブ（Bangladesh Pharmacy Model Initiative）のプロジェクトが進められている。国内の薬局を 2 種類にレベル分けし、販売できる医薬品の種類、店舗保有者の資格、店舗の設備・環境、薬の調剤、ラベル表示などを規定し、評価認定を行っている。2016 年に発行された「モデル薬局（Model Pharmacy）およびモデル薬店（Model Medicine Shop）の設立・運営基準[43]」によると、プレ認定の査察の結果、基準に満たない薬局の店舗保有者は 1 年の猶予期間を与えられ、それまでに基準を満たせない店舗は閉店を命じられるとある。

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[37] PMDA の Web サイト（http://www.pmda.go.jp/kenkouhigai_camp/general01.html、2018 年 10 月 16 日閲覧）

[38] 刑法 304 条 A の原文：Causing death by negligence；Whoever causes the death of any person by doing any rash or negligent act not amounting to culpable homicide shall be punished with imprisonment of either description for a term which may extend to five years, or with fine, or with both.

[39] 医薬品規則 1946（http://www.dgda.gov.bd/index.php/laws-and-policies/85-drug-rules-1946、2018 年 8 月 8 日閲覧）

[40] DGDA の Web サイト（http://www.dgda.gov.bd/index.php/2013-03-31-05-16-29/guidance-documents、2018 年 8 月 24 日閲覧）

[41] DGDA の Web サイト（http://www.dgda.gov.bd/index.php/faqs、2018 年 8 月 22 日閲覧）

[42] 保健システムの構築など、保健医療分野で活動する非営利団体

[43] Standards for the Establishment and Operations of Model Pharmacies and Model Medicine Shops（http://www.dgda.gov.bd/index.php/2013-03-31-05-16-29/guidance-documents/175-guideline-for-model-pharmacy、2018 年 8 月 15 日閲覧）

薬局のレベルとそれぞれの設立・運営基準の主な概要を表 3-4 に示す。

表 3-4：モデル薬局およびモデル薬店の設立・運営基準

項目	Model Pharmacy（レベルⅠ）	Model Medicine Shop（レベルⅡ）
在店薬剤師のレベル	・カテゴリーA*の薬剤師 ※カテゴリーB*または C*の薬剤師はカテゴリーA の薬剤師の監督の下、薬の調剤ができる。	・カテゴリーC 以上の薬剤師
販売が許可される製品・サービス	・DGDA によって登録された全ての処方せん薬 ・DGDA によって登録された全ての非処方薬（OTC 薬） ・DGDA の確立された品質基準を満たす医療用品および医療機器 ・化粧品や衛生用品、健康促進商品	・DGDA により登録された全ての処方せん薬（但し、DGDA が制限する薬品群・医薬品を除く） ・DGDA によって登録された全ての非処方薬（OTC 薬） ・DGDA の確立された品質基準を満たす医療用品および医療機器 ・化粧品や衛生用品、健康促進商品

*薬剤師のカテゴリーについては、下記の参考を参照。

出典：Standards for the Establishment and Operations of Model Pharmacies and Model Medicine Shops[43]

(参考)

バングラデシュの薬学教育は3 つのタイプがある。薬学修士（Masters）は4～5 年（カテゴリーA）、薬学準学士（Diploma）は 3～4 年（カテゴリーB）、薬学修了（Certificates）は 2 カ月以上（カテゴリーC）の就学期間をそれぞれ要する。 大学は、バングラデシュ薬剤師会（the Bangladesh Pharmacy Council）の監督下で、カテゴリーA および B の教育をしている。 DGDA は、バングラデシュ薬剤師会およびバングラデシュ化学者協会（the Bangladesh Chemists）および薬剤師協会と共に、医薬品販売業者の研修を実施している[44]*。*

また、2018 年 3 月 18 日付で薬局管理に関する通達文書も DGDA から発出されている（添付資料 4 参照）[45]。内容は、前述の「モデル薬局（Model Pharmacy）およびモデル薬店（Model Medicine Shop）の設立・運営基準」と同様の内容で、在店薬剤師の種別や医薬品の保管方法や偽薬や期限切れの医薬品の販売の規制など、概要が記されている。

3.9 開発方針、必要な試験の内容、試験計画等に関する相談の仕組み

非臨床試験に関しては、バングラデシュで製造されている医薬品の大半がジェネリック医薬品のため非臨床試験は不要であるとともに、臨床試験が必要な医薬品も現時点では限定的である。DGDA は、臨床試験のための標準的なオペレーティングシステムを開発することを検討している。現時点では、開発方針、必要な試験の内容、試験計画等に関する相談の仕組みは整備されていないのが現状である [18]。

[44] Medicines in Health Care Delivery Bangladesh, WHO（http://www.searo.who.int/entity/medicines/country_situational_analysis/en/、2018 年 8 月 15 日閲覧）

[45] 薬局管理に関する DGDA の通達文書（http://www.dgda.gov.bd、2018 年 8 月 24 日閲覧）。ベンガル語の仮英訳。

第 4 章　医療機器に関する規制

4.1 定義・分類

4.1.1 一般的な医療機器の定義

医療機器（Medical Devices）の明確な定義は DGDA が発行した「Registration Guidelines for Medical Devices Bangladesh 2015」（以下、「医療機器登録ガイドライン」。添付資料 5 を参照）の第 1 章に、以下のように定められている。

「器具（instrument）、装置（apparatus）、生体内への埋め込み器具（implant）、機械（machine）、検体検査用の試薬（reagent for in vitro use）、ソフトウェア（software）、医療材料（material）もしくは他の類似あるいは関連する物品（other similar or related article）」であって、「その製造者によって、それ単体もしくは組み合わせることで人体のために 1 つ以上の特定の医療目的（medical purpose (s)）[46]*のために使用されることが想定されたもの」であって「人体上もしくは人体内で薬理学上もしくは免疫学上、代謝上の手段によって上述の作用を達成するものではないが、機器の意図された機能においてそれらの手段が補助となりうるもの」*

また、上述の定義を補完する注釈として医療機器に付随するアクセサリー[47]や医療機器の構成品、また半製品の医療機器について以下のとおり記載されている。これらは各製品の原産国の規定に従って規制されるとされている。

表 4-1：ガイドライン上の分類と規定

分類	ガイドライン上の規定
アクセサリー	医療機器と同じ規定に従うが、クラスは、その物品自体で分類される（そのため「親機（本体機器）」と異なるクラスとなる可能性がある）。
構成品	一般的にその機器の製造者の品質マネジメントシステムと適合性評価手順によって管理される。
半製品	下請けの製造者による製造過程下の半製品も一般的に元請け製造者の品質マネジメントシステムとその機器の適合性評価手順を通じて管理される。

また滅菌物質（disinfection substances）、障害者用の補助器具、動物もしくはヒト由来細胞を含む製品、体外受精もしくは生殖補助技術のための機器を含む、特定の行政区（in some jurisdictions）でのみ医療機器と見なされる製品もその原産国の規定によって規制されると記載されている。

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[46] ここでいう医療目的は以下のとおりに定められている。
① 疾病の診断（diagnosis）もしくは予防（prevention）、経過観察（monitoring）、治療（treatment）、緩和（alleviation）
② 傷害の診察もしくは経過観察、治療、緩和、補償（compensation）
③ 解剖学上もしくは生理学上の調査（investigation）、置換（replacement）、矯正（modification）、支持（support）
④ 生命の維持・延命（supporting or sustaining life）
⑤ 妊娠の抑制（control of conception）
④ 医療機器の滅菌（disinfection of medical devices）
⑤ 人体から採取された検体の体外検査（in vitro examination）による情報の提供（providing information）

[47] ある医療機器がその本来の意図に従って使用できるよう、製造者によって明確に「親機（本体機器）」とともに使用されることが企図されたもの。

4.1.2 体外診断用医療機器の定義

体外診断用医療機器（in vitro diagnostic、以下 IVD）については、上述の定義を踏まえて、別途、「医療機器登録ガイドライン」の 2 章において以下のように記載されている。

「医療機器であって、それ単体もしくは組み合わせて使用されるかに関わらず、その製造者によって、診断あるいは経過観察、比較を目的として、専らもしくは主に情報を提供するために人体から採取された検体を体外検査することを企図されたもの」

同定義の補足として、IVD は試薬、較正器、制御材料、検体容器、ソフトウェア、関連する器具または装置、その他の物品であって、診断、診断支援、スクリーニング、経過観察、素因検査、予後検査、推測、生理状態の把握といった検査目的に使用されるものも含むが、その一方で、一般的な検査室で使用される製品は IVD の定義に含まないとされる。

4.1.3 医療機器登録ガイドライン適応範囲外の医療製品

上述のとおり、医療機器登録ガイドラインの適応範囲は広いが、反対にその範囲から外れるものも、同ガイドラインの 2 章に以下のとおりに定められている。

- 「医薬品法」の対象となる医療製品[48]
- 化粧品
- 人血、血液製品、ヒト由来の血漿もしくは血球、ヒト由来の組織もしくは細胞、ヒト由来の組織・細胞を含む、もしくはヒト由来の組織・細胞から製造されている製品
- 医薬品・医療機器の専売に関し、かつ人血や血漿に由来する医薬品・医療機器のための特別規定についての法律、規制、行政措置によって定められた近似規定（approximation of provisions）によって、成育不能にされた動物細胞、動物細胞に由来する成育不能な製品を利用して製造されている物品を除く動物由来の移植組織もしくは組織、細胞

4.1.4 分類

「医療機器登録ガイドライン」において、医療機器の分類は、その機器が企図された目的、その機器の設計と製造者に付随する潜在的危険性を考慮した人体への影響に基づき、A、B、C、D の 4 つの区分に分類されるとされている。

IVD 以外の医療機器の分類は下表 4-2 のとおりとなる。また IVD 以外の医療機器のクラス分類の手順は「医療機器登録ガイドライン」の「Annexure 1: Classification Rules (procedures)」に、「非侵襲機器」、「侵襲機器」、「能動機器」の 3 つのカテゴリーごとに記載されている（下図 4-1、 4-2、 4-3 参照）。

表 4-2：IVD 以外の医療機器の分類

クラス	リスクレベル	該当機器の例	図 4-1, 2, 3 上の色分け
A	低リスク	手術用開創器、舌圧子	青
B	低～中リスク	皮下注射針、吸引器	緑
C	中～高リスク	人工呼吸器、骨固定プレート	黄
D	高リスク	人工心臓弁、植え込み型除細動器	赤

[48] 特定の製品が医薬品法上で「医薬品」に分類されるか、同ガイドライン上の「医療機器」に分類されるかは、その製品の効用の主な作用機構を特に考慮する必要があるとのこと。

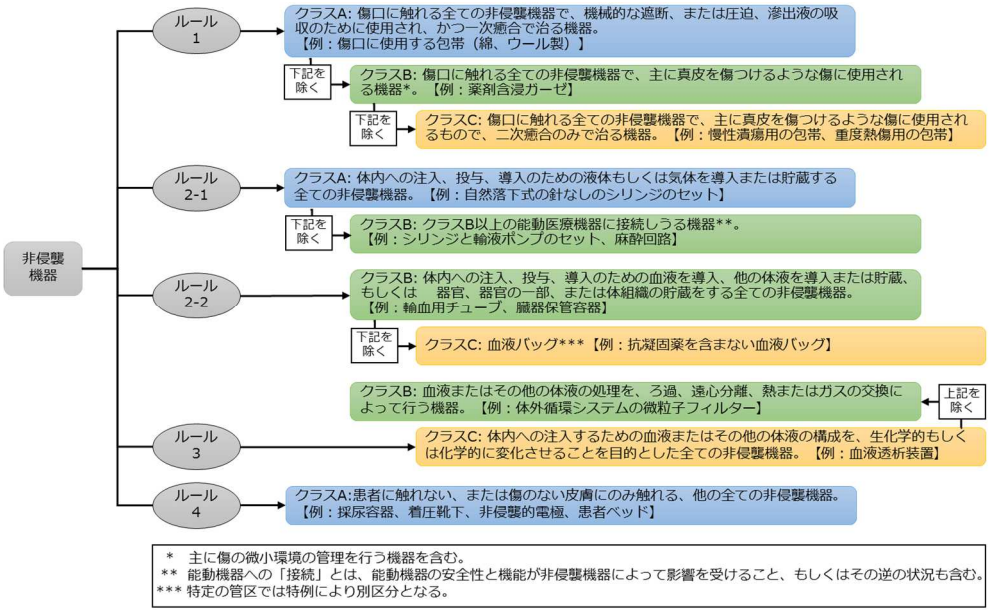

図 4-1：非侵襲機器のクラス分類手順

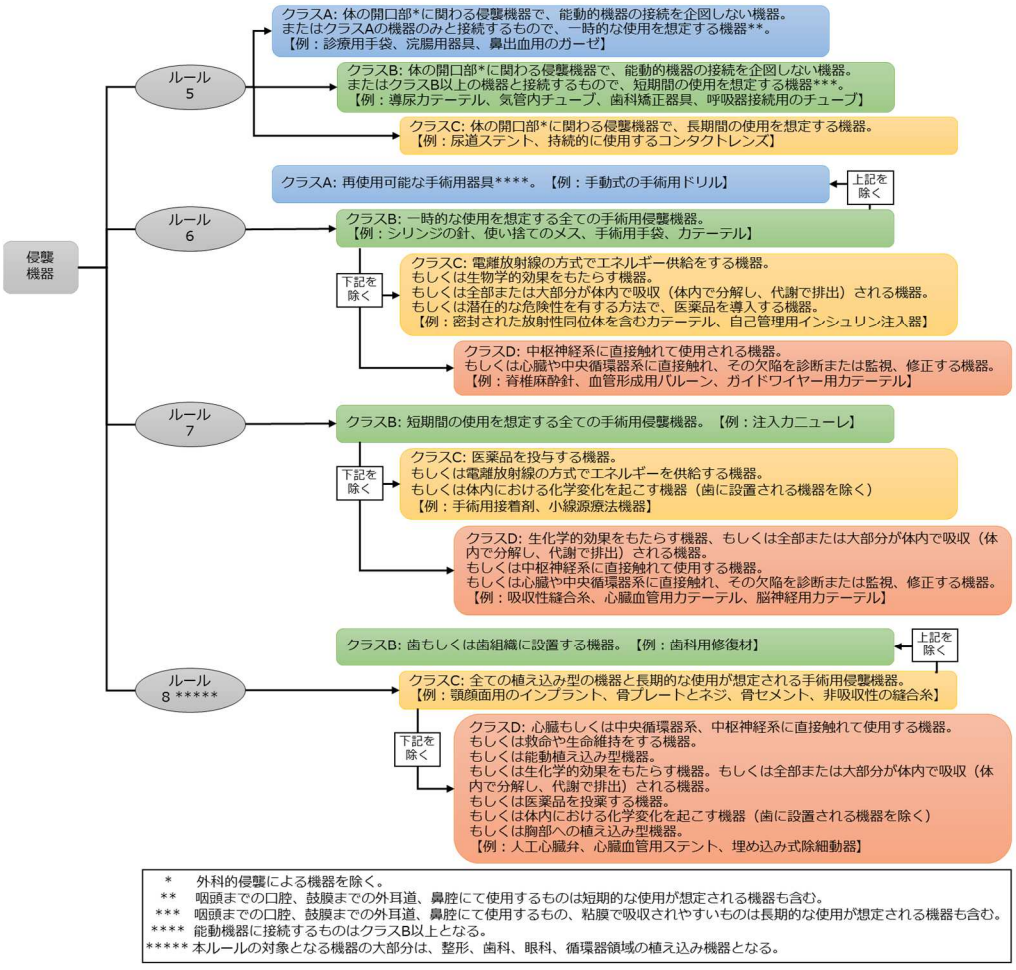

図 4-2：侵襲機器のクラス分類手順[49]

[49] 図 4-2 中の「一時的」、「短期間」、「長期間」の定義は以下のとおり。

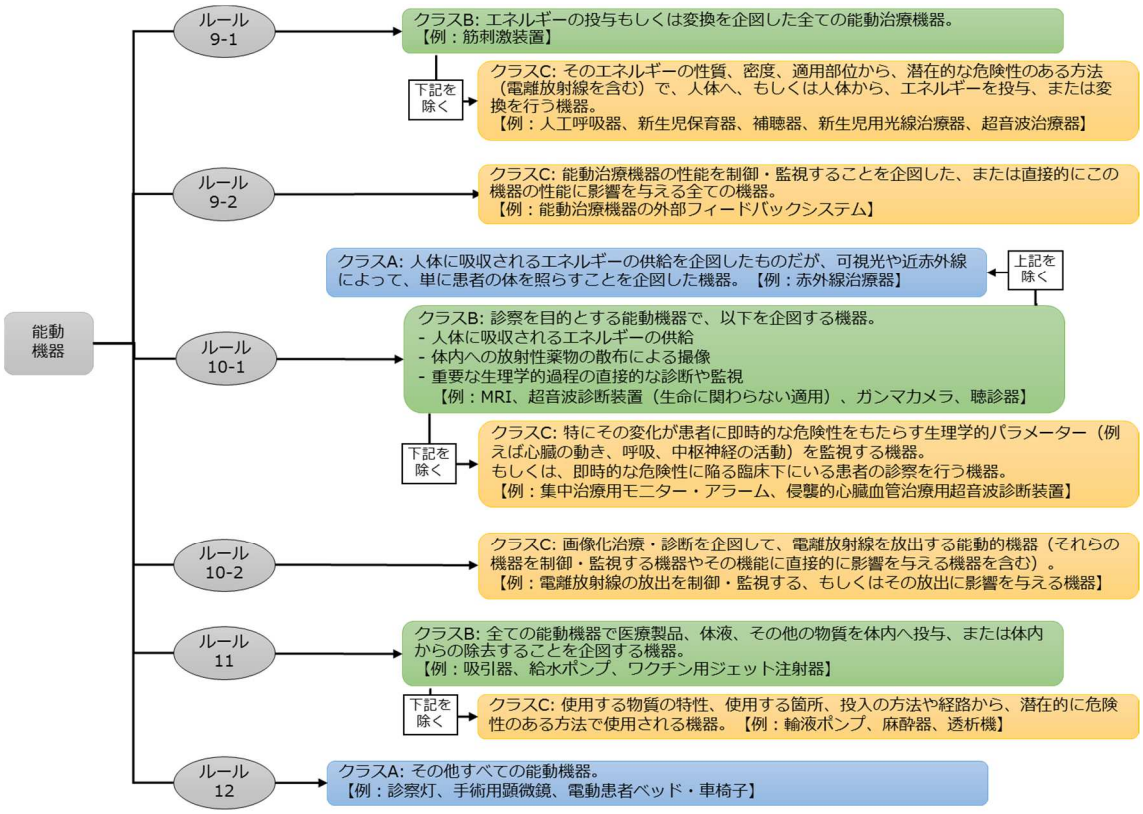

図 4-3：能動機器のクラス分類手順

この定義による分類から漏れる製品もわずかに存在する。そのため、DGDA は、上述の分類（ルール 1 からルール 12）の基準とは異なる要素を考慮して分類されるよう、下図 4-4 のとおり、追加ルール 13 から 17 を提示している（図中のクラスごとの色分けは表 4-2 に準じる）[50]。

① 一時的：通常、60 分未満連続して使用する場合を示す。
② 短期間：通常、60 分から 30 日間連続して使用する場合を示す。
③ 長期間：通常、30 日間を超えて連続して使用する場合を示す。

[50] この追加ルールの提示した背景として、国際的な医療機器整合性の調整活動を協議する医療機器規制国際整合化会議（Global Harmonization Task Force、以下「GHTF」とする。）が、医療機器の規制に係る調査を支援・促進する一方で、マイナーな医療機器の分類は、その地域固有の要望や社会的な要素に配慮する必要があるとの理解から、特に GHTF の創設メンバーでない国々への理解を促すためのガイダンスとして示していると説明されている。

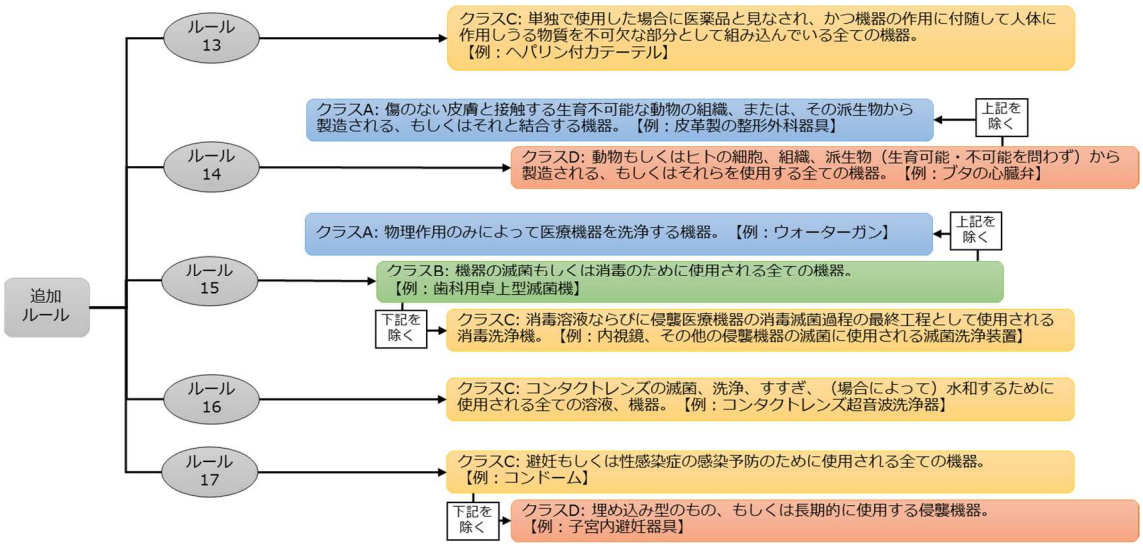

図 4-4：追加ルール上のクラス分類手順

なお、もし当該機器が既定の分類に従わない場合には、国際的に受け入れられている分類方法が、その機器に適用される。

IVD は以下の各点を基準とし、各クラスに分けられる。

- 製造者によって明確化された使用目的と使用に係る指示（その機器の検査が対象とする特定の体調、疾患、対象群、状態、危険因子を含む）
- 想定される使用者（一般人または医療従事者）の技術的、科学的、医学的専門性
- 医師の指針となるような現在の兆候や症候を含む疾病や不調の自然経過を考慮した上で、診察によって得られた情報の重要性（1 つ、もしくは複数のうちの 1 つを問わず）
- 個人かつ/または公衆衛生上における結果（真または偽）の重要性

上記の基準に従い、IVD のクラスは下表 4-3 のとおり、4 つとなる。なお IVD のクラス分類の手順は「医療機器登録ガイドライン」の「Annexure 1: Classification Rules (procedures)」に、以下の図 4-5 のとおり、記載されている。

表 4-3：IVD のクラス

クラス	リスクレベル	該当機器の例	図 4-5 上の色分け
A	個人もしくは公衆衛生上、低リスク	臨床化学分析装置、選択培地	青
B	個人もしくは公衆衛生上、低～中リスク	ビタミン B12、妊娠自己検査薬、抗核抗体検査装置、尿検査試験紙	緑
C	個人もしくは公衆衛生上、中～高リスク	自己検査用血糖値測定器、HLA 検査装置、PSA 検査装置、風疹抗体検査薬	黄
D	個人もしくは公衆衛生上、高リスク	献血用 HIV スクリーニング機器、HIV 血液検査機器	赤

製造者は、以下の 4 つの観点から、当該製品のクラスを決定する。

(1) 4.1.2 の定義に則って、使用目的と使用に係る指示内容に基づき、当該機器が IVD となるのか否かを決定する。

(2) その機器を適切に分類するために、4.1.2 に挙げられている全ての規定を考慮する。もしその IVD 機器が多目的に使用されることが製造者によって明確化されており、それぞれの使用目的に基づき 2 つ以上のクラスに分類される場合、高い方のクラスに分類する。

(3) その機器に対し、もし複数の分類のルールが適用される場合、より高いクラスに分類する。

(4) 特定の管轄区内で適用される特別な規定に従うかを決定する。もし特別な規定が適用され、既定の分類ルールと異なるクラスとなった場合、異なる適合性評価手順が求められることになる。この場合、他の、もしくは追加での適合性評価が実施されない限り、国際的な自由移動規定（Free Movement）のための機器の利用可能性に影響する。

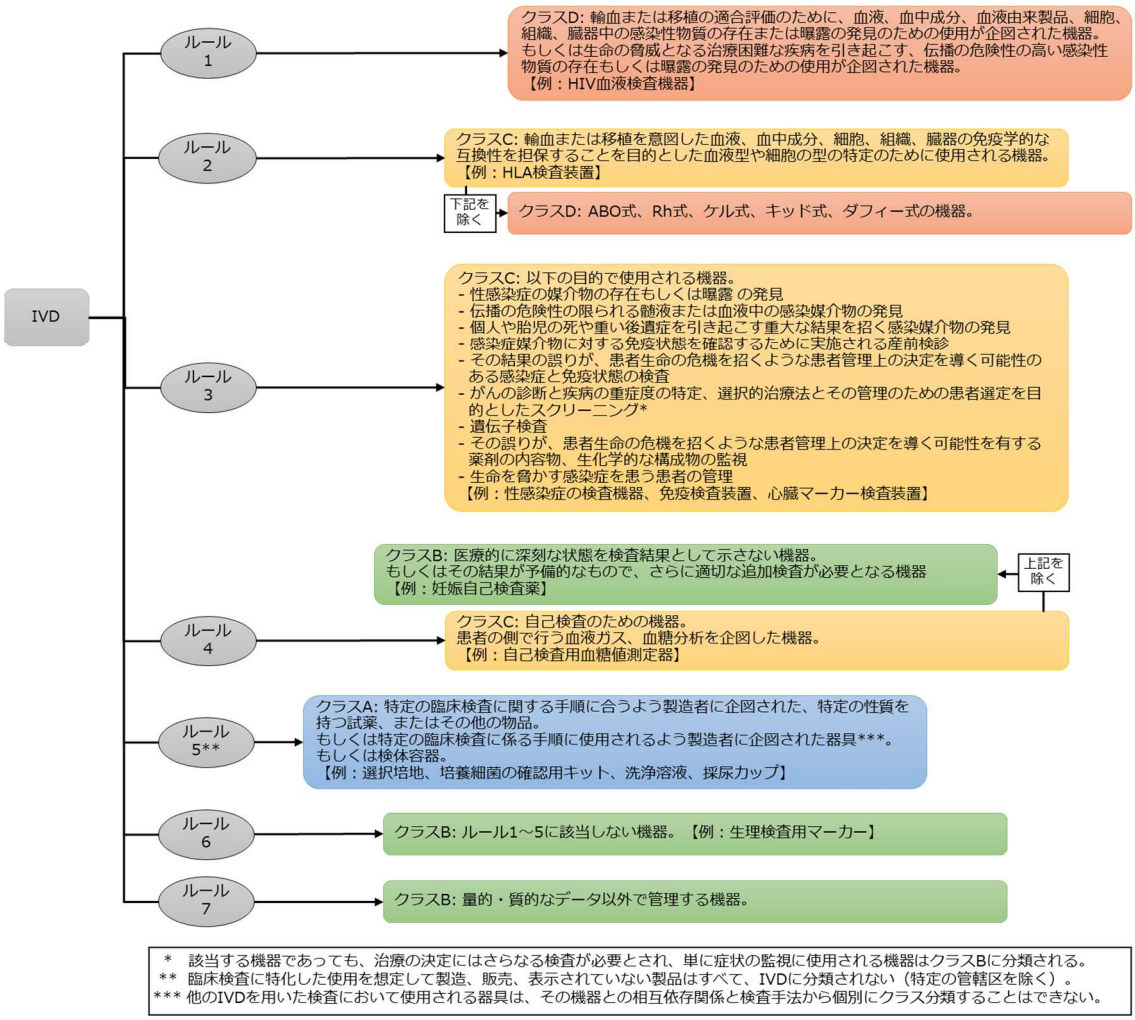

図 4-5：IVD のクラス分類の手順

以上が「医療機器登録ガイドライン」上に記載されている医療機器の分類方法となるが、バングラデシュに進出している日本企業へヒアリング調査（以下、「ヒアリング調査」）を行ったところ、2015 年の同ガイドライン策定後、実際の運用がまだ開始されていないとのことである。

4.2 承認等に関する規制

医療機器の承認手続きは「医療機器登録ガイドライン」の「Annexure 2: Procedure for registration of Medical Devices for manufacture and import into Bangladesh」に定められている。しかし、ヒアリング調査の結果では同ガイドラインに記載されている医療機器の分類と同様、承認に係る審査、登録はまだ実施されていないとのことであった。

一方、バングラデシュ国内で外国の医療機器を販売する際には、輸入登録が義務付けられており、こちらは既定の手続きに沿って輸入登録がされる。また放射線を使用する機器については、バングラデシュ国で放射線を管理する機関である「バングラデシュ原子力規制委員会（Bangladesh Atomic Energy、以下 BAEC）」への登録申請も必要となる[51]。

4.2.1 対象となる医療機器

「医療機器登録ガイドライン」上は、同規制の対象となる医療機器はクラス B、C、D の機器のみとされている。同ガイドライン策定時点で既にバングラデシュへ輸入されている、もしくは製造されている医療機器は、同ガイドラインの発行後、速やかに登録申請（Application of registration）を行わなければならないとされている。一方で、これ以降にバングラデシュに輸入される、もしくは製造される医療機器は、それが輸入もしくは製造される前に登録申請を行わなければならないことが明記されている。

4.2.2 申請手続き

「医療機器登録ガイドライン」上、登録申請には、まず医療機器登録申請書の作成が必要で、登録申請自体は製造者の権限保持者、海外の納入業者、権限代行者によって行われる必要があると記載されている。また申請書に盛り込むべき情報として下表 4-4 の各項目が挙げられている。

[51] ヒアリング調査にご協力いただいた企業様の場合、BAEC への登録申請と輸入登録申請の両方の手続きを合わせて半年以上の時間を要したとのこと。過去に、バングラデシュにて粗悪な放射線機器が輸入され、それらの故障が相次いだことから、放射線機器の輸入に対する取り締まりが強化されたとのことであった。

表 4-4：申請書に必要な情報

一般情報	• 現地権限代行者の名前、住所、電話番号、Eメールアドレス • 製造者から代行者への委任状原本（ただしバングラデシュに自社支店のある製造者は不要） • もし当該製品の市販に係る責任者が製造者が異なる場合、その責任者の名前、住所、電話番号、Eメールアドレス（法的権限者による証明が必要） • もしバングラデシュで部分的に製造することを計画している場合、その現地製造者の詳細
製品情報	• 製品名（商標名、一般名称を含む） • GHTFに基づく機器の分類クラス • 機器の詳細と用例 • 機器のサイズ • 機器の主な用途 • MAF（CEもしくはFDAに準拠していない場合） • 機器の製造過程に関する簡潔な記述 • ラベルと梱包の詳細 • 機器の使用に必要なアクセサリーの詳細 • 基礎となっている、もしくは同等の機器 • 準拠している基準（ISO等の一般的な国際基準） • ユーザーマニュアル
その他	• 原産国ならびにその他の先進国における規制適合状況で、適合性評価証明書または同等の証明書と、クラスBの場合は原産国の自由販売証明書、クラスC、Dの場合は原産国及びEU、米国、カナダ、豪州、日本のいずれかの国の自由販売証明書 • 機器を販売している国のリスト • 直近2年間における規制当局の主導による市場からの撤退やリコールの状況 • 医薬品と組み合わせて使用する機器の医療上の利点の詳細 • 機器に付随する医薬品とその効能、安全情報 • 新規医薬品を含む場合は、その臨床試験データ（医薬品法およびその修正法の新薬の定義を要参照） • 製品の販売、サービス、普及モデルの詳細、申請者もしくは製造者による販売手段 • 市販後の対応：有害事象報告書の取り扱い、現場対応、製品リコール、苦情対応手続き

申請書作成後はその申請書と共に、既定の手数料を支払うことが記載されているが、金額は明示されていない。

なお、申請書と申請手数料は製品ごと、製造者の店舗ごとに個別に用意しなければならないが、同種の医療機器を製造者の同店舗から販売する場合には単一の申請で構わないと記載されている。

4.2.3 申請のためのチェックリスト

申請書のフォームは明らかではないが、その申請書に記載すべき項目のチェックリストが「医療機器登録ガイドライン」の「Annexure 3: Application checklist for permission for Manufacture & import of Medical devices」として、下表 4-5 のとおり、添付されている。

表 4-5：申請書に記載すべき項目のチェックリスト項目

No.	詳細
1	現地における製造者もしくは現地代理人の名前、住所、連絡先の詳細
2	代理人委任状
3	製造者の名前、住所、連絡先の詳細
4	その製品が既にバングラデシュに輸入されているか。そうであればいつからか
5	製品名（ジェネリック製品名があれば、それを含む）
6	機器のクラスと準拠した分類制度、適合性評価証明書を要添付
7	適合性評価機関の詳細
8	商業ベースで当該機器がいつから使用されているか。臨床評価や安全性の課題に対処されているか
9	機器の主な使い方
10	医薬品を組み合わせて使用する機器か
11	上記の回答が「はい」の場合、使用する医薬品は新薬か
12	1つ以上の機器から構成される製品一式であるか
13	機器の大きさ
14	MAFは提出しているか
15	機器の製造過程の簡潔な記述
16	消毒する手段
17	機器の市販を開始するための方法
18	製造と品質保証担当の技術者の名前と資格
19	製造所のレイアウトおよびフロアプラン
20	QMSの詳細とそのマニュアル
21	市販前に製品が検査されているか。もしそうであれば、その詳細。そうでない場合には市販の基準
22	これまで機器が何らかの理由により、市場から撤退したことがあるか。その場合にはその詳細
23	市場から撤退する際に、従うべきリコール手順
24	その機器が輸出されている国の名称

4.3 市販後の安全対策に関する規制

4.3.1 一般的な医療機器の市販後の安全対策

一般的な医療機器への市販後の安全対策に係る規制は「医療機器登録ガイドライン」の5章によると以下のとおり。

市販後の安全対策の対象となる機器は、低リスク以外の機器であるクラスB、C、Dの機器のみとなり、これらの対象となる機器が市販された後、同製品がバングラデシュで使用される間、その製造者もしくは輸入者は、組織的にその性能を監視するために市販後の安全対策（post-marketing surveillance）の規定に従うことが義務付けられている。

仮に「深刻な有害事象（Serious Adverse Events）」[52]が発生した際には、製造者は、それを調査・分析し、製造者もしくは輸入者がその事象の発生を認知した日から換算し、10営業日以内にDGDAの既定の部署に安全性監視報告書（Vigilance Report）を提出する義務があるとされている。

[52] 「深刻な有害事象」は同ガイドラインに「バングラデシュにおける医療機器に関連するか否かに関わらず、患者もしくは使用者、その他の人々に対する予期しない全ての医療的事象、意図しない疾病や傷害、もしくは予期しない臨床的な兆候（異常な臨床検査結果を含む）」と定義されている。
またこの定義に対する補足として、同定義は、治験中の医療機器もしくは対照機器（comparator）に係る事象、関連する手順に係る事象も含む。しかし治験中の医療機器に係る事象以外は、患者に対する事象のみをその範囲に含み、使用者やその他の人々に対する事象は含まない。

また、製造者はその品質マネジメントシステムの一部として、有害事象の再発を予防もしくは再発生率を減少させるために適切な改良や予防措置を取ることが許可されている。

しかし、ヒアリング調査の結果、一般の医療機器の市販後の安全対策についても、同ガイドラインに記載されている規制は、同調査時点では、まだ運用されていないとのことであった。

4.3.2 特殊な医療機器の市販後の安全対策

オーダーメイドの機器、展示用の機器、複数の製品が組み合わされた機器等、特殊な機器に対する規定も、「医療機器登録ガイドライン」の 6 章と 11 章に以下のとおり記載されている。

オーダーメイドの機器は、バングラデシュにおいて市販可能であると明記されているが、名前もしくは略語コード、数値コードで識別された特定の患者のみを対象とするか、同じ方法で特定された使用者のみが使用できるという旨のステートメントが必要となる。

商業上のフェア、展示会、実演等における展示用の機器は、展示する時点で同ガイドラインに準拠していない機器であっても、それが「既定の規制に従って製造され、かつ製造者もしくは輸入者がその機器の目的を DGDA に通達してはじめて、その機器の販売や使用が可能となる」といった旨が明記してあれば、展示することは可能である。またこれらの機器をその目的（商業上のフェア、展示会、実演等）のために原産国から輸入したり、その目的を達成した後に原産国へ再輸出したりすることも可能である。

製造者が意図する目的内、かつ製造者によって特定された使用制限の範囲内で、複数の医療機器を 1 つのシステムである「プロシージャ―パック（Procedure packs/Kits/Bundle）」としてバングラデシュで市販するためには、製造者は DGDA に対し、以下を含む宣言文を作成することが求められている。

- 製造者の指示に従って機器の相互互換性を証明し、機器を運用していること。
- プロシージャ―パックとして機器を組み合わせており、製造者から使用者に対し、明確な指示を含む明確な情報を提供していること。
- その機器に係る全ての活動に対し、内部統制や監査等を受けるようになっていること。
- 本来意図された使用上の観点から、その組み合わせのために選択された機器に互換性がない場合、そのプロシージャ―パックは 1 つの機器として扱われ、その分類に合った適合性評価手段を受けること。

しかし、ヒアリング調査の結果、特殊な医療機器の市販後の安全対策についても、ヒアリング調査時点では同ガイドラインに記載されている規制はまだ運用されていないとのことであり、ヒアリングをさせていただいた企業が、試供品の輸入を検討していた際に、試供品の輸入手続きがないとの理由で断念せざるを得なかったとのことであった[53]。

4.3.3 情報の提供と守秘義務

「医療機器登録ガイドライン」の 15 章において、既存の国家規定と医療上の守秘義務に抵触しないよう、このガイドラインが適応される全ての利害関係者が、それぞれの業務を

[53] 同国の展示会では既に国内で販売されている製品の紹介に留まっているとのことであった。

実施する上で得られた全情報について守秘義務に従えるよう、DGDA が努力することが記載されている。

一方で、この守秘義務は、相互情報伝達や警告の通達といった DGDA の業務や、刑法に基づく関係者からの情報提供の義務に影響を与えないこと、また以下の情報は、守秘すべき情報としないことも同時に明記されている。

- 本ガイドラインに則って機器の市販責任者を登録するための情報
- 本ガイドラインに従った手段で製造者、規制当局、販売者から使用者に提供された情報
- 証明書の発行、修正、補完、一時停止、取り消しを含む情報

4.4 製造・品質管理に関する規制

製造・品質管理に関する規制については、「医療機器登録ガイドライン」の第 4 章の各節に関連する記載がある。しかし、ヒアリング調査の結果では、医療機器の品質検査を行える人員が限られ、品質検査体制も整備中であることから、同ガイドラインに記載されている規制はヒアリング調査時点では、まだ実施されておらず、欧米や日本で信頼されている企業が製造する医療機器を積極的に輸入することで品質を担保しているのが現状とのことであった。

今回ヒアリングさせていただいた企業では、米国 FDA や ISO13485 等の国際的な認知度の高い規格に準拠していれば問題はないという理解の下で、輸入登録の際にこれらの証拠書類を提出していた。

4.4.1 製造・品質管理に関する基準

特に新規に市場に参入した医療機器の製造・品質管理に関して、以下のとおり、記載がある。

医療機器という製品の性質上、その製品を使用することで高い効果を得る必要があるが、それとともに患者、使用者、または第三者に対して高水準の防護も提供される必要がある（第 4 章第 1 節）。そのため、製造者は、製造する医療機器によって期待される成果を得るために必要不可欠な原理、安全上の原理に則るため、最新の ISO、IEC、もしくはその他の公的もしくは製造者独自の基準に従うことが求められる（第 4 章第 2 節）。

4.4.2 適合性評価

医療機器の適合性評価については、以下のとおり、明記されている。

製造者と規制当局の責任下において、製造者が企図した機器の分類に応じた適合性調査が実施される（第 4 章第 3 節）。その適合性評価の手続きのために機器を 4 つの分類に分けることが必要不可欠となる（第 4 章第 4 節）。

クラス A の機器の適合性評価は、その脆弱性が低レベルであるとの観点から、基本的には製造者単独の責任下において実施することができる。また、その製造者は DGDA より製造者のライセンスを取得する必要はなく、DGDA に適合宣言書の内容に従っていることを通達するだけでよい（第 4 章第 5 節）。

クラス B、C、D の機器の適合性評価は、それらの機器が中程度から高程度の潜在的危険

性を有しているとの理解から、QMS に係る認証機関による認定証が求められる[54]。製造者もしくは輸入者は、DGDA が指定した書類を添えて登録申請することが求められており、これらの書類（必要に応じて実施される検査結果を含む）に基づき、DGDA によって登録される（第 4 章第 6 節）。QMS を既に適用し、バングラデシュ国外の規制当局ならびに第三者認定機関により、製品の認定証と市販許可を与えられている製造者は、その製品をバングラデシュ国内で市販できるかを DGDA が検討できるよう、そうした証明書・許可書類を提示する必要がある（第 4 章 7 節）。尚、規制当局による評価や認定に係る申請によって生じるいかなる費用も、製造者のみが負担する（第 4 章 8 節）。

加えて、医薬品法 1940 に規定されている手続きに沿って DGDA は医療機器の標本抽出検査を可能な限り実施する。検査対象となる機器の性質上、その対応が難しい場合には、製造者もしくは輸入者の主張とその機器の規制上の適合性を検証するために、DGDA は標本抽出検査以外の手段をとる可能性がある（第 4 章 9 節）。

4.5 非臨床試験の実施方法等に関する規制

調査実施時点では、公開されている情報からは非臨床試験実施方法等に関する規制は確認できなった。

4.6 臨床試験（治験）の実施方法等に関する規制

臨床試験の実施方法等に関する規制は「医療機器登録ガイドライン」の 13 章において以下のとおり規定されているが、ヒアリング調査の結果、臨床試験（治験）の実施方法等の関する規制についても、同ガイドラインに記載されている規制はヒアリング調査時点では、まだ運用されていないとのことであった。

規定上は、臨床試験（治験）の実施方法等に関する規制の対象となる機器は、低リスク以外の機器であるクラス B、C、D の機器のみとなる。

また製造者もしくは製造者の代理人、輸入者は治験開始前に DGDA に事前連絡を行うとともに、広く認知されている国際基準（ISO14155 もしくはそれと同等の基準）に従って治験を実施する必要がある[55]。もし治験を早期中止する場合には、製造者もしくは製造者の代理人、出資者は、その理由と共に DGDA に治験の終了を通達しなければならない。

なお 4.3 で述べたとおり、同ガイドラインでは「深刻な有害事象」が定義されており、治験中の医療機器に関連する事象であれば、患者、使用者、その他の関係者のいずれのものが被った事象も「深刻な有害事象」と見なされる。一方で対照機器（comparator）に係る事象、関連する手順に係る事象は、患者が被った事象のみが「深刻な有害事象」として見なされる。

[54] クラス D の機器については機器の設計についての認定証も求められるとのこと。

[55] これは既にバングラデシュ内で市販が認められている医療機器の治験は、その機器を以前認められた目的の別の目的で使用するための治験でない限り、適用されない。

4.7 副作用等の被害救済に関する制度

調査実施時点では、公開されている情報からは確認できなった。ヒアリング調査の結果においても、同国内は医療機器の維持管理体制が脆弱であるため、整備不良による医療機器不具合は頻繁に起こるが、それによって患者等への健康被害があったと明確に結論付けられた事例は、ヒアリング調査時点ではないとのことであった。

その背景としては、公的医療機関で患者が医療サービスを受ける場合、その医療費は無料となるが、その診療に使用する医療材料や薬剤を患者自身が購入しなければならないことが多く、安価だが粗悪な製品を購入・使用することで発生する問題といった医療機器以外に起因するリスクが多くあること、また医療機関内部で有害事象を積極的に公表する体制がないため、医療機器に起因する有害事象が表に出ないことなどが、一因として考えられるとのことであった。

4.8 販売規制に関する制度

同ガイドラインに以下のとおり記載されているが、ヒアリング調査の結果、実際の運用は同調査時点では、まだ実施されていないとのことであった。

4.8.1 市販の制限・禁止

「医療機器登録ガイドライン」の 10 章ならびに 14 章に以下のとおり規定されている。

健康や安全を守るため、もしくは公衆衛生上の要件を順守するために、特定の医療機器（もしくは医療機器一式）の市販や使用を禁止、制限する、または特定の条件付きで市販や使用を認めるか検討する際に、DGDA は必要かつ正当な暫定的手段をとることが述べられている。

また、その際に DGDA は、製造者もしくは輸入者、全ての利害関係者に対し、本ガイドラインに沿ってなされた市販・使用・治験の禁止または制限、もしくは市販の取り消しのためのいかなる決定においても、その決定の根拠を明確化することが述べられている。

加えて、DGDA は当事者と可能な限り、相談することも定められており、DGDA は当事者に対し、彼らが医薬品法下で提供可能となっている問題の解決方法と、それに従うべき期限も通達しなければならないことが明記されている。

4.8.2 セーフガード（緊急輸入制限）の規定

同ガイドラインの 9 章にセーフガードについて、以下のように規定されている。

機器が適切に納入、維持され、本来の目的に使用されているにもかかわらず、患者もしくは使用者、その他の人の健康や安全を損なう可能性があると DGDA が判断したとき、その機器の市場からの引き上げ、販売禁止、もしくは販売や使用を制限するためのあらゆる暫定措置が取られる。

特に以下の理由による場合、DGDA は製造者もしくは輸入者に対し、直ちにその決定の理由と共にその手段を通達しなければならないとされている。

・当該機器が同ガイドラインに規定されている要求事項を満たすことができなかった場合
・当該機器の 広く認知されている国際基準の申請が不適切であった場合

・準拠基準そのものに欠陥があった場合
・そのほか、誰かの健康を損なう可能性がある場合

また「医療機器登録ガイドライン」の 12 章に、医療機器の販売については、卸売、小売に関わらず、適宜修正される医薬品法や既定の規制、布告によって管理されることが述べられている。

4.9 開発方針、必要な試験の内容、試験計画等に関する相談の仕組み

調査実施時点では、公開されている情報からは開発方針、必要な試験の内容、試験計画等に関する相談の仕組みについては確認できなった。

第 5 章　政府ならびに薬事規制当局の取り組みとその評価

5.1 規制当局による薬事規制の現状と課題

前述のとおり、バングラデシュでは、2011 年から 2018 年にかけて USAID による「医薬品およびサービスへのアクセス向上プログラム（SIAPS プログラム）」[56]が実施され、保健家族福祉省に対して質の高い医薬品と有効な医薬品サービスの可用性の向上を目的とした技術支援が提供された。

SIAPS プログラムにより 2012 年に実施されたバングラデシュにおける医薬品規制当局の規制制度および能力に係る現状調査の結果では、次の点が課題として指摘されていた。

- 複数の法律や規則は内容が時代に即していない、または医療機器の定義、医療機器の分類、医療機器の規制要件、臨床試験の義務、処方せんの管理、バイオシミラー製品（バイオ後続品）に対する規制、生物学的同等性試験の要求、医薬品安全性監視の内容が他国の法律や規則と互換性がなく、包括的な規制枠組みを提供するため、法律の近代化および統合が重要である。
- 品質政策および品質マニュアルが策定されているが、品質管理システム（Quality Management System：QMS）の実践は弱い。
- 医薬品統制委員会（DCC）の会議の開催頻度の少なさ、不規則な開催、人材不足、電子情報管理システムの欠如により新製品の登録に時間を要している。
- 申請書式が共通技術文書（CTD）に準拠していない。
- 登録料が不適切である（登録料指数は 0.3 未満）[57]。
- 査察官の著しい人員不足により査察に掛ける時間が不十分で GMP の質が担保されていない。
- 臨床試験に関するガイドラインが整備されていない。
- 体系的な医薬品の価格監視システムがない。

上記の課題を踏まえ、2012 年以降、SIAPS プログラムの下、DGDA に対してオンライン医薬品登録システムの導入、医薬品安全性監視プログラムの活性化、バイオシミラー製品の登録ガイドラインの作成、共通技術文書（CTD）ガイドラインの作成、DGDA の 5 カ年戦略計画（2017～2021 年）の策定などが支援されている[58]。

[56] 実施機関は、Management Sciences for Health (MSH)

[57] 2012 年 11 月発行の報告書内の数値。

[58] Abdullah M, Zahedul I, Azad SN, Liza Talukder L, Khaled M. (2018). SIAPS Bangladesh End of Project Report. This report is submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health. (http://siapsprogram.org/publication/siaps-bangladesh-end-of-project-report/、2018 年 8 月 24 日閲覧)

5.2 規制当局の審査、調査等のパフォーマンス

5.2.1 規制当局による各サービスに要する期間

各種審査にかかる期間（実績）については、公開されている情報からは入手することができなかった。DGDA の年次報告書（2017-2018）では、市民憲章（Citizen Charter）の中で DGDA が示している各サービスに要する期間が記載されており、その内容を表 5-1 に示す。

表 5-1：各サービスに要する期間

サービス項目	期間
製薬所新設の評価（プロポーザル）	120 日間（労働日）
生物学的および非生物学的製剤の製造ライセンス（新規）	120 日間（労働日）
生物学的および非生物学的製剤の製造ライセンス（更新）	90 日間（労働日）
ホメオパシー、アーユルヴェーダ、ハーブおよびウナニの製造ライセンス	120 日間（労働日）
ホメオパシー、アーユルヴェーダ、ハーブおよびウナニの製造ライセンス（更新）	60 日間（労働日）
医薬品の製造工程承認（既存）	90 日間（労働日）
医薬品の製造工程承認（新規）	120 日間（労働日）
医薬品原材料および包装材料の事前承認	30 日間（労働日）
サンプルテスト（承認工程）	7 日間（労働日）
ラベルの切り取りと挿入の承認	20 日間（労働日）
承認された医薬品の登録	60 日間（労働日）
原材料と包装材料の通関証明書交付	5 日間（労働日）
医薬品小売価格承認	30 日間（労働日）
医薬品輸入登録	90 日間（労働日）
医薬品輸入登録の更新	60 日間（労働日）
医薬品輸出ライセンス登録	5 日間（労働日）
海外からの医薬品輸入の事前承認	40 日間（労働日）
海外への輸出（承認）	7 日間（労働日）
医薬品の広告宣伝（承認）	90 日間（労働日）
医薬品卸売販売のためのライセンス（更新）	30 日間（労働日）
医薬品小売販売のためのライセンス	30 日間（労働日）
医薬品小売販売のためのライセンス（更新）	5 日間（労働日）
宣伝材料（Promotional Materials）承認	90 日間（労働日）
原材料の検証	7 日間（労働日）
医薬品製造所有権移転の事前承認	30 日間（労働日）

注）実績ではなく、市民憲章の中で DGDA が示している期間。

出典：DGDA 年次報告書 2017-2018

5.2.2 各種承認、監査件数

DGDA が実施している医薬品製造の承認や小売販売ライセンスの発行、薬局や製薬所に対する監査等の実績を DGDA の年次報告書（2017-2018）の情報を基に表 5-2 から表 5-5 に示す。

表 5-2：医薬品製造に係る承認件数（2017 年度*）

項目	承認数
承認された医薬品製造プロジェクト	32
医薬品製造ライセンス（更新）	132
医薬品製造ライセンス（新規）	6

*2017 年 7 月～2018 年 6 月

出典：DGDA 年次報告書 2017-2018

表 5-3：小売販売ライセンスの年間更新数

年度	更新数
2012	21,337
2013	27,296
2014	27,875
2015	32,991
2016	34,844
2017	29,095

出典：DGDA 年次報告書 2017-2018

表 5-4：薬局および製薬所の監査実施数

年度	監査実施数	
	薬局	製薬所
2012	28,019	787
2013	34,473	975
2014	49,814	1,094
2015	57,734	1,338
2016	61,945	1,481
2017	57,175	1,136

出典：DGDA 年次報告書 2017-2018

表 5-5：各種証明書、許可書の発行件数（2017 年度*）

項目	件数
医薬品製造証明書（Certificate of Pharmaceuticals Products）	4,111
自由販売証明書 （Free Sales Certificate）	388
輸出許可書（Export License Form 10 A）	1,492
GMP 証明書	44

*2017 年 7 月～2018 年 6 月

出典：DGDA 年次報告書 2017-2018

5.2.3 有害事象の報告

DGDA の年次報告書（2017-2018）に記載のある有害事象の報告件数を表 5-6 に示す。また、DGDA の Web サイトにおいて概要情報が提供されている。有害事象の深刻度別件数、有害事象発生後の患者の容体別件数、有害事象発生後の対応別件数について、表の 5-7 から表 5-9 に示す。

表 5-6：有害事象の報告件数（2017 年）

組織名	評価報告件数	備考
薬物有害反応モニタリング室	531	不備のない報告書件数：497 不備のある報告書件数：34
医薬品技術小委員会	497	因果関係評価（WHO の定義）ごとの件数 Certain、Probable、Possible：183 Unlikely、Unclassifiable：314
薬物有害反応諮問委員会	183	

注）上記報告がなされた期間は明記されていないが、DGDA の年次報告書 2017-2018 に記載される他の統計データと同様、2017 年 7 月～2018 年 6 月と推察。

出典：DGDA 年次報告書 2017-2018

表 5-7：有害事象の深刻度別件数

有害事象の深刻度	2017	2018 注)
深刻ではない	24	32
入院、または入院延長 （hospitalization or prolongation of hospitalization）	14	5
障害または恒久的な損傷（disability or permanent damage)	6	0
先天性異常/先天異常（congenital anomaly/birth defect）	5	1
生命の危険（life threatening）	7	0
死亡（Death）	8	0
その他（Other serious)	1	1

注）2018 年 1 月から 11 月までの件数。

出典：DGDA の Web サイト（http://www.dgda.gov.bd/index.php/2013-03-31-04-35-57/adrm-summary-reports、2018 年 12 月 11 日閲覧）の情報を基に、筆者が集計したもの。

表 5-8：有害事象発生後の患者容体別件数

患者容体	2017	2018 注)
回復（Recovered）	25	12
後遺症を伴う回復（Recovered/resolved with sequela）	9	1
回復せず（Not recovered)	15	1
不明（Unknown）	13	25
死亡（Fatal）	3	0

注）2018 年 1 月から 11 月までの件数。

出典：DGDA の Web サイト（http://www.dgda.gov.bd/index.php/2013-03-31-04-35-57/adrm-summary-reports、2018 年 12 月 11 日閲覧）の情報を基に、筆者が集計したもの。

表 5-9：有害事象発生後の対応別件数

対応	2017	2018 注)
服用停止（Dose stopped）	21	25
用量を減少（Dose reduced）	32	2
対応せず（No action taken)	12	12

注）2018 年 1 月から 11 月までの件数。

出典：DGDA の Web サイト（http://www.dgda.gov.bd/index.php/2013-03-31-04-35-57/adrm-summary-reports、2018 年 12 月 11 日閲覧）の情報を基に、筆者が集計したもの。

5.3 外国規制当局の基準および評価結果への依拠に関する制度

有識者へのヒアリングによると、米国および英国の薬局方を参照している [18]。また、輸入医薬品に関しては、先進国における臨床試験の結果を採用している [18]。

5.4 政府での規制改革の取り組み

法律については、「国家医薬品政策 2016」の中で、「既存の政策、法律および関連する規則は、医薬品製造、品質管理、販売、流通、保管、輸出入の異なるシステムの管理と監視には不十分なため、既存の法律をさらに更新することを考慮して、『医薬品法 1940』、『医薬品（統制）令 1982』を統合した最新の法律を制定する」と謳われている。現在、2020 年までに改正法の制定と施行に向けた作業が行われている [18]。

また、化粧品と食品の規制は DGDA の所管ではなく、バングラデシュ基準検査機関（Bangladesh Standards Testing Institutions：BSTI）が担っている。しかし、BSTI が規制している製品は限定的で、どちらにも属さず市場に流出してしまうものがあるのではないかと、USAID の調査報告書では指摘している [5]。国家医薬品政策 2016 では、DGDA を食品医薬品総局として組織再編し、医療に関連する食品および化粧品（加工食品、食品サプリメント、栄養補助食品、プレバイオティクス、プロバイオティクス、医療機器および外科用機器、ビタミンプレミックス、生理学的変化をもたらす医療関連の化粧品）なども規制の対象として拡大するとしている。

5.5 産業界からの規制当局に対する要望

産業界（医薬品および医療機器）からの規制当局に対する要望について、ヒアリング調査の結果について以下に記述する。

【医薬品】

医薬品のオンライン登録の利便性が高いため導入促進の徹底を望む声があった。

【医療機器】

- 既に多くの医療機器がバングラデシュに輸入・使用されており、適切に品質管理された機器であっても正しい使用方法や適切な維持管理が行われていないことによる機器の故障や不調が見られるため、機器を正しく使用する技術指導や教育にまず注力した方がよいのではないかとのことであった。また、機器の維持管理も重要で、特に公的医療機関で使用される医療機器が適切に使用されるために保健家族福祉省

において維持管理の予算が確保される必要があるとの意見があった。

- バングラデシュではガイドラインは整備されているものの、まだ実際の運用が始まっていない状態であるが、かえって薬事規制が厳しくないことで販売者にとって商業上の展開がしやすい面もある。また後述の金融制度等、販売者が同国で事業の展開を促進するような制度が未整備な状態で、薬事規制のみを厳しくすると、既定の規制に沿って適切に対応している販売者ほど営業に支障が出る可能性があり、規制整備の際にはその点を配慮する必要がある。
- 販売以外に係る制度について整備されると販売者として商業上の展開がしやすい。例えば金融制度が整っていないために行えないリースサービスの提供や、試供品の提供に関する制度もあるとよいとの意見があった。

添付資料

共通

添付資料 1：国家医薬品政策 2016（英語版）

医薬品

添付資料 2：バングラデシュ・コモン・テクニカルドキュメント（CTD）ガイドライン

添付資料 3：医薬品登録等の手数料に関する規制当局（DGDA）の通達文書
（ベンガル語の仮英訳）

添付資料 4：薬局管理に関する規制当局（DGDA）の通達文書（ベンガル語の仮英訳）

医療機器

添付資料 5：医療機器の登録ガイドライン

添付資料 1

国家医薬品政策 2016（英語版）

English Version

National Drug Policy 2016

Index:

NATIONAL DRUG POLICY 2016

1. Proposal

1.1 The Government of Bangladesh is committed to provide effective health care service for the people of the country as per the constitution of the People's Republic of Bangladesh sections 15 (a), 15(d), and 18(1). Good quality drugs are pre-requisite along with the skilled physicians and standard medical devices and supplies for promoting improved health care service. Quality and safe veterinary drugs and vaccines are required to ensure safe food and keep live stocks healthy for protection of public health.

1.2 The pharmaceutical industry of Bangladesh is one of the first growing sectors. Once where almost 80% demand of drugs were imported, currently more than 97% of medicines are being produced in the country. Quality drugs locally produced are now being exported to 113 countries across the globe, including developed countries. Already, a number of drug manufacturing companies have been awarded with Good Manufacturing Practice (GMP) certificates by drug regulatory agencies of developed countries. Due to attaining required technology, Bangladesh pharmaceutical sector is capable of producing almost all conventional and high technology based dosage forms. The pharmaceutical sector is enriched with not only higher technological resources but also experienced and skilled pharmacists as well as other affiliated competent manpower. Since 2009, sufficient medicines of required quality are being supplied in line with expansion of health care center/facilities.

1.3 In the country raw material of medicine is being produced far less than in need. Moreover, scaling up of the production of essential drugs is required for effective treatment interventions. It is essential to comply strictly the recommended GMP by WHO, to prevent the sales of fake-adulterated, expired-unregistered-counterfeit-misbranded and smuggled drugs, to ensure rational use of drugs as per WHO recommendation, to establish community pharmacies progressively in the country and to set up hospital pharmacy in all tertiary level hospitals. Overall, in the context of the changing global economic it is necessary to prepare the pharmaceutical sector of the country in the light of intellectual property rights and trade law or TRIPS (Trade Related Aspects of Intellectual Property Rights) agreementof World Trade Organization (WTO) for public health protection and expansion of drug exports. From the inception of Present Government as per their election manifesto, initiate to formulate the

National health Policy, the National Population policy and the National Drug policy (NDP). The National Drug policy (NDP) 2016 has been formulated by keeping compliance with the National health policy 2011 and the National population policy 2012.

1.4 Newly independent Bangladesh had to import more than 80% of its demanded drugs. Among the domestically produced drugs many harmful and un necessary drugs were in the market. After the independence in 1973, Father of the Nation Bangabandhu Sheikh Mujibur Rahman formed a cell to import necessary medicines under the trading corporation of Bangladesh in order to prevent the loss of valuable foreign currency. Through this, the waste of huge foreign currency for importations of pharmaceuticals ended. Besides, Bangabandhu formed the 'Directorate of Drug Administration' in 1974 to increase production of quality medicines in the country and to help and control this industry. In order to safeguard the public health, he kept Bangladesh out of patent law as a poor country for production of foreign companies' patented drugs by local companies; As a result, domestic companies got huge incentives and due to the competitive market, life-saving medicines became available through reducing prices.. Thus both the people of the country and domestic pharmaceutical industries are benefitted.

1.5 The first National Drug Policy was formulated by the Government of Bangladesh in 1982 which was hailed and immensely praised by WHO and other international organizations. The first National Drug Policy led to ensure the drug safety, quality and control of drug prices. Reducing Import dependency country started to become more self-reliance in drugs, foreign dominance on the drug sector was lessened and local pharmaceutical industries began establishing large and modern technology based drug manufacturing facilities. Bangladesh pharmaceutical sector attained a glorious image in the international arena, transition of Bangladesh from a drug importing country to a drug exporting country.

1.6 The second National Drug Policy of 2005 consisted of a number of promising initiatives for the drug industry of the country; however those initiatives did not achieve the expected targets of the drug policy. It is therefore essential to formulate an updated third National Drug Policy by the government embracing the expectations that created in the field of possibilities in home and abroad for the pharmaceutical sector as well as protecting public interest. With this aim, the pharmaceutical sector of the country has to be more responsible and compliant with stringent adherence to the WHO recommended GMP guidelines in drug production and quality control.

1.7 Substantial progress has been made in the field of traditional medicine alongside that of allopathic drug sector. Now, the Ayurvedic, Unani, Herbal, Homeopathic and Biochemic drug industries that are local resource based according to their self-fundamental principles and in pursuance of GMP guidelines of WHO, successfully trying to produce drugs. The interest of a large segment of people towards traditional treatment system and effective incorporation of traditional methods of treatment into the national health care system, in light of WHO recommendations and alongside of modern treatment system the Ayurvedic, Unani, Herbal, Homeopathic and Biochemic drug industries need cooperation to make advancement. The National Health Policy 2011 has emphasized on alternative treatment system.

1.8 It is necessary to follow the GMP guidelines of WHO in the manufacture of veterinary drugs and vaccines to ensure livestock development, prevention and treatment of disease, ensure the control of safe food and maintain of nutrition.

2. Objectives of National Drug Policy

2.1 To ensure people can have easy access to safe, effective and good quality drugs at affordable prices.

2.2 To ensure rational and safe use of drugs and proper dispensing.

2.3 To achieve self-sufficiency in the manufacture of drugs and raw materials by providing services and facilities on a priority basis to all local drug manufacturing industries.

2.4 To expand the export of drugs that manufactured in the country.

2.5 To establish effective surveillance system of medicines.

3. Elements of National Drug Policy

3.1 The drug registration process has to be updated in accordance with the standards of the developed countries time to time, to ensure safe use, efficacy and usefulness.

3.2 The Directorate General of Drug Administration has to be strengthened through appropriate expansion of existing human resources and infrastructural facilities to serve as an effective National Regulatory Authority (NRA). The National Regulatory Authority has to be, at least, recognized by WHO and to be a member of PIC/S (The Pharmaceutical Inspection Convention /The Pharmaceutical Inspection Scheme).

3.3 The manufacture, sale and distribution of fake, adulterated, harmful, un-registered, counterfeit, misbranded and substandard drugs and medical devices must be forbade and exemplary punishment bestowed upon people responsible for such offences.

3.4 The selection, quantity fixation, procurement, storage and distribution system of drugs must be strengthened so that drugs are accessible to the public throughout the country. Appropriate preservation methods, such as temperature and humidity control, must be ensured at all drug wholesale shops or pharmacies or drug storage facilities and during drug transport and distribution in order to maintain quality, appropriate use and dispensing.

3.5 Develop and implement apposite guidelines to regulate all sorts of advertisements and promotion of drugs in public media and prevent unethical marketing and multi-level marketing of all recognized system of drugs to ensure safe, rational and effective use.

3.6 Ensure accessibility to drugs at affordable price and fix drug prices by transparent and rational methods. The government from time to time is to continue the process of drug pricing /re-pricing of enlisted drugs.

3.7 Encourage foreign research-based pharmaceutical industries to invest, produce and market drugs in the country with the objective of promoting transfer of technology and technical knowledge for innovative drugs or high-technology (e.g. biotechnology) based drugs. Motivate research-based drug manufacturers to invest, manufacture and sell drugs in Bangladesh with assurance of new technology and technical knowledge transfer.

3.8 Inspire drug manufacturers to carry out effective Research and Development (R&D) in their respective pharmaceutical industries. To reduce taxation on imported machineries for research laboratories and also provide encouragement for the universities, competent research agencies and drug manufacturers to engage in collaborative joint effort for applied research. Encourage collaboration among government, universities, research

institutes, professionals and drug manufacturers to adopt basic and applied research programs.

3.9 To ensure Pharmacovigilance and appropriate monitoring of Adverse Drug Reactions (ADR) through motivation for all concerned people to be accurately informed about adverse drug events.

3.10 To ensure employment of skilled staff and their regular training, so that Good Manufacturing Practices (GMP) are effectively followed and implemented in drug manufacturing companies of all recognized systems.

3.11 To take necessary steps and provide diverse incentives to expand export of drugs manufactured in the country.

3.12

a. To modernize the National Control Laboratory (NCL) as central drug testing laboratory to test and analysis of drugs and established its branches in different divisional level phase wise; to establish central autonomous national reference laboratory, to establish specialized modern laboratories for Unani, Ayurvedic, Herbal and Homeopathic-Biochemic system of drugs.

b. As a competent research organization involve Bangladesh Council of Scientific and Industrial Research (BCSIR) in test and analysis of modern and traditional medicine and with the activities of reference laboratory.

c. To recognize research organizations as third party quality evaluator, established at public, private and autonomous level for testing and analysis.

3.13 With a view of protecting public health, prepare separate essential drug lists for Allopathic, Unani, Ayurvedic, Herbal and Homeopathic system of medicines.

3.14 To prohibit sales and distribution of drugs without prescription from registered physician to ensure rational use of drugs.

3.15 Publish list of Over-the-Counter (OTC) drugs for general use aligning with the systems of developed countries.

3.16 Include scientific technology based quality control system in the manufacturing of Unani, Ayurvedic, Herbal and Homeopathic-Biochemic system of drugs for quality improvement.

3.17 Consider those substances as drugs that have medicinal value, manufactured as pharmaceutical dosage form and possess therapeutic indications and ensure appropriate regulation accordingly. The cosmetic products that lead to physiological changes in the body should bring under the regulatory control of Directorate General of Drug Administration.

3.18 Enlist medical devices and surgical equipment that come in contact with the human body under the regulatory control of Directorate General of Drug Administration.

3.19 To create Clinical trials and Bio-equivalence study facilities at public and private sectors with expert and trained personnel of relevant field.

3.20 Support the development of the pharmaceutical sector in Bangladesh in light of the WTO/TRIPS agreement.

3.21 Transform the 'Directorate General of Drug Administration' to 'Directorate General of Food and Drug Administration' for assurance of quality and safety of different types of food in addition to drugs and rearrange the jurisdiction and organizational structure to establish legal control over these products.

4. Areas of National Drug Policy

4.1 Implementation and Amendment of Current Law and Rules:

a. At present the existing different policies, laws and relevant rules become insufficient and inapt to control and monitoring of different system of medicines manufacturing, quality-

control, sale, distribution, storage, import and export. At the changed perspective, it is imperative to appositely amend these laws and rules in order to make them updated and effective.

b. An updated law will be formulated in Bangla version merging the 'Drug Act 1940' and the 'Drug (control) Ordinance 1982' in view of updating existing laws furthermore. Necessary rules will be made as soon as possible to execute the aforementioned laws.

c. Furthermore, for protection of public health by preventing spurious, adulterated and substandard food, required law for the Directorate General of Food and Drug administration will be formulated, considering the inadequacy of existing law.

d. The provisions of existing laws will be effectively implemented to ensure appropriate, effective and accountable drug management system in the country and to protect the consumer rights in this regard.

4.2 Availability to efficacious, safe and quality drugs:

a. The government will ensure availability of all kinds of drugs with essential drugs at all level considering the safety, usefulness and affordability as per the requirement of the people to ensure appropriate and effective health care system.

b. Accessibility to all drugs needed for prevention and eradication of Malaria, Kala-azar, Nipah virus, SARS, Tuberculosis, AIDS, and Dengue as well as other contagious diseases will be ensured.

c. Availability to different types of quality vaccines and related medicines for promotion of maternal and child health and disease prevention and availability to necessary quality vaccines and medicines for promotion of animal health and disease prevention will be ensured.

4.3 Rational and safe use of drugs:

a. Rational and safe use of drugs will be assured through pursuance of Standard Treatment Guidelines (STG).

b. To assure rational use of antibiotics all 100 or more than 100 bed hospitals at government and private level of the country must have their own 'Antibiotic user guidelines' which must be regularly updated and followed during delivery of health care services, later on subsequently 'Antibiotic user guidelines' will be formulated and implemented for all hospitals.

c. Bangladesh National Formulary- BDNF will be regularly updated and published in the website with the approval of Drug Regulatory Authority (DRA) to disseminate drug information and promote rational use of drugs. Similarly, as per approval of Drug Regulatory Authority, the 'Bangladesh National Ayurvedic Formulary', 'Bangladesh National Unani Formulary', 'Bangladesh National Herbal Formulary', and 'Bangladesh National Homeopathic Pharmacopoeia' will be regularly formulated, updated and published in the website.

d. Sale and dispensing of drugs will be conducted under direct supervision of professional pharmacists for providing counseling to patients on the appropriate use and storage of drugs. With this aim, Community Pharmacy will be accordingly established and developed.

e. Necessary steps will be taken to operate "Hospital Pharmacy" in all public and private hospitals phase wise under the direct supervision of graduate pharmacists. To ensure rational use of drugs each and every hospital will develop and update its own drug formulary and publish it in the website regularly.

f. Medicines will have to be manufactured and marketed mentioning generic or the name included in respective formulary perspicuously, alongside of trade name to make easy identification of all recognized system of drugs to all. The supply and use of drugs at all government levels will be encouraged by generic name.

g. Retail sales of drugs is prohibited without prescription by registered physicians/ veterinarians other than the OTC drugs.

h. To evaluate the rational use of drugs medical prescription and dispensing system of drugs will be monitored regularly in certain time interval.

i. Drugs and Therapeutic committee will be formed in all public and private hospitals to ensure rational use of drugs including antibiotics.

j. Essential Medicine List (EML) will be updated regularly based on Essential Medicine concept.

4.4 Drug registration:

a) Selection of drugs for registration:

1. All drugs that are produced in different dosage forms, imported, distributed or marketed or used have to be registered by licensing authority based on the recommendation of Drug Control Committee (DCC). Regular meetings of the DCC will convene to make faster availability of new life-saving drugs for the public.

2. The function of Drug Control Committee will be to give opinion/recommend for registration through evaluation of safety, efficacy and usefulness of all applied drugs and medical device for locally manufacture or for importation.With this objective the Drug Control Committee will be constituted with specialists and professionals.

b) Registration Criteria:

1. Registration will be given in accordance with established indication. No new indications for any drugs will be approved without the recommendation of Drug Control Committee.

2. Approval will not be given to manufacture drugs without appropriate infrastructure and quality assurance management. High-tech drugs or those that required different infrastructure and dedicated facilities for production will not be registered without required manufacturing infrastructure as per GMP guidelines of WHO. It is also mentionable that drugs already registered can be produced by competent pharmaceutical industries subject to re-evaluation.

3. Unless essential for treatment, the registration of combination allopathic drugs will be generally discouraged. The possibility of misuse of Combination Product will be given special consideration. In case of registration of allopathic drugs the reference of approval byUnited States Food and Drug Administration (US-FDA), the Medicines and Health Care Products Regulatory Agency (MHRA), or inclusion in British National Formulary (BNF) has to be pursued. If necessary, the registration of existing combination products will be re-evaluated.

4.Ayurvedic, Unani, Herbal, Homeopathic and Biochemic system of drugs will be registered on the basis of recommendation of Drug Control Committee (DCC). Only drugs included in Unani, Ayurvedic and Homeopathic Formulary/Pharmacopoeia will be considered for registration.

5.Only the 1x potency will be required for registration for mother tincture, crude trituration and 12 bio-chemic medicine, but no registration will be required for enhanced potencies of homeopathic and biochemic medicines.

6.As per Homoeopathic Pharmacopoeia it is usable by admixture/ converting with the addition of liquid form of medicine in solid vehicle, e.g., lactose/ globules etc. and solid form of medicine in liquid vehicle e.g., purified water/ alcohol etc. In case of potentized medicine through converting from liquid to solid form or solid to liquid form will not require to be registered.

c) Registration for import:

1. Foreign manufactured drugs registered in Bangladesh can be imported, subject to approval of licensing authority. Information of Bioequivalence Study and Clinical Trials have to be submitted for registration of imported products. For the registration of imported drugs, newly invented life-saving drugs will be given priority. The concerned drugs under same brand name have to be registered for marketing in at least one of the following developed countries: USA, UK, Germany, France, Switzerland, Japan and Australia, However, the imported drug must be collected from the original manufacturing site or from the manufacturing factories of any of the aforementioned countries.

2. Free Sale Certificate has to be submitted of at least any one of the following countries: European Union countries, USA, Switzerland, Canada, Australia, Japan, South Korea and Singapore along with the Source country for import registration and marketing of drugs used in treatment of live stocks &fish. It is noteworthy that such drugs must be registered for marketing under the same brand name in the listed country or countries.

3. With the objective of ascertaining the imported drugs and raw materials are being produced with GMP compliance accurately or not, submission of valid certificates, and if required, inspection of manufacturing premises by national drug regulatory authority will be arranged. In accordance with GMP guidelines and check list, the drug manufacturing sites of drug exporting countries will be subjected to validation and certification.

4. Herbal and Homepathic-Biochemic system of drugs has to be registered for import by Directorate General of Drug Administration (DGDA) based on the recommendation of Drug Control Committee. Import of Unani and Ayurvedic drugs will not be considered as these are derived from local medicinal plants, but the essential Unani and Ayurvedic medicines which are not produced locally may be considered for importation.

5. Certain specific drugs, even with the known possibility of their serious side-effects, in the absence of any other alternative drugs, can be approved for import in specific quantities only for regulated use.

4.5 Drugs and raw materials production:

a. The principle aim of the National Drug Policy is to ensure adequate production of good quality drugs. Therefore, the current Good Manufacturing Practices (cGMP) guidelines of WHO will be stringently followed.

b.As per the check list prepared by Directorate General of Drug Administration the drug manufacturing companies will conduct the internal audit at periodic intervals. Directorate General of Drug Administration will update the checklist on regular basis.

c. Drug companies will be classified based on their capabilities of drug manufacturing, taking into consideration the various aspects of drug production, such as: skilled manpower, establishments/premises, utility/services, installed machinery/equipment, therapeutic class of their finished drug products and dosage forms.

d. Exchanging views with internal resource division that is national board of revenue about remission of VAT or duty will be reduced logically for import of chemicals for production of raw materials and initiatives will be taken to provide incentives for motivation to produce raw materials. For this purpose institutions that are engaged in research for development of pharmaceutical raw materials will be encouraged and necessary incentives will be given. Finished drug products will not be allowed to manufacture under the license issued for raw material manufacture.

e. With a view of achieving self- sufficiency in drug sector, dependency on imported raw materials of all recognized system of medicine will be reduced. Initiatives will be taken to provide incentives in different stages to set up industries for drug raw material production, for contract based production, for

production under license agreement with foreign companies and for joint investment of domestic and foreign investors. In the same way the expansion of local drug packaging industry will be encouraged.

f. Raw materials used in drug manufactured in the country must meet with the specifications of quality as stated in the concerned Pharmacopoeia.

g. The allopathic drug manufacturer will be allowed to manufacture drugs in other allopathic drug manufacturing plant as per their choice under toll manufacturing agreements those have their own manufacturing plant in Bangladesh.

h. Foreign pharmaceutical industries not having drug manufacturing factories in Bangladesh, under contract manufacturing agreement/loan license can manufacture drugs of all recognized system of medicine for export only. By no means, the manufactured drugs will be marketed locally.

i. With a view to technology transfer or to ensure availability of newly developed drugs, foreign companies without manufacturing plant in the country will be granted approval to produce their research drug locally in partnership with any of their preferred local drug manufacturing company under the licensing agreement, provided the drug of same brand name is registered for marketing in, at least, any one of the following developed countries: USA, UK, Switzerland, Germany, France, Japan and Australia.

j. With the prior approval of Directorate General of Drug Administration, drugs that required high-technology test and analysis procedure, any pharmaceutical companies can have it tested and analyzed according to their choice of any public, private and autonomous organization recognized by Directorate General of Drug Administration which possess facilities for respective test and analysis under contract analysis agreement, this type of organization will be recognized. For this purpose, Directorate General of Drug Administration will prepare necessary guidelines.

k.Small quantities of raw materials used in manufacturing of drugs and reference standards could be imported by Drug manufacturing companies jointly having approval from Directorate General of Drug Administration (DGDA). In this respect, the GMP compliance has to be ensured by importers.

l. In any urgent necessity of the country or for public health protection, the government can direct any drug manufacturing company to produce any drugs and the companies will be obliged to do so.

m.Such foreign and multinational companies will be permitted to establish companies and manufacture drugs in Bangladesh on condition of having at least three of their original research drug products registered in at least two of the following countries: USA, UK, Switzerland, Germany, France, Japan and Australia.

n. Drugs that are not included in any of the previous three editions of British Pharmacopoeia (BP), United States Pharmacopoeia (USP), European Pharmacopoeia (EP), International Pharmacopoeia (IP), or British Pharmaceutical Codex (BPC) or not been included in the list of International Non-proprietary Names (INN) published by World Health Organization (WHO), will not be approved for manufacture.

o.In view of assurance of drug quality, the drug manufacturing companies will arrange regular training on cGMP for concerned human resources.

p. Inspectors of the Directorate General of Drug Administration will be trained up regularly on GMP guidelines and pertinent issues. Initiatives for training both at home and abroad will be undertaken and will arrange funding for the training courses.

4.6 National Regulatory Authority

a.It is essential to upgrade the Directorate General of Drug Administration (DGDA)as a more strengthen Drug regulatory agency. To accomplish all different activities as a drug regulatory authority, required number of professionally qualified and experienced human resources will be appointed. Regular training will be provided for the appointed personnel to enhance their skill and competency those involved in the area of drug registration, manufacturing, storage, distribution, sale, import, export and quality control. In case of veterinary medicines, training also will be provided by the veterinary specialist to enhance the skill of the personnel engaged in aforementioned areas.

b. An effective human resource development plan will be undertaken for the staff of Directorate General of Drug Administration and a career development plan must be put in effect along with promotion system based on skill, experience and performance of staff.

c. All necessary measures will be undertaken to fulfill prerequisites that will facilitate the Directorate General of Drug Administration (DGDA) to become WHO accredited and achieve PIC/S membership.

d. A legal cell with competent manpower will be established to execute the legal functions effectively of National Regulatory Authority. Judicial or executive magistrate in the Directorate General of Drug Administration will be appointed to expedite legal proceedings against the manufacture, distribution, storage and sale of fake, adulterated and substandard drugs.

e. The official website of National Regulatory Authority (NRA) will be regularly updated and the relevant information, procedures, and measures taken of Directorate General will be published. To accelerate the performance of Directorate General of Drug Administration, the activities will be conducted through on-line system respectively.

4.7 Prevention of production, sale & distribution of fake, adulterated, sub-standard drugs

a. The selling of fake, adulterated, expired, unregistered, counterfeit and misbranded drugs are punishable offences and due to hindrance to good governance in drug sector; consequently, drug manufacturers, importing organization, wholesale and retail sellers are all accountable. Any person or organization associated with the production, marketing, sale, distribution and storage of such drugs shall be subjected to stringent legal action and the respective license will be revoked by Directorate General of Drug Administration.

b. The existing laws will be amended for awarding exemplary punishment to unauthorized manufacturers and sellers, prescribing physicians and health care establishments of substandard, fake, adulterated and unregistered drugs (Allopathic, Ayurvedic, Unani, Herbal, Homeopathic and Biochemics) and medicines in the name of food supplements.

c. Storage, display of expired medicine in the pharmacy, selling drugs by changing or obscuring the expiry date on package or container will be considered as punishable offences.

d.The existing law will be amended to ensure appropriate compensation of the consumers harmed from the use of substandard, fake, adulterated, smuggled food or drugs.

4.8 Drug selection, quantity fixation. Drug procurement, storage and distribution processes

a. The government in times of national crisis or disaster with the opinion of Directorate General of Drug Administration (DGDA)will be enable to import unregistered drugs or receive as donations.

b. Drugs that are not registered can only be imported in specified quantity for personal use of patients or for research and clinical investigations in view of non-commercial purpose with prior approval of licensing authority.

c.A guideline on Good Distribution Practices (GDP) will be prepared by Directorate General of Drug Administration very soon. The transportation, distribution and storage of drugs will be ensured according to the guideline.

d.To ensure appropriate procurement, storage and sales/distribution of drugs all pharmacies, government and private drug storage facilities, and hospital-pharmacies will operate under the supervision of pharmacists registered by Bangladesh Pharmacy Council.

e.The pharmacies will be operated by the supervision of registered physicians of relevant systems or registered pharmacist to ensure the appropriate procurement, storage, sale and distribution of Ayurvedic, Unani, Herbal and Homeopathic-Biochemic system of drugs.

4.9 Control of drug advertising and promotion

a. 'Code of Pharmaceutical Marketing Practices' approved by Directorate General of Drug Administration (DGDA)will be followed in drug (Including OTC listed drugs) marketing to prevent circulation of false, unwanted, and misleading information. Drug manufacturing companies and drug marketing organizations will operate their marketing functions in accordance with the 'Code of Pharmaceutical Marketing Practices'. The aforementioned 'Code of Pharmaceutical Marketing Practices' will be regularly updated.

b. Drug advertisement of any type is prohibited without prior approval of licensing authority, and legal actions will be undertaken against unapproved advertising. With the same objective, any unethical marketing and multi-level marketing will be rigorously restrained.

c.With the prior approval of Drug Regulatory Authority, substantive, educational and public awareness typeof advertisement on oral rehydration salt, family planning drugs and devices, water purifying drugs, antiseptic drugs and vaccines used in expanded program on immunization will be permitted.

4.10 Transparent and rational pricing of drugs

a. The government will regularly update the guidelines for control of drug prices, taking public health interest into account.

b. At least once a year drug prices will be updated based on the government formulated guidelines .For public information, the retail prices of all drugs will be published in the official website of Directorate General of Drug Administration.

c. Prices of Ayurvedic, Unani, Herbal, Homeopathic and Biochemic system of drugs that are locally produced and imported will be fixed-up by the government.

d. Legal actions will be taken against person or establishments associated with selling of drugs above the fixed price.

4.11 New technology and technical knowledge transfer in Country

a. The role of research based domestic, foreign, public, private &autonomous organizations is important in technology transfer and in development of qualified professionals of international standards. With appropriate assurance of technology and technical knowledge transfer, research-oriented foreign companies will be encouraged to manufacture and market innovative and high-tech drugs such as-recombinant technology generated vaccines, Bio-similar, Hormones, Insulin, Anticancer drugs etc.

b. The country requires more of PIC/s, US_FDA, EMA, UK-MHRA, Australian-TGA certified drug manufacturing companies as pre-requisite to satisfy the conditions for entering in the international drug market. Henceforth; collaborative initiatives to jointly establish industry between research-based foreign drug manufacturing companies and drug companies of Bangladesh will be encouraged.

4.12 Joint collaborative research and development of drugs

a. Both local and multinational drug and raw material manufacturers will be encouraged to establish research and development facilities in the country. The initiative will be taken to reduce imposed duties on imported machineries for such research laboratories. Creating collaborative environment among universities, research institutes and drug manufacturers will be encouraged to conduct basic and applied research jointly on drugs.

b. Course of action to be undertaken to include: GMP, quality assurance, drug related law, National Drug Policy, concept of rational & safe use of drugs, essential drug concept and list and code of pharmaceutical marketing practices in all recognized pharmacy courses and in case of veterinary drugs above mentioned subjects will be included in veterinary pharmacology courses.

c. Drug manufacturing organizations will donate a certain proportion of their income under the monitoring of Ministry of Health &Family Welfare to the person, public, private and autonomous organization involved in research and development of drugs.

4.13 Effective Monitoring of Pharmacovigilance or Adverse Drug Reactions (ADR)

a. Pharmacovigilance programs will be strengthened at the national level for all drugs used in the country. The prevailing ADRM cell under Directorate General of Drug Administration will be strengthened further. Hospitals and clinics of the country, physicians, pharmacists and other health service providers, patients, drug manufacturers, drug marketing organizations and pharmacies will assist the ADRM cell by regularly providing relevant information, findings and reports.

b. 'Focal point' will be fixed up in all public and private hospitals having 100 or more than 100 bedded for monitoring the adverse drug reaction. A medical college will be declared as the 'National Centre' to strengthen the campaign. Subsequently, the program will be undertaken in all hospitals.

c. Phase wise 'Pharmacy and Therapeutics Committee' comprising physicians and pharmacists will be constituted in each of the specialized hospitals, medical colleges, and district level hospitals of the country.

d. Measures will be taken to conduct pharmacovigilance programs by Drug manufacturing and marketing organizations on their own

e. A National Drug Information Centre will be established under the disposal of DGDA.

4.14 Skilled human resources in drug manufacturing industries

a. The appointment of required number of graduate pharmacists and other skilled personnel as per GMP guidelines of World Health Organization will be ensured in allopathic drug manufacturing companies.

b. Required number of quality control and production officers will be appointed in Ayurvedic, Unani, Herbal, Homeopathic and Biochemic drug manufacturing companies having Bachelor of Ayurvedic (BAMS), Diploma in Ayurvedic (DAMS), Bachelor of Unani (BUMS), Diploma in Unani (DUMS), Bachelor of Homeopathic (BHMS), Diploma in Homeopathy (DHMS)degrees, bachelors' degree with honors in microbiology, pharmacy, botany, chemistry, biochemistry and applied chemistry.

4.15 Drug Export:

a. The export of manufactured drugs in the country will be encouraged and incentives will be provided to boost drug export.

b. Measures will be taken to eliminate all tariff and non-tariff barriers related to drug export.

c. In case of drug export, as per the demands of the importing countries, registration of desired drugs will be granted. However, registration will not be given to any drug which is deemed to be harmful to human or to any other animal or that are detrimental to the environment declared by World Health Organization and any other internationally recognized organization.

d. Foreign currency limit will be enhanced and sending of adequate drug samples for marketing &promotion of drugs in importing country will be permitted

e. In similar fashion, the permission for exporting of Ayurvedic, Unani, Herbal and Homeopathic drugs and the raw materials will be granted.

4.16 National Control Laboratory-NCL

a. National Control Laboratory-NCL will play the role of central laboratory for drug testing and analysis. Initiatives will be taken to achieve WHO accreditation for NCL enriched with modern facilities, apposite machineries and skilled human resources.

b. Branches of NCL will be established in all divisions of the country phase wise.

c.Centrally an autonomous Nationalreference laboratory will be established.

d.Specialized, modern laboratories for Unani, Ayurvedic, Herbal, Homeopathic and Biochemic system of drugs will be established.

e.Separate cell will set up in the drug testing laboratory for testing of Unani, Ayurvedic, Herbal, Homeopathic and Biochemic system of drugs.

f.National Control Laboratory will be given responsibility to prepare working standards importing reference standards in order to make reference standard/working standard easily available and cost-effective. These standards could be sold to drug manufacturers as per

requirement. In addition, the current practices of granting permission to drug manufacturers to import reference and working standards will be continued.

g. For test and analysis of modern and traditional system of medicines, ,capable public, private and autonomous research organizations will be recognized as reference laboratory of NCL.

h.BCSIR (Bangladesh Council of Scientific and Industrial Research), as capable research organization, will be endorsed for test and analysis of modern and traditional system of medicines and as a reference laboratory.

4.17 Formulationof separate Essential Drug Lists for Allopathic, Ayurvedic, Unani and Homeopathic system of drugs:

To effectively protect public health of the country, especially considering the emergency needs, affordability and accessibility of the majority of the people, separate "essential drug lists" have been published (appendix 1, 2, 3, 4) selecting a few number of drugs from drugs all system of treatment (Allopathic, Ayurvedic, Unani and Homeopathic) exists in the country. As per WHO recommendation and opinions of experts of respective system of drugs, the lists will be updated in every two years. In case of veterinary drugs, the list of essential veterinary drug will be prepared and published having opinion of the veterinary specialists and the list will be updated accordingly. The production and distribution of the essential drugs will be ensured as per the need.

To Adopting the fundamental principle of formulating the essential drug list nationally, a committee will be formed headed by the Secretary of Health and Family Welfare and members from Principals of Different Medical Colleges, Specialists in Different disciplines, Professors of Universities, representative from Concerned professional body, representative from Unani-Ayurvedic and Homeopathic Board, Director General of the Health Services, Director General of livestock and Director General of Drug Administration.

4.18 Over-the-counter (OTC) drugs

a. A number of drugs selected from locally registered Allopathic, Ayurvedic, and Unani system of drugs that can be used for general purposes and possess least side-effects, have been published(Appendix 5, 6, 7), as Over-the-Counter (OTC) drugs. These lists

will be up dated time to time by Directorate General of Drug Administration, based on the recommendation of WHO and relevant expert opinions. . In case of veterinary drugs, a list of Over the Counter (OTC) drugs will be prepared and published on the basis of the opinion of experts of veterinary specialists.

b. List of Homeopathic OTC drugs need not be published as because their uses are symptom-based and probable risk is associated in use without the prescription.

4.19 GMP guidelines and technology-based quality control system for quality improvement of Ayurvedic, Unani, Herbal, Homeopathic and Biochemic drugs

a. The GMP Guideline of WHO for Herbal Medicinal Products will be followed in the manufacture of Ayurvedic, Unani, Herbal, Homeopathic and Biochemic drugs. Considering the overall circumstances, an interim GMP guideline will be formulated for the next five years. In this respect, the Directorate General of Drug Administration will form a committee with relevant experts.

b. For Ayurvedic, Unani, Herbal, Homeopathic and Biochemic drugs, alongside to generic names, on the drug labels and cartons have to be mentioned clearly'Ayurvedic drugs', or 'Unani drugs', or 'Homeopathic-Biochemic drugs' or Herbal drugs.

c. No chemicals, other than active ingredient those stated in the Ayurvedic, Unani, formularies, can't be used as active ingredients in the manufacture of Ayurvedic, Unani, and Herbal drugs.

d. The test criteria and specifications for the raw materials, intermediate products and finished products for quality control of Ayurvedic, Unani, Homeopathic and Biochemic Herbal drugs will be formulated with the support of experts, in accordance with World Health Organization proposals, and following the procedures practiced in USA, UK, France, Germany, China and India.

e. As per the relevant standard criteria of World Health Organization and considering the technological competence and infrastructural facilities of the Ayurvedic, Unani, Herbal, Homeopathic and Biochemic drug manufacturers will be classified as per capability.

f. The Homeopathic drug industry of the country will be expanded by improving the quality of homeopathic drugs. Test criteria will be set by experts as per the homeopathic

Pharmacopoeia of USA and other developed countries and drug manufacturers will be directed to test drugs as per the test criteria.

g. In manufacturing of Ayurvedic, Unani, Herbal, Homeopathic drugs cannot use any unapproved chemicals (steroids, hormone, sexual stimulants or any other chemical substance). Moreover, the use of any color and flavoring agents, other than FDC color or certified food / color of pharmaceuticals grade is prohibited.

h. In case of manufacturing of homeopathic mother tincture and potentization of drugs only as per instructions of Homeopathy reference books the required quantity of ethyl alcohol(rectified spirit) stated therein will be allowed to prevent the abuse of alcohol Pack size more than 30ml Alcohol based Homeopathic potentized (potency/dilution) drugs, will not be approved

4.20 Products with medicinal substances and therapeutic value consider as drugs

a. Food or Nutritional or Herbal or Natural supplements manufactured as pharmaceutical dosage forms having substances of medicinal value and therapeutic indication will be under the regulation of Directorate General of Drug Administration.

b. The manufacture and import of the aforementioned Food or Nutritional or Herbal or Natural supplements will be in pursuance of the set directives of the Directorate General of Drug Administration. The manufacture of such products will be according to enforced GMP and quality control prerequisites of the National Regulatory Authority. The unapproved manufacture, import, distribution, storage and sales of such products are prohibited and will be tantamount to punishable offences.

4.21 Import of medical devices and surgical equipment

a. Medical devices and surgical equipment are installed/connected inside and outside the body for diagnosis, treatment or prevention of diseases, will be sustained under the regulation of Directorate General of Drug Administration.

b. GMP certificates issued by the regulatory authority of the manufacturing countries (under the circumstance where the concerned country does not have process to issue GMP

certificate in that case certificate/registration certificate from proper authority) must be submitted to import medical devices and surgical equipment.

c. 'Registration Guideline for Medical Devices, Bangladesh 2015'formulated by DGDA will be followed in case of registration of imported medical devices and surgical equipment.

4.22 Clinical trial and Bio-equivalence studies of drugs

Bioequivalence studies are being essential to be ensured about the quality and effectiveness of drugs, for this purpose an initiative will be taken to quickly establish a globally accredited Bioequivalence Study Centre and Clinical Trial Centre. In this respect, the public and private enterprises will be encouraged. For conducting the activities of Bioequivalence Study and Clinical Trial, the guideline formulated by the Directorate General of Drug Administration should be followed. The guidelines will be updated with time.

4.23 Assist the expansion of Pharmaceutical Industry of Bangladesh in the light of WTO/TRIPS agreement

a. The old drug patent law will be refurbished for public benefit. The pharmaceutical sector of the country will be prepared in the light of the World Trade Organization's Intellectual Property and Trade Laws or TRIPS Agreement.

b. Herbs and other plants used as medicine that are innate and grown within the geographical boundaries of the country, medicinal substances of them and their formula are part of our culture and heritage as well as legally our medicinal assets.For the protection of national assets and public health, initiative at government level will be taken to achieve intellectual property right.

4.24 Transformation to Directorate General of Food and Drug Administration and rearrangement of its Organizational Structure

a. For public health protection, with the necessary amendment of the existing law, 'Directorate General of Drug Administration' will be transformed to 'Directorate General of Food and Drug Administration', taking into consideration the importance for proper regulation of the manufacture, import, quality control, storage , sale , and distribution of different categories of medicine related processed food along with the medicines.

b. Medicine related processed food, food supplement, nutraceuticals, prebiotics, probiotics, medical devices and surgical equipment, vitamin premixes will be under the regulation of this proposed Directorate General.

c. Medicine related cosmetic products that claim to bring physiological changes in the body will be under the regulation of Directorate General of Drug Administration.

4.25 Ensuring of waste disposal by Drug manufacturer for prevention of environmental pollution

a. All recognized system of medicine manufacturing factories must have waste disposal management system for public health protection and prevention of environmental pollution.

b. Drug manufacturing companies that have factories at present in residential areas must relocate within the next five years to industrial or non-residential areas to reduce environmental pollution.

c. All drug manufacturing establishments must have Effluent Treatment Plants (ETP). The installation of incinerators for disposal of solid wastes will be encouraged; however, the approval of utilization of incinerators of other establishments for such disposal can be given.

4.26 Drugs used in treatment of livestock and fish

a. Appropriate quality control measures as per GMP guideline will be undertaken to manufacture drugs used for treatment of livestock.

b. Indications of use have to be specified on the label, literature, and packaging of drugs used in the treatment of livestock and fish and drugs that are used in livestock will be discouraged from being used in fish.

c. In addition to discouraging the use of Veterinary Medicinal Product (VMP) in fish, instruction will be given to the pharmaceutical companies to increase the production of Aquaculture Medicinal Product (AMP) for the treatment purpose.

4.27 Cancellation of drugs harmful for public health

a. Amendment of indications, dose, strength /potency, and dosage forms will be done evaluating the safety of drugs at periodic intervals for of all system of drugs in accordance with specific procedures.

b. All drugs declared harmful by international organizations such as: WHO, USFDA, UKMHRA, TGA, Australia, Health Canada, EMEA and similar international reputed drug regulatory authorities will be subjected to cancel the registration evaluating by Drug Control Committee (DCC).

c. Allopathic, Ayurvedic, Unani, Herbal, Homeopathic and Biochemic system of drugs that are harmful to public health will be cancelled the registration by re-evaluation of Drug Control Committee (DCC).

5Conclusion

National Drug Policy 2016 has been formulated upon review of National Drug Policy 2005. In this National Drug Policy, well-defined directives for drug safety, efficacy, rational use, effective drug control management, production, marketing, distribution, storage and import-export. This drug policy will facilitate further growth and expansion of the pharmaceutical sector, enhance capabilities of production of better quality drugs, and also augment the scopes and opportunities for drug export in many folds.

添付資料 2

バングラデシュ・コモン・テクニカル ドキュメント（CTD）ガイドライン

MINISTRY OF HEALTH & FAMILY WELFARE

DIRECTORATE GENERAL OF DRUG ADMINISTRATION

GUIDELINES[1] FOR THE SUBMISSION OF BANGLADESH COMMON TECHNICAL DOCUMENT:

GENERAL GUIDELINES, MODULE 1, MODULE 2 (QUALITY OVERALL SUMMARY) and MODULE 3 (QUALITY)

This document provides instructions to applicants intending to submit applications for the registration of medicines. The guidelines are governed by the Directorate General of Drug Administration's (DGDA) current thinking on safety, quality, and efficacy of medicines. The DGDA reserves the right to request additional information to establish the safety, quality, and efficacy of a medicine in keeping with current knowledge at the time of the evaluation of a medicine. The DGDA is committed to ensuring that all registered medicines are of the required quality, safety, and efficacy. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

First Edition

May 2017

USAID FROM THE AMERICAN PEOPLE

SIAPS Systems for Improved Access to Pharmaceuticals and Services

[1] Adapted from Australian Government Department of Health, *Therapeutic Goods Administration, CTD Module 1 – Version 2.1,* May 2013, and *South African Medicines Control Council CTD General & Module 1*, August 2012.

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MESSAGE FROM THE DIRECTOR GENERAL, DIRECTORATE GENERAL OF DRUG ADMINISTRATION

To ensure safety, efficacy, and quality medicines, the Directorate General of Drug Administration (DGDA), the National Regulatory Authority (NRA) of Bangladesh, has taken steps to improve the current processes of medicine registration by adopting Common Technical Document (CTD) guidelines to meet international standards for medicine registration. CTD guidelines are based on a common format of the International Conference for Harmonization for Technical Requirements for Pharmaceuticals for Human Use (ICH).

I sincerely hope that our effort to adopt CTD will open a new door for the pharmaceutical sector. It ensures the medicines manufactured in the country are safe, effective, and of standard quality, which will help to increase the acceptability of Bangladesh medicinal products by other countries. Effective use of CTD will also help DGDA to get the World Health Organization (WHO) accreditation as a functional NRA, which will be a milestone achievement for the DGDA and pharmaceutical sector.

I acknowledge the continuous technical assistance that the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, implemented by Management Sciences for Health (MSH), provided to DGDA to adopt the CTD formats and guidelines. I also extend my sincere thanks to the members of the taskforce team who reviewed the CTD modules and customized them to Bangladesh context with SIAPS support.

Major General Md. Mustafizur Rahman
Director General
Directorate General of Drug Administration (DGDA)
Ministry of Health and Family Welfare
Government of the People's Republic of Bangladesh

ABBREVIATIONS AND ACRONYMS

API	active pharmaceutical ingredient
BCS	biopharmaceutical classification system
BP	British Pharmacopoeia
CoA	certificate of analysis
CTD	Common Technical Document
DGDA	Directorate General of Drug Administration
DMF	drug master file
EMA	European Medicines Agency
EU	European Union
FDC	fixed-dose combination
FPP	finished pharmaceutical product
FPRC	finished product release control
GCP	good clinical practice
GMP	good manufacturing practices
ICH	International Conference On Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
INN	international nonproprietary name
IPI	inactive pharmaceutical ingredient
IR	Infrared
MHRA	Medicines and Healthcare Products Regulatory Agency
NCE	new chemical entity
Ph Eur	European Pharmacopoeia
PI	package insert
PI	prescribing information
PIC/S	Pharmaceutical Inspection Cooperation Scheme
PIL	patient information leaflet
PMF	plasma master file
QOS	quality overall summary
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SmPC	summary of product characteristics
TGA	Therapeutic Goods Administration
UK	United Kingdom
USFDA	United States Food and Drug Administration
USP	United States Pharmacopoeia
VAMF	vaccine antigen master file
VP	validation protocol
VR	validation report
WHO	World Health Organization

INTRODUCTION

These guidelines provide instructions for applicants preparing a Common Technical Document (CTD) for the registration of medicines for submission to the Directorate General of Drug Administration (DGDA). The document describes how to organize applications based on the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines on the CTD. The CTD is currently applicable only to human, not veterinary, medicines.

According to the CTD format, each application is a collection of documents, grouped into five modules. Bangladesh has adapted and will implement modules 1, 2, and 3. Module 4 is currently not applicable to Bangladesh because almost all of the products that are locally manufactured are generic versions of brand-name products and therefore do not require nonclinical studies (in vitro and in vivo). Additionally, because of the complexity in adopting this international standard, the DGDA decided to defer the request for clinical studies (module 5) to focus on implementing modules 1, 2, and 3. Even then, in rare cases concerning well-known APIs, the DGDA may be able to grant exemption from the submission of bioequivalence study data/reports in module 5.

Module 1: Administrative Information and Prescribing Information

Relevant administrative documentation and the proposed label for use in Bangladesh should be submitted in module 1 of the CTD dossier. This module should be divided into the relevant sections, as described in Part B of this document.

Module 2: Summary of the Dossier

Module 2 of the CTD dossier contains the summaries and overviews for the quality, nonclinical, and clinical sections of the dossier (refer to ICH M4Q, M4S, and M4E). The module begins with a general introduction to the medicine, including its pharmacological class, mode of action, and proposed clinical use. The summary of quality information should be provided according to WHO's Quality Overall Summary–product dossier (QOS-PD) template.

The clinical overview section should include a statement regarding good clinical practice (GCP) compliance.

Module 3: Quality

Module 3 of the dossier contains the chemical, pharmaceutical, and biological data relevant to the application. This information should be structured as described in the Bangladesh CTD modules 2 (Quality Overall Summary) and 3 (Quality) guidelines.

Also, refer to the ICH Guidelines M4Q (M4Q (R1): Quality Module 2: Quality Overall Summary (QOS) and Module 3: Quality.

Module 4: Nonclinical Study Reports

Module 4 of the dossier contains the nonclinical (pharmacotoxicological) data relevant to the application.

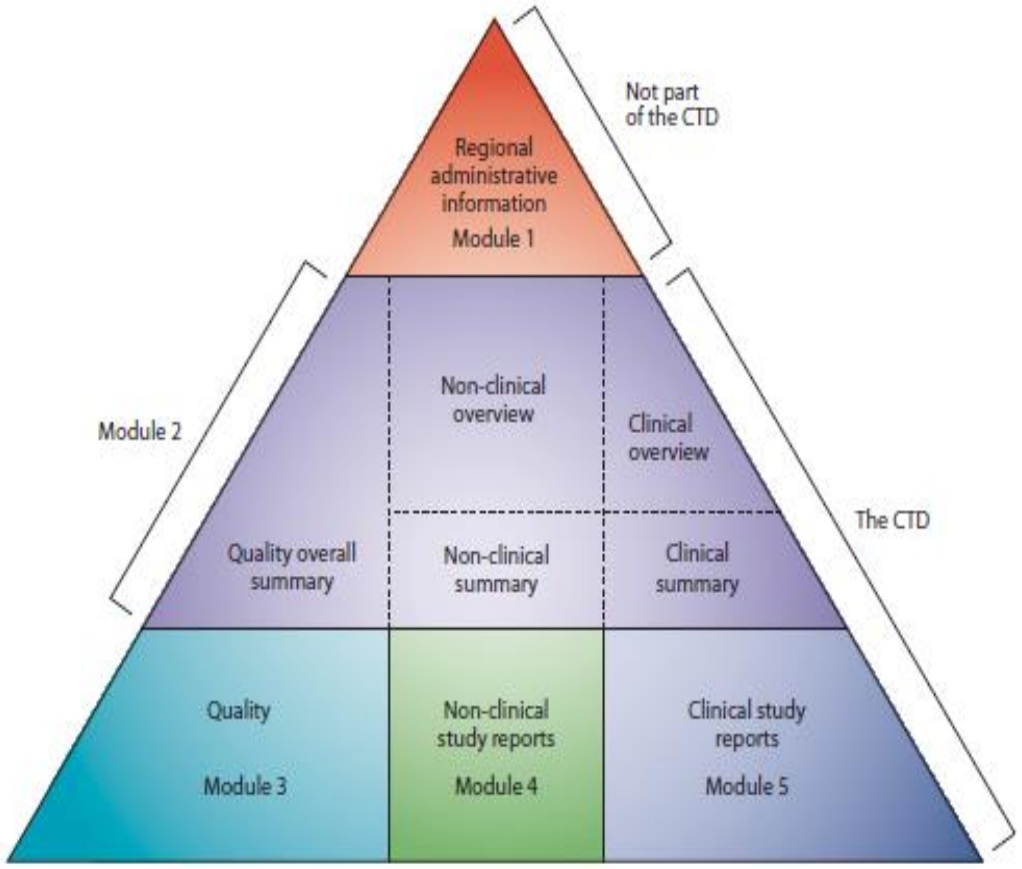
Exemptions apply to multisource (generic) products.

Module 5: Clinical Study Reports

Module 5 of the dossier contains the clinical data relevant to the application. In most circumstances, the clinical studies included in module 5 of the dossier will be international studies used to establish the pharmacodynamics, pharmacokinetics, safety, and efficacy of the medicine across an international patient population. However, where there is evidence to suggest that the pharmacokinetics or pharmacodynamics of the product may vary across the populations that will use the medicine in Bangladesh, the applicant should consider submitting studies relevant to those target populations. These reports should be presented in the order described in the Bangladesh CTD Module 2 (Clinical Overview), Guideline for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products, Bangladesh: Annexure 3, and CTD Module 5 (Bioequivalence Studies) guidelines. Also, refer to the ICH guideline M4E (M4E (R1): Efficacy, Module 2: Clinical Overview and Clinical Summary, and Module 5: Clinical Study Reports.

In cases concerning well-known active pharmaceutical ingredients, the DGDA may grant exemption from the submission of clinical study reports, other than bioequivalence study reports, in module 5.

Schematic of the Organization of the ICH CTD



The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

This document provides information on the contents of the Bangladesh CTD Module 1: Administrative Information and Prescribing Information (which is specific to the region), Module 2: Quality Overall Summary, and Module 3: Quality. General information for the applicant on preparing and organizing the dossier is also provided.

This is one in a series of guidelines that provide recommendations for applicants preparing the CTD for the registration of pharmaceuticals for human use. The document presents the agreed upon ICH common format for the preparation of a well-structured, harmonized application that will be submitted to regulatory authorities. The CTD format is intended to save time and resources and to facilitate regulatory review and communication. This document also draws on the World Health Organization (WHO) guidelines on submission of documentation for a multisource (generic) finished pharmaceutical products (FPP): preparation of product dossiers in CTD format, 2010; and the European Notice to Applicants: Medicinal products for human use, Volume 2B: Presentation and format of the dossier CTD (July 2003). The CTD does not provide information about the content of a dossier and does not indicate the studies and data that are required for successful approval.

Regional requirements may affect the content of the dossier submitted in each region; therefore, the dossier will not necessarily be identical for all regions.

The CTD guidelines, together with other existing Bangladesh Regulatory Guidelines, provide detailed information about the contents of an application. These guidelines apply to applications to register medicines and all related variations. Applicants should not modify the overall organization of the CTD. If not contained in the bulk of the documentation, any additional data should be included as addenda to the relevant part, together with additional expert comment that may be provided as a supplement to, or incorporated into, the relevant summary, overall summary, or overview.

PART A: GENERAL INFORMATION FOR APPLICATIONS

1 Preparing and Organizing the Common Technical Document

To facilitate the review of the basic data and to help the evaluator become oriented with the application's contents, the presentation of information should be unambiguous and transparent throughout the CTD.

If additional or supplementary data are submitted, the appropriate module(s) should be identified and section numbering should follow from the original documentation.

The applicant should not submit modules that are not used (i.e., it is unnecessary to include "not applicable" pages for any unused CTD headings).

For new applications, detailed statements justifying the absence of data or specific CTD sections should be provided in the relevant quality overall summary and/or nonclinical/clinical overviews (modules 2.3, 2.4, 2.5). If relevant, justification for blank sections of module 1 should be provided in the cover letter. Acronyms and abbreviations should be defined the first time they are used in each module.

2 Documentation

2.1 Submissions

Set 1 – Full dossier. The dossier should also be submitted on a CD along with the paper copy (if desired).

Ensure that:

- **Modules 1 and 3 are in MS Word format.**
- **Module 2 is in both MS Word and PDF format.**
- **PDF documents are text searchable (produced from an electronic source document).**

A complete application for registration dossier should include the following items:

- Proof of payment in accordance with DGDA approved fees (proof of payment should be included in section 1.2.2.1 of module 1)
- Sample and a copy of the sample's active pharmaceutical ingredient(s) (API) and final product release certificates of analysis
- Copy of the sample's API certificates of analysis (if applicable)
- Copy of the final product release certificates of analysis

On completion of the administrative screening the following should be included:

- Original letter of application for final submission should be included in section

1.0 of module 1 (this date becomes the date of the application and should be amended in section 1.2.1. by the applicant)
- All administrative screening outcome correspondence (if applicable) (module 1.10)
- Application fee or proof of payment according to DGDA approved fees (proof of payment should be included in section 1.2.2.1 of module 1)
- The number of copies of dossier sets requested by the DGDA (for paper submission)

2.1.1 Composition of Copy Sets

Only the information indicated should be included in each set. If sub-modules are not singled out, a module implies all the sub-modules included under that section. For example, “module 1.7” implies modules 1.7.1 to 1.7.11.

The sets should be compiled in the chronological order of the CTD.

3 Organizing Documents

Documents may be combined in volumes as long as they are separated by appropriately named tab identifiers. For example, the package insert should be separated from the other documents by a tab identifier. In general, documents from different CTD modules should not be included in the same volume. Documents from different modules may be combined in the same volume for amendments consisting of a small number of short documents.

Administrative documents (e.g., application letter) are included in module 1. The organization of such documents should be consistent with the structure described in these guidelines. Since the administrative documents are limited in number, they should be placed in the same volume, separated by tab identifiers.

4 Volume Identification

Volumes should be numbered by module, resulting in a separate set of numbers for each module. The labeling of each volume should include:

- Name of applicant
- Name of medicine

Module and volume number: The volumes for each module should be numbered separately and sequentially using the format: *x of y volumes,* where x is the number of the specific volume and y is the total number of volumes submitted for the

respective module, e.g., module 3, Vol.1 of 6.

- Copy number: The copies of modules 1, 2, and 3 should be numbered as copies *x of y.*
- Contents: Each volume should also be labeled according to the section(s) it contains, e.g., section 3.2.P.4 means:

3. – Module 3 – Quality
2. – Body of data
P. – Product
4. – Control of excipients

5 Pagination

A document is a set of pages, numbered sequentially and separated from other documents by a tab.

Page numbering should be at the document level and not at the volume or module level. (The entire submission should never be numbered consecutively by page.) In general, all documents should have page numbers. Since the page numbering is at the document level, there should only be one set of page numbers for each document.

Documents should be cross-referenced by referring to the CTD module, volume, tab identifier, and page number (for example: "*see Module 3, Vol. 6, P.4.3 Method validation, p. 23"*).

Documents should be printed on both sides of the page. Legibility should not be impaired and margin space should be sufficient on both the left and right side so that information is not obscured when the page is placed in a binder. However, module 1.3 Bangladesh Labeling and Packaging (1.3.1, 1.3.2, 1.3.3) and patient information leaflet amendments/updates should be single sided. Each document should start on a new page and be separated from the next document by a tab.

6 Paper Size

Standard A4 paper should be used for all submissions. Text and tables should be prepared using margins that allow the document to be printed on A4 paper. The left-hand margin should be sufficiently large that information is not obscured by binding.

7 Fonts

Font sizes for text and tables should be of a style and size that are large enough to be easily legible, even after photocopying or when provided electronically. Arial 12

point font is preferred for narrative text, but printing in a font size with a legibility equivalent to at least Arial 10 point black on white may be used. The copies, including figures, tables, and photos, should be clearly legible. Shading and/or colored filling/background and/or print (e.g., in tables and headers or across pages) is unacceptable and should be avoided.

Table 1: Presentation of Information in the CTD Format

Module number	Title and main section headings	Cross-reference to modules	Binder/label color	Number of paper copies (if applicable)
1	**Administrative and Prescribing Information**			
1.0	Letter of application			
1.1	Comprehensive table of content (module 1)			
1.2	Application			
1.3	Bangladesh labeling and packaging			
1.4	Information about the experts			
1.5	Specific requirements for amendment application of registered products	2, 3, 4, & 5	Red	1*
1.6	Environmental risk assessment			
1.7	Good manufacturing practice			
1.8	Foreign regulatory status			
1.9	Pharmacovigilance plan			
1.10	Details of compliance with screening outcomes			
1.11	Bioequivalence trial information			
1.12	Information on price			
1.13	Pediatric development program			
1.14	Risk management plan			
2	**CTD Summaries**			
2.1	Table of contents (modules 2 to 5)	2 to 5		
2.2	Background	2 to 5		
2.3	Quality overall summary	2 to 3		
2.4	Nonclinical overview	2 and 4	Yellow	1*
2.5	Clinical overview	2 and 5		
2.6	Nonclinical written and tabulated summaries	2 and 4		
2.7	Clinical summary	5		
3	**Quality**			
3.1	Table of contents of module 3		Green	1*
3.2	Body of data			
3.3	Literature references			
4	**Nonclinical study reports**			
4.1	Table of contents of module 4		Blue	1*
4.2	Study reports			
4.3	Literature references			
5	**Clinical study reports**			
5.1	Table of contents of module 5			
5.2	Tabular listings of all clinical studies		Black	1*
5.3	Clinical study reports			
5.4	Literature references			

*For combination products that require a joint review, an additional copy of modules 1, 2, and 3 is required.

PART B: BANGLADESH MODULE 1 – ADMINISTRATIVE AND PRESCRIBING INFORMATION

Module 1 should contain all administrative documents (e.g., application forms and certifications), labeling, general correspondence, and annexes. Generally, all of the documents in module 1, other than the annexes, can be provided in a single volume. The annexes to the module should be submitted in separate volumes.

Module 1.0 Letter of Application

Documentation		
1.	1.0	Letter of Application

Applicants should include a *Letter of Application* with all applications. A copy of the letter should be placed at the beginning of module 1.

The letter of application should address the following information, at a minimum:

- If the application is being submitted simultaneously with one or more additional applications for the identical product, this should be stated. It should also be confirmed that the submissions are identical except for the proprietary name.
- The brand name(s), generic name, active ingredient name(s), dosage forms, and strengths of the medicine(s).
- Clarification if the proprietary name in the original dossier (e.g., where a product has been licensed) differs from the proposed brand name included in the application.
- Justification for any empty sections in module 1 should be provided in the cover letter, as relevant.

For further submissions during the registration process or post-registration amendments, the cover letter should be included in this section of the dossier.

If replying to a letter from the DGDA, a copy of this letter should be included here.

Module 1.1 Comprehensive Table of Contents

Documentation		
1.	1.1	Comprehensive table of contents

Module 1 should include a comprehensive table of contents for the entire application. The comprehensive table of contents should include a complete list of all documents provided in the application, by module.

In the table of contents, the location of each document should be identified by referring to the volume number that contains the document and any tab identifier. In

general, the name for the tab identifier should be the name of the document (section heading according to the CTD format, e.g., 3.2.P.4.2). If the full name of the document is too long for the tab identifier, an alternative name that adequately identifies the document should be given.

Page numbers should not be used in the table of contents to refer to documents. Instead, tab identifiers as described above should be used. Page numbers, in addition to the tab identifier, should be used to facilitate location within documents, where relevant.

Module 1.2 Application

Documentation		
1.	1.2.1	Application form
2.	1.2.2	Annexes to the application form

1.2.1 Application Form

An application to register a prescription medicine for human use in Bangladesh must be accompanied by a completed application form.[2] The application form is available from the automated medicine registration system (Pharmadex) on the DGDA's website.[3]

The application form should also be submitted with every response to a DGDA recommendation and/or an application for amendment of the dossier.

1.2.2 Annexes to the Application Form

1.2.2	1.2.2.1	Proof of payment
	1.2.2.2	Letter of authorization for communication on behalf of the applicant
	1.2.2.3	Summary of the dossier product batch information (details are presented in module 3)
	1.2.2.4	Electronic copy declaration (applicable to paper submission)
	1.2.2.5	Curriculum vitae of the qualified person for pharmacovigilance
	1.2.2.6	Copy of written confirmation from the manufacturer of the API to inform the applicant in case of modification of the manufacturing process or specifications (API change)
	1.2.2.7	Certificate for a Vaccine Antigen Master File (VAMF), if applicable
	1.2.2.8	Certificate for a Plasma Master File (PMF), if applicable

1.2.2.1 Proof of Payment

Include the original copy of the receipt from the Bangladesh Central Bank. For the various fees, refer to information about medicine registration fees available on the DGDA website.[3]

[2] Printout of the completed and signed application form on Pharmadex.
[3] www.dgda.gov/bd.

1.2.2.2 Letter of Authorization for Communication on Behalf of the Applicant

The application should be signed by the pharmacist/person responsible for the compilation of the application. There should be an original signature; a scanned signature is not acceptable. An individualized, person-specific letter of authorization for the signatory should be attached, issued by the person responsible for the overall management and control of the business (i.e., the chief executive officer).

1.2.2.3 Dossier Product Batch Information

The table below should be completed to clarify the pharmaceutical development of the dosage form, from which data furnished in the modules mentioned below were derived:

	3.2.P.3	3.2.P.5	3.2.P.8	3.2.R.1	
	Manufacture	Control of final pharmaceutical product	Stability	Bioequivalence	Dissolution
Types of batches*					
Batch/lot number(s)					
Batch/lot size(s)					
Date(s) of manufacture					
Composition and manufacturing process					
Site of API**					

*Experimental, pilot, or production

**Add as many rows as necessary for API manufacturing sites

1.2.2.4 Electronic Copy Declaration (applicable paper submission)

When paper dossiers are submitted, the applicant should submit an affidavit in which it confirms that the data on the paper application are identical to the checked documents in Pharmadex for the online medicine registration application.

1.2.2.5 Curriculum Vitae of the Qualified Person Responsible for Pharmacovigilance

Provide a copy of the curriculum vitae of the qualified person responsible for pharmacovigilance.

1.2.2.6 API Change Control

A formal agreement (letter of commitment) exists between the applicant for medicine registration and each manufacturer of the API(s) ensuring that information will be communicated between them and to the DGDA before any significant change is made to the site of manufacture, manufacturing procedure, or quality control

specifications of the API. Except as permitted by any DGDA amendment to guidelines relating to changes to medicines, changes will not be made to the API(s) to be used in the manufacture of medicines destined to be distributed in Bangladesh before written approval is granted by the DGDA. Both parties understand that the consequences of failure to obtain approval for changes, where approval is necessary, may include de-registration and recall of batches of medicines containing the material in Bangladesh.

1.2.2.7 Certificate for a Vaccine Antigen Master File, if applicable

Insert a copy of the certificate for a VAMF, if applicable. This is based on the countries as required by the Government of Bangladesh by the notification released in the official Gazette.

The VAMF is a medicine application dossier for a vaccine. It contains all relevant information of a biological, pharmaceutical, and chemical nature for a given vaccine antigen, which is common to several vaccines from the same applicants.

1.2.2.8 Certificate for a Plasma Master File, if applicable

Insert a copy of the certificate for a PMF, if applicable. This is based on the countries as required by the Government of Bangladesh by the notification released in the official Gazette.

A PMF is a medicine dossier for applicants that provides all relevant detailed information on the characteristics of the entire human plasma used as a starting material and/or a raw material for the manufacture of sub/intermediate fractions, constituents of the excipient, and active substance(s) that are part of medicinal products incorporating stable derivatives of human blood or human plasma.

Module 1.3 Bangladesh Labeling and Packaging

Documentation	
1.3	Bangladesh labeling and packaging
1.3.1	Package insert (PI)
1.3.2	Patient information leaflet (PIL)
1.3.3	Labels (outer and inner)

Applicants should include the proposed or approved texts of the package insert (PI) (module 1.3.1) and the patient information leaflet (PIL) (module 1.3.2). Bangladesh-specific labels should be submitted in module 1.3.3 (drafts, specimens, or text). For more information, refer to the DGDA's Guidelines on Product Information on packaging materials available on its website.[3]

1.3.1 Bangladesh Package Insert

Module 1.3.1 should include a copy of the Bangladesh PI, either the proposed PI in the case of a new application, or the currently approved PI in the case of amendments. A PI guideline and any class labeling requirements may be issued by the DGDA periodically.

PI requirements:

1. Product name
2. Name and strength of active ingredient(s)
3. Product description
4. Pharmacokinetics/pharmacodynamics
5. Indication(s)
6. Recommended dose
7. Mode of administration
8. Contraindication(s)
9. Warnings and precautions
10. Interactions with other medications
11. Pregnancy and lactation
12. Undesirable effects
13. Overdose and treatment
14. Storage conditions
15. Dosage forms and packaging available
16. Name and address of manufacturer/marketing authorization holder
17. Date of revision of PI

1.3.2 Bangladesh Patient Information Leaflet

Module 1.3.2 should contain a copy of the proposed or approved Bangladesh consumer medicine information, also known as the *PIL*.

PIL requirements:

1. Name of product
2. Description of product
3. What is the medicine?
4. Strength of the medicine
5. What is the medicine used for?
6. How much and how often should you use this medicine?
7. When should you not take this medicine?
8. Undesirable effects
9. What other medicine(s) or food(s) should be avoided when taking this medicine?

10. What should you do if you miss a dose?
11. How should you keep this medicine?
12. Signs and symptoms of overdose
13. What should you do when you have taken more than the recommended dosage?
14. Name/logo of manufacturer/importer/marketing authorization holder
15. Care that should be taken when taking the medicine (drug interactions)
16. When should you consult your doctor?
17. Date of the PIL revision

1.3.3 Labels

If the applicant has a specimen or drafts of the sales presentation of the medicine available at the time of the initial application, it should be included in module 1.3.3.

A mock-up is a copy of the flat design (artwork) in full color that provides a replica of both the outer and immediate packaging and a two-dimensional presentation of the packaging/labeling of the medicine. It is also referred to as a paper copy or computer-generated version.

A specimen is a sample of the actual printed outer and inner packaging materials and package leaflet.

If there are multiple strengths and/or pack sizes, one representative specimen or mock-up is sufficient. If batch number and expiry date are to be printed on the label during packaging, a statement to this effect should accompany the labels. If mock-ups or specimens are not available at the time of the initial application, a text version may be submitted.

Labeling parameters required for unit carton and inner label:

1. Product name
2. Dosage form
3. Name of active ingredient(s)
4. Strength of active ingredient(s)
5. Batch number
6. Manufacturing date
7. Expiration date
8. Route of administration
9. Storage conditions
10. Registration number
11. Name and address of marketing authorization holder or product owner
12. Name and address of manufacturer

13. Special labeling (if applicable), e.g., sterile, external use, cytotoxic, alcohol content
14. Warning (if applicable)
15. Pack sizes (unit/volume)

Labeling parameters required for blisters/strips:

1. Product name
2. Name of active ingredient
3. Strength of active ingredient
4. Batch number
5. Expiration date
6. Name/logo of manufacturer/product owner/marketing authorization holder
7. Country's registration number

Module 1.4 Information about the Experts

Documentation	
1.4.1	Particulars of quality control manager
1.4.2	Name and qualifications of production manager
1.4.3	Name and qualifications of clinical manager (when applicable)

Experts must provide detailed reports of the documents and particulars, which constitute modules 3, 4, and 5. The requirement for these signed expert reports may be met by providing:

- The Quality Overall Summary, Nonclinical Overview/Summary, and Clinical Overview/Summary in module 2
- A declaration signed by the experts in module 1.4
- Brief information on the educational background, training, and occupational experience of the experts in module 1.4

References must be provided for any additional claims not supported by the dossier.

Module 1.5 Specific Requirements for Amendment Application of Registered Products

Documentation		
1.	1.5.1	Literature-based submissions
2.	1.5.2	Amendments/variations • Tabulated schedule of amendments • DGDA registration details (include the original or copy of the registration certificate) • Affidavit by responsible person
3.	1.5.3	Proprietary name applications and changes
4.	1.5.4	PI and PIL amendments/updates

1.5.1 Literature-based Submissions

If clinical evidence in support of efficacy is not submitted, studies and data to demonstrate the pharmaceutical and/or biological availability of the product should be included. If in the opinion of the applicant no data are required to substantiate efficacy (e.g., parenteral solutions), the rationale for accepting safety and efficacy, including reference to standard reference books, should be clearly stated.

For package insert amendments, refer to the Package Insert Guideline.[3]

1.5.2 Amendments/Variations

Amendments to the registered products or registration dossier are necessary to maintain the safety, quality, and efficacy of a medicine and to ensure compliance with current technical requirements. They also ensure adherence to administrative aspects of the dossier, keep the DGDA abreast of scientific progress, and reflect new therapeutic indications/warnings or other safety matters. It is therefore the objective of the DGDA to process, as quickly as possible, amendment applications made by the applicants.

1.5.2.1 Tabulated schedule of amendments (refer to Amendments Guideline)[3]
1.5.2.2 DGDA registration details
1.5.2.3 Affidavit by responsible person (refer to Amendments Guideline)[3]

1.5.3 Trade Name Applications and Changes

Submit a letter with details on the current and proposed names and the reason for the change in module 1.0. Include any information in support of a proposed name or alternative proposed names in this section 1.5.3.

Changing the trade name during the evaluation and registration phase will only be permitted if the regulatory authority has not accepted the name originally proposed by the applicant.

The policy on trade name and detailed requirements may be found in the Amendments Guideline and proof of payment must be filed.

1.5.4 Package Insert and Patient Information Leaflet Amendments/Updates

Include the annotated PI/PIL for any proposed amendments to an approved PI/PIL.

When updating or amending clinical aspects of the PI/PIL, the storage instructions should be updated to reflect the currently accepted wording. Refer to the Amendments Guideline for additional information.

Module 1.6 Environmental Risk Assessment

An environmental risk assessment of medicinal products for human use is the process through which the regulatory authority ensures that the potential effects of pharmaceuticals on the environment are studied and adequate precautions are taken in case specific risks are identified. It is performed to evaluate and limit the potential effects of medicines on the environment.

The applicant should perform and submit the environmental risk assessment of their medicinal products during development.

Module 1.7 Good Manufacturing Practice

Documents required by the DGDA		
1.	1.7.1	Date of last inspection of each site
2.	1.7.2	Inspection reports or equivalent documents
3.	1.7.3	Latest Good Manufacturing Practice (GMP) certificate or copy of the appropriate license
4.	1.7.4	Batch release procedures
	1.7.4.1	Active pharmaceutical ingredients
	1.7.4.2	Inactive pharmaceutical ingredients
	1.7.4.3	Finished Product Release Control (FPRC) tests (for imported products)
	1.7.4.4	Finished Product Release Responsibility (FPRR) criteria (for imported products)
5.	1.7.5	Confirmation of contract
6.	1.7.6	Certificate of a pharmaceutical product (CPP); WHO certification scheme, if applicable
7.	1.7.7	Proof of current registration of the responsible pharmacist
8.	1.7.8	Sample and documents
	1.7.8.1	Confirmation of submission of the sample
	1.7.8.2	Batch manufacturing record of the sample
	1.7.8.3	Certificate of analysis (CoA) of the sample
9.	1.7.9	Certified copy of permit to manufacture
10.	1.7.10	Inspection flow diagram (self-inspection)
11.	1.7.11	Organogram

For all medicines, regardless of country of origin, it is expected that key manufacturing and/or processing steps in the production of active ingredients and finished pharmaceutical products are performed in plants of acceptable standards (see WHO Guide to Good Manufacturing Practices).

1.7.1 Date of Last Inspection of Each Site

The applicant should provide a list of the manufacturers', packers', and FPRCs' names and license numbers and a list of the dates of inspection by the regulatory authorities of either the DGDA, US Food and Drug Administration (USFDA), Medicines and Healthcare Products Regulatory Agency (MHRA), Therapeutic Goods Administration (TGA), European Union (EU), or Pharmaceutical Inspection Cooperation Scheme (PIC/S) country at each site.

1.7.2 Inspection Reports or Equivalent Documents

The applicant should provide copies of inspection reports or equivalent documents, not older than two years, from the regulatory authorities of the DGDA, USFDA, MHRA, TGA, EU, Canada, or PIC/S country at each site.

1.7.3 Latest GMP Certificate or a Copy of the Appropriate License

Include the latest GMP certificate, not older than two years, for the manufacturer(s), packer(s), and FPRCs or a copy of the appropriate license.

1.7.4 Batch Release

1.7.4.1 Active Pharmaceutical Ingredients (API)

The following minimum requirement should be confirmed and the name and physical address of all laboratories performing the tests provided:

a) Identification and assay of the API will be performed by the product manufacturer regardless of the possession of a CoA from the API manufacturer.
b) Any tests included in the specifications and not included in a valid CoA will be performed.

1.7.4.2 Inactive Pharmaceutical Ingredient (IPI)

1) The following minimum requirement should be confirmed and the name and physical address of all laboratories performing the tests provided:

    a) Identification of the IPI will be performed regardless of the possession of a CoA from the supplier.
    b) Any tests included in the specifications and not included in a valid CoA will be performed.

2) For IPIs for which a conclusive identification test is not described, all parameters that are specific to the identification of such ingredients should be listed and the tests performed regardless of the possession of a CoA from the supplier.

1.7.4.3 Finished Product Release Control Tests

For imported products, at least the identification and assay of the API content should be performed by an approved laboratory (FPRC) after importation. This is to verify that the product has not been adversely affected during transport.

1.7.4.4 Finished Product Release Responsibility Criteria

The final non-analytical release criteria should include the verification of the appearance of the dosage form, the container, the package insert, the label, the batch number, the expiry date of the product, the CoA (including re-analysis for imported products), and the batch release documents (batch manufacturing record compliance).

1.7.5 Confirmation of Contract

The applicant should include a signed declaration that contracts with all third-party manufacturer(s) and/or packer(s) and FPRC(s) are in place. These contracts should be available for inspection purposes.

1.7.6 CPP (WHO Certification Scheme) (if applicable)

The WHO certification scheme on the quality of pharmaceutical products is an administrative instrument that states that registration of a medicine in the country of origin is a prerequisite for exporting to other countries. If the exporting country has authorized the product to be placed on its own market, the WHO-type certificate, in addition to certifying the manufacturing standard at the site in question, implies that the country issuing the certificate accepts that the product is of adequate quality, safety, and efficacy to remain on its own market. For details, refer to WHO Technical Report Series, No. 863, 1996 (Annex 10): Guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

The CPP is required by the DGDA, if applicable.

1.7.7 Bangladesh Pharmacist Registration

1.7.7.1 Proof of Current Registration of the Responsible Pharmacist by the Bangladesh Pharmacy Council

Submit a copy of the Bangladesh Pharmacy Council Registration certificate of the responsible pharmacist and also proof of current registration (annual registration card).

1.7.7.2 Proof of Current Registration by the Bangladesh Pharmacy Council of the Pharmacist Signing the Dossier

Submit a copy of the Bangladesh Pharmacy Council Registration certificate of the pharmacist signing the dossier and also proof of current registration (annual registration card), if different.

1.7.8 Sample and Documents

1.7.8.1 Confirmation of Submission of a Sample

All medicine applications for registration must include a sample. It should be submitted to the National Control Laboratory, Drug Testing Laboratory.

1.7.8.2 Batch Manufacturing Record of the Sample

a) Included in module 3.2.R or
b) Available for inspection

1.7.8.3 CoA of the Sample

Include the CoA of the FPP and of the API used in the sample. Ensure that the batch number on the CoA corresponds with the batch number on the sample.

1.7.9 Certified Copy of a Permit to Manufacture

Include a duly certified license to manufacture.

1.7.10 Inspection Flow Diagram

Submit the inspection flow diagram, also of FPP intermediates, clearly indicating the sites and processes, including a clear distinction between primary and secondary packers.

1.7.11 Organogram

Include the current company organogram, reflecting the responsible pharmacist and other key positions.

Module 1.8 Foreign Regulatory Status (Importers Only)

Documentation		
1.	1.8.1	List of countries to which an application for the same product has been submitted
2.	1.8.2	Information and signature of manufacturer's authorized agent
3.	1.8.3	Number of manufacturer(s)/importer(s) already manufacturing/importing to Bangladesh
4.	1.8.4	Estimated market for this product/product group in Bangladesh
5.	1.8.5	Registration certificates or marketing authorization
6.	1.8.6	Foreign prescribing and patient information
7.	1.8.7	Data set of similarities

1.8.1 List of Countries to which an Application for the Same Product has Been Submitted

The applicant should provide a list of countries to which an application for the same product has been submitted and the dates of submission (if available). This list should include details about approvals (with indications).

1.8.2 Information about the Manufacturer's Authorized Agent

The name, address, and signature of manufacturer's authorized agent in Bangladesh should be provided.

1.8.3 Number of Manufacturer(s)/Importer(s) Already Manufacturing/Importing in Bangladesh

Provide the total number of companies already manufacturing/importing the same product in Bangladesh.

1.8.4 Estimated Market for this Product/Product Group in Bangladesh

The proposed prices for the product/product group should be provided for DGDA review.

1.8.5 Registration Certificates or Marketing Authorization

In the case of registration in the country of origin, or where a marketing authorization has been granted by the regulatory authority of a country with which the DGDA aligns, copies of the registration certificates or marketing authorization should be provided.

1.8.6 Foreign Prescribing and Patient Information

In the case of marketing authorizations in the country of origin, or where marketing authorizations have been granted by the regulatory authority of a country with which the DGDA aligns, copies of relevant prescribing and patient information should be provided, e.g., the Canadian product monograph, the summary of product characteristics (SmPC) in the EU, and US prescribing information (PI). If the overseas SmPC, monograph, or PI has not been approved at the time the application is made in Bangladesh, a draft document may be included. The approved overseas SmPC, monograph, or PI should be supplied to the DGDA when it becomes available.

1.8.7 Data Set Similarities

Module 1.8.7 should contain a summary of the similarities/differences in the data packages submitted in other countries.

Module 1.9 Pharmacovigilance Plan

This should include proof that the applicant has the services of a qualified person responsible for pharmacovigilance and the necessary means for the notification of any adverse reaction occurring either in Bangladesh or in a third country. The description of the marketing authorization holder's pharmacovigilance system should follow the requirements and format given in the DGDA's adverse drug events guidelines, which are available on its website.

Module 1.10 Details of Compliance with Screening Outcomes

Documentation	
1.	Details of compliance with screening outcomes
2.	Details of any additional data submitted

Address the screening comments, and where documentation is involved, provide only an overview of the relevant documentation submitted. Applicants should not modify the overall organization of the CTD; amended modules should be filed under the appropriate CTD section.

A copy of the completed screening template should be included in module 1.10, with the original completed form submitted separately with the application.

Module 1.11 Bioequivalence Trial Information

Documentation		
1.	1.11.1	Study title(s) (or brief description giving the design, duration, dose, and subject population of each study)
	1.11.2	Protocol and study numbers
	1.11.3	• Investigational products (test and reference) details, including: o Active ingredient o Strength o Dosage form o Manufacturer o Batch number o Expiry or retest date o Country in which procured
	1.11.4	Confirmation that the test product formulation and manufacturing process are what is being applied for
	1.11.5	Proof of procurement of the biostudy reference product
	1.11.6	Name and address of the contract research organization (CRO) where the bioequivalence studies were conducted
	1.11.7	Sponsor and responsible sponsor representative: name and address, contact details
	1.11.8	Duration of clinical phase: dates of dosing and last clinical procedure
	1.11.9	Date of final report

Bangladesh's requirements for biopharmaceutical studies are described in the Guideline for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products, Bangladesh, Annexure 3 and Bioequivalence Guidelines.[3]

The Bioequivalence Guideline is largely based on the ICH M4E(R1) Efficacy module 5 and relevant WHO guidelines. It also takes into account relevant USFDA guidelines.

In relation to the content of biopharmaceutical study reports, this guideline states that: The report of a bioavailability or bioequivalence study should give the complete documentation of its protocol, conduct, and evaluation complying with GCP rules.

The DGDA considers it essential that the principal investigator(s) sign the study reports after their completion, either in an unqualified fashion or clearly taking responsibility for all aspects of the conduct of the study for which they might reasonably be held responsible. If the signature of the principal investigator is absent from the report of a bioavailability or bioequivalence study, it will be requested by the DGDA during the evaluation process.

Module 1.12 Information on Price

Documentation	
1.12.1	Proposed maximum retail price/indicative price
1.12.2	Estimated price per dose, per day treatment, and cost of the recommended course of treatment

1.12.1 The manufacturer should provide the proposed maximum retail price for the product.

1.12.2 The estimated price/dose/day treatment and cost of the recommended course of treatment for the medicine should be provided by the manufacturer.

Module 1.13 Pediatric Development Program (For Future Implementation by DGDA)

Documentation	
1.	References to pediatric development program

There is a recognized global problem with the availability of pediatric-specific formulations and a lack of information from proper investigations of the use of medicines in children. This problem leads to medicines being used outside of their approved indications, and at times, being reformulated by pharmacists to make them more suitable for use by children. However, the basic precept that children should not be discriminated against by being supplied poorly investigated medicines has been accepted internationally.

The CTD guidelines require that the safety and efficacy in the pediatric population should be routinely analyzed in applications for a proposed indication that occurs in children.

Please state whether there is a pediatric development program for this medicine and if so, refer to the relevant sections of the dossier.

Module 1.14 Risk Management Plan

The applicant should include a risk management plan for biological products and for a generic medicine, where a safety concern with the reference product requires additional risk minimization activities.

Unless the DGDA has agreed that it is not required, include a risk management plan for applications involving:

- A significant new registration (for example, new dosage form, new route of administration, significant change in indications).

- A significant variation in a registration (for example, new manufacturing process of a biotechnologically derived product).

In some circumstances, products, such as fixed-dosed combination applications, may require a risk management plan.

PART C: MODULE 2 – QUALITY OVERALL SUMMARY

MODULE 2.2 BACKGROUND OF THE QUALITY OVERALL SUMMARY

The Quality Overall Summary (QOS) is a summary that follows the scope and the outline of the Body of Data in module 3 (Quality) of the dossier, which contains the chemical, pharmaceutical, and biological data relevant to the application. The QOS should contain the summary data of what is already provided in module 3 or in other parts of the Common Technical Document (CTD). The QOS should include sufficient information from each section of module 3 to provide the quality reviewer with an overview of the quality of the product. The QOS should also emphasize critical key parameters of the medicine and provide, for instance, justification in cases where guidelines were not followed. The QOS should include a discussion of key issues that integrate information from sections in module 3 and supporting information from other modules, including cross-referencing to volume(s) and page number(s) in other module(s).

This QOS should normally not exceed **40 pages** of text, excluding tables and figures. For biotech products and products manufactured using more complex processes, the document may be longer, but normally should not exceed **80 pages** of text, excluding tables and figures. *For a sample template of the QOS, refer to WHO Quality Overall Summary - Product Dossier (QOS-PD), 2014-12-11.*[4]

Although the CTD is organized by modules, the guidance providing recommendations for applicants on preparing the CTD is organized by topic: quality, safety, and efficacy. As a result, guidance discussed in module 2 is divided into three sections:

- Guidance on the quality section of the CTD (module 2, Quality Overall Summary [QOS], and module 3) may be found in the ICH M4Q: The CTD — Quality.
- Guidance on the safety section of the CTD (module 2, the Nonclinical Overview and the Nonclinical Written and Tabulated Summaries, and module 4) may be found in the ICH M4S: The CTD — Safety.
- Guidance on the efficacy section of the CTD (module 2, the Clinical Overview and the Clinical Summary, and module 5) may be found in the ICH guideline M4E: The CTD — Efficacy.

[4] http://apps.who.int/prequal/ (go to A-Z Listings of Documents).

MODULE 2.3 BODY OF DATA OF QUALITY OVERALL SUMMARY

2.3.S Active Pharmaceutical Ingredient (API) [Name, Manufacturer]

2.3.S.1 General Information [Name, Manufacturer]

Information from section 3.2.S.1 of module 3 should be included here.

2.3.S.2 Manufacture [Name, Manufacturer]

Information from section 3.2.S.2 of module 3 should be included here.

- Information on the manufacturer.
- A brief description of the manufacturing process (including, for example, reference to starting materials, critical steps, and reprocessing) and the controls that are intended to result in the routine and consistent production of materials of appropriate quality.
- A flow diagram, as provided in section 3.2.S.2.2 of module 3, should be imported directly to this section.
- A description of the source and starting material and raw materials of biological origin used in the manufacture of the API, as described in section 3.2.S.2.3 of module 3.
- A discussion of the selection and justification for critical manufacturing steps, process controls, and acceptance criteria. Highlight critical process intermediates, as described in section 3.2.S.2.4 of module 3.
- A description of process validation and/or evaluation, as described in section 3.2.S.2.5 of module 3.
- A brief summary of major manufacturing changes made throughout the development process and conclusions from the assessment used to evaluate product consistency, as described in section 3.2.S.2.6 of module 3. The QOS should also cross-reference the nonclinical and clinical studies that used batches affected by these manufacturing changes. For more information, also refer to the ICH guidelines M4S and M4E sections of the application.

2.3.S.3 Characterization [Name, Manufacturer]

<u>For New Chemical Entities (NCE):</u>

A summary of the interpretation of evidence of structure and isomerism, as described in section 3.2.S.3.1 of module 3, should be included.

When the API is chiral, please specify whether specific stereoisomers or a mixture of stereoisomers were used in the nonclinical and clinical studies. Information should

also be given as to the stereoisomer of the API that is to be used in the final product intended for marketing.

For Biotech:

A description of the desired product and product-related substances and a summary of general properties, characteristic features, and characterization data (for example, primary and higher order structure and biological activity), as described in section 3.2.S.3.1 of module 3, should be included.

For NCE and Biotech:

The QOS should summarize the data on potential and actual impurities arising from the synthesis, manufacture, and/or degradation and should summarize the basis for setting the acceptance criteria for individual and total impurities. The QOS should also summarize the impurity levels in batches of the API used in the nonclinical studies, in the clinical trials, and in typical batches manufactured by the proposed commercial process. The QOS should state how the proposed impurity limits are qualified.

A tabulated summary of the data provided in section 3.2.S.3.2 of module 3, with graphic representation, where appropriate, should be imported directly to this section.

2.3.S.4 Control of Active Pharmaceutical Ingredient [Name, Manufacturer]

A brief summary of the justification for the specifications, the analytical procedures, and validation should be included.

Specifications from section 3.2.S.4.1 of module 3 should be imported directly to this section.

A tabulated summary of the batch analyses from section 3.2.S.4.4 of module 3, with graphic representation, where appropriate, should be imported directly to this section.

2.3.S.5 Reference Standards or Materials [Name, Manufacturer]

Information from section 3.2.S.5 of module 3 (tabulated presentation, where appropriate) should be included.

2.3.S.6 Container Closure System [Name, Manufacturer]

A brief description and discussion of the information from section 3.2.S.6 of module 3 should be included.

2.3.S.7 Stability [Name, Manufacturer]

This section should include a summary of the studies undertaken (conditions, batches, analytical procedures) and a brief discussion of the results and conclusions, the proposed storage conditions, and the retest date or shelf life, where relevant, as described in section 3.2.S.7.1 of module 3.

The post-approval stability protocol, as described in section 3.2.S.7.2 of module 3, should be included.

A tabulated summary of the stability results from section 3.2.S.7.3 of module 3, with graphic representation, where appropriate, should be imported directly to this section.

Note: A separate section 2.3.S should be provided for each API. For example, for a second substance, the sections would be labeled 2.3.S [name 2, manufacturer]. For a substance coming from another manufacturer, the sections would be labeled 2.3.S [name, manufacturer 2].

2.3.P Pharmaceutical Product [Name, Dosage Form]

2.3.P.1 Description and Composition of the Pharmaceutical Product

Information from section 3.2.P.1 of module 3 should be provided.

The description and composition of the pharmaceutical product from section 3.2.P.1 of module 3 should be imported directly to this section.

2.3.P.2 Pharmaceutical Development [Name, Dosage Form]

A discussion of the information and data from section 3.2.P.2 of module 3 should be presented. A tabulated summary of the composition of the formulations used in clinical trials and a presentation of dissolution profiles should be imported directly to this section, where relevant.

2.3.P.3 Manufacture [Name, Dosage Form]

Information from section 3.2.P.3 of module 3 should be included here.

- Information on the manufacturer.
- A brief description of the manufacturing process and the controls that are intended to result in the routine and consistent production of a product of appropriate quality.

- A flow diagram, as provided in section 3.2.P.3.3 of module 3, should be imported directly to this section.
- A brief description of the process validation and/or evaluation, as described in section 3.2.P.3.5 of module 3, should be provided.

2.3.P.4 Control of Inactive Pharmaceutical Ingredients (Excipients) [Name, Dosage Form]

A brief summary of the quality of excipients, as described in section 3.2.P.4 of module 3, should be included here.

2.3.P.5 Control of Pharmaceutical Product [Name, Dosage Form]

A brief summary of the justification for the specifications, a summary of the analytical procedures and validation, and characterization of impurities should be provided.

Specifications from section 3.2.P.5.1 of module 3 should be imported directly to this section.

A tabulated summary of the batch analyses provided under section 3.2.P.5.4 of module 3, with graphic representation, where appropriate, should be imported directly to this section.

2.3.P.6 Reference Standards or Materials [Name, Dosage Form]

Information from section 3.2.P.6 of module 3 (tabulated presentation, where appropriate) should be included here.

2.3.P.7 Container Closure System [Name, Dosage Form]

A brief description and discussion of the information in section 3.2.P.7 of module 3 should be included here.

2.3.P.8 Stability [Name, Dosage Form]

A summary of the studies undertaken (conditions, batches, analytical procedures) and a brief discussion of the results and conclusions of the stability studies and analysis of data should be included. Conclusions regarding storage conditions and shelf life (and in-use storage conditions and shelf life, if applicable), should be given. A tabulated summary of the stability results from section 3.2.P.8.1 of module 3, with graphic representation, where appropriate, should be imported directly to this section.

The post-approval stability protocol, as described in section 3.2.P.8.2 of module 3, should be provided.

Note: A separate section 2.3.P should be provided for each dosage form. For example, for a second dosage form, the sections would be labeled 2.3.P [name, dosage form 2].

2.3.A Appendices

2.3.A.1 Facilities and Equipment

For Biotech:

A summary of facility information described under Appendix 3.2.A.1 of module 3, Facilities and Equipment, should be included here.

2.3.A.2 Adventitious Agents Safety Evaluation

A discussion of measures implemented to control endogenous and adventitious agents in production should be included.

A tabulated summary of the reduction factors for viral clearance from Appendix 3.2.A.2 of module 3, Adventitious Agents Safety Evaluation section of module 3, should be imported directly to this section.

2.3.A.3 Novel Excipients

A brief discussion of information described under section 3.2.A.3 of module 3 should be included.

2.3.R Regional Information

A brief description of information specific to the region, as provided under section 3.2.R Regional Information, should be included, where appropriate.

PART D: MODULE 3 – QUALITY

MODULE 3.2 BODY OF DATA

3.2.S Active Pharmaceutical Ingredient (Name, Manufacturer)

Neither the complete nor the open part of the drug master file (DMF) should be sent directly to the DGDA.

The information should be submitted in the dossier under the headings provided below.

The documentation must comply with the WHO Good Manufacturing Practices[5] that has been adopted by the DGDA.

Starting materials for in situ API preparation are treated as APIs.

For a mixture of API(s) or API(s) with inactive pharmaceutical ingredients (IPI), the blending of the ingredients is considered the first step in the manufacture of the final product, and therefore does not fall under the definition of an API even though it may take place in a different facility. The resultant mixture, or partially completed final product (e.g., coated or uncoated granules) is regarded as a finished pharmaceutical product (FPP) intermediate.

The only exceptions can be made where the API cannot exist on its own, for example, due to insufficient stability without a stabilizing agent.

The mixing of the API with an IPI or another API therefore forms part of the manufacturing procedure for the final product, which is addressed in section 3.2.P.3 of module 3, while the API(s) used in such mixtures should be included in section 3.2.S of module 3, according to the requirements of sections 3.2.S.1 to 3.2.S.7 and 3.2.R.6 of module 3. The formulation, API, and IPI specifications and control procedures, packaging materials, stability, and pharmaceutical development of the FPP intermediate are addressed in sections 3.2.P.3, 3.2.S.2, 3.2.P.4, 3.2.P.7, 3.2.P.8, and 3.2.P.2, respectively, in accordance with the requirements of the relevant sections.

In case of blood fractions, a Plasma Master File should be included in the dossier, if applicable.

A separate 3.2.S should be submitted for:

- Each API (in the case of a fixed-dose combination product)
- Each API manufacturer applied for

[5] http://dgda.gov.bd

- Those sections that are relevant to the FPP manufacturer in terms of testing of the API (e.g., section 3.2.S.4)

3.2.S.1 General Information (Name, Manufacturer)

3.2.S.1.1 Nomenclature (Name, Manufacturer)

The brand name, generic name, or international nonproprietary name (INN), or chemical description of the API(s), should be provided.

3.2.S.1.2 Structure (Name, Manufacturer)

The structural formula (indicating stereochemistry, where appropriate), systematic name, the empirical formula, and the relative molecular mass should be provided.

3.2.S.1.3 General Properties (Name, Manufacturer)

The physical and chemical properties of the API, including, for example, solubility, particle size, and hygroscopicity, should be indicated.

The solubility of each API should be specified in terms of a unit part of the substance per number of parts of the solvent, or in unit mass of substance in a given volume of solvent, at a specific temperature. The solvents should include water and the solvent(s) relevant to the product formulation.

If the API has a low solubility in water in accordance with the Biopharmaceutical Classification System (BCS) definition, the solubility should be quantified (mg/ml).

Evidence of the occurrence of isomers, chirality, and polymorphism, where applicable, should be indicated. The absence of isomers, chirality, and/or polymorphism should be confirmed.

For a multisource product, the API must be identical in structure and stereochemistry to the API used as the reference product (pharmacopoeia structure).

3.2.S.2 Manufacture (Name, Manufacturer)

3.2.S.2.1 Manufacturer(s) (Name, Manufacturer)

The name, business, and physical address of each manufacturer of the API being applied (including any intermediate manufacturer) should be provided.

No API from any manufacturer, other than the approved manufacturer(s), may be used.

3.2.S.2.2 Description of Manufacturing Process and Process Controls (Name, Manufacturer)

A short description of the synthesis and a flow chart that includes the structures and stereochemistry of starting materials and intermediates; reagents, catalysts, solvents, isolation, and purification; and any other relevant aspects. Note that specifications and control procedures for substances used in this process are not generally required. (The specific processes carried out by any intermediate manufacturer should be identified.)

Other relevant aspects, for example, preparation of sterile material (full description of aseptic or sterilization process, including conditions), should be included or if there is no further sterilization of the FPP.

See 3.2.R. below for alternative to this section.

3.2.S.2.3 Control of Materials (Name, Manufacturer)

1. Full details of tests and specifications for pharmaceutical ingredients used in the production of the primary production lot should be provided; refer to the applicable guideline of the WHO Technical Report Series: biological products: general recommendations.[6]

2. In the case of biological medicines produced using the cell bank or seed lot system, the history (origin and sources) and preparation of the seed lot and/or cell lines should be described with specific reference to the tests that are carried out on such a seed lot or cell bank to establish and maintain the integrity. Refer to the European Medicines Agency (EMA)[7] and or the applicable guideline of the WHO Technical Report Series: biological products: general recommendations.

3. Particulars of the composition of all culture media used in the preparation and testing of a biological medicine should be given. All raw materials of animal or human origin must be specified as well as suppliers (indicating the country of origin) and the certificate of analysis (CoA).

4. Particulars should be given of the other biological source material from which a biological medicine (e.g., blood fractions) is extracted, including the origin of the culture or blood.

[6] http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html.

[7] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000082.jsp&mid=WC0b01ac0580027547.

3.2.S.2.4 Controls of Critical Steps and Intermediates (Name, Manufacturer)

Submit information relevant for the FPP manufacturer (e.g., sterile material).

Critical Steps: Tests and acceptance criteria (with justification, including experimental data) performed at critical steps identified in section 3.2.S.2.2 above on the manufacturing process to ensure that the process is controlled should be provided.

Intermediates: Information on the quality and control of intermediates isolated during the process should be provided. For details, refer to ICH Guidelines: Q6A and Q6B.

Additionally for biotech: Stability data supporting storage conditions should be provided. For details, refer to ICH Guideline Q5C.

3.2.S.2.5 Process Validation and/or Evaluation (Name, Manufacturer)

Provide full validation data on the aseptic processing and sterilization process, where there is no further sterilization of the FPP.

3.2.S.2.6 Manufacturing Process Development (Name, Manufacturer)

For NCEs, refer to ICH M4Q.

3.2.S.3 Characterization (Name, Manufacturer)

3.2.S.3.1 Elucidation of Structure and other Characteristics (Name, Manufacturer)

Provide structure (including stereochemistry) elucidation for NCEs.

Proof of correctness of structure for a well-known API (e.g., infrared [IR] spectrometric comparison against an official standard, such as US or BP pharmacopoeia) may be acceptable. In the case of enantiomers, an additional test is required to confirm its identity.

If the API is not described in a monograph of any of the official pharmacopoeias, no official standard is available, in which case sufficient evidence (nuclear magnetic resonance, IR, mass spectrometry, elemental analysis, etc., with interpretation) should be provided in support of the structure and stereochemistry.

3.2.S.3.2 Impurities (Name, Manufacturer)

Provide a description of impurities, indicating the possible source of impurities and a clear distinction between actual and possible impurities.

Provide a description of possible degradation products.

3.2.S.4 Control of Active Pharmaceutical Ingredient (Name, Manufacturer)

3.2.S.4.1 Specifications (Name, Manufacturer)

Include the API manufacturer's and FPP manufacturer's (if different) specifications of the API in tabulated format, not narrative. Indicate clearly if these specifications are the same.

Additional specifications (e.g., isomers, chirality, polymorphs, as well as impurities, particle size distribution, residual solvents, where relevant) should be submitted for all APIs.

Specifications and the control procedures for the particle size of APIs that have a low solubility in water in accordance with the BCS definition and for those which the DGDA may request should be submitted, and the solubility quantified, unless justified. Particle size should be given in International Systems of Units (SI). Exemption from this requirement may be granted if the API is administered as a clear solution.

3.2.S.4.2 Analytical Procedures (Name, Manufacturer)

Include detailed methods used for quality testing (identification, assay, determination of related substances, residual solvents, etc.), including chromatograms for the API manufacturer and FPP manufacturer (if different). When pharmacopoeia methods are used, these should be current and may be referred to.

3.2.S.4.3 Validation of Analytical Procedures (Name, Manufacturer)

Include validation reports, where relevant. In-house methods require full validation. Pharmacopoeia methods require system suitability and linearity, where applicable.

3.2.S.4.4 Batch Analyses (Name, Manufacturer)

For NCEs, extensive batch analysis is required, as well as for batches used in clinical studies.

Submit valid CoAs from the API manufacturer relating to at least two batches for NCEs and generics.

3.2.S.4.5 Justification for Specifications (Name, Manufacturer)

Full justification is required for in-house standards claimed. For details refer to ICH Q6A.

No justification is required for pharmacopoeia standards claimed unless there are additional tests.

3.2.S.5 Reference Standards or Materials (Name, Manufacturer)

For NCEs and well-known non-compendial APIs, at least the following information on the primary reference standard should be provided:

- Purification method, if applicable
- Establishment of purity (potency)
- CoA, with a potency statement

If a pharmacopoeia monograph is claimed, the pharmacopoeia standard should be used.

Secondary standards should always be established against the pharmacopoeia/primary standard. Refer to WHO Technical Report Series 943, Annex 3 (2009)[8] for more details.

3.2.S.6 Container Closure System (Name, Manufacturer)

A description of the container closure system(s) should be provided, including the identity of construction materials for each primary packaging component, and their specifications. The specifications should include a description and identification (and critical dimensions, with drawings, where appropriate). Non-compendial methods (with validation) should be included, where appropriate.

For non-functional secondary packaging components (e.g., those that do not provide additional protection) only a brief description should be provided. For functional secondary packaging components, additional information should be provided.

The suitability should be discussed with respect to, for example, choice of materials, protection from moisture and light, compatibility of the construction materials with the API, including absorption to container and leaching, and/or safety of materials of construction.

3.2.S.7 Stability (Name, Manufacturer)

3.2.S.7.1 Stability Summary and Conclusions (Name, Manufacturer)

The storage requirements for the API, as specified by the manufacturer of the API and/or prescribed in the pharmacopoeia or acceptable standard reference, should be specified, and a description of the API container closure system should be included.

[8] http://apps.who.int/prequal/info_general/documents/TRS953/TRS_953-Annex3.pdf.

If a specific storage temperature is not specified in any acceptable reference, an instruction to protect from excessive heat, freezing, moisture, and light should be included, unless justified.

The proposed retest period should be indicated.

3.2.S.7.2 Post-Approval Stability Protocol and Stability Commitment (Name, Manufacturer)

The post-approval stability protocol and stability commitment should be provided. For more details, please refer to the ICH guidelines Q1A and Q5C.

3.2.S.7.3 Stability Data (Name, Manufacturer)

1. Include results of stability studies performed on the API obtained by the route of synthesis described in section 3.2.S.2.2 when stored in the proposed container closure system.

2. Provide the conditions under which degradation products are formed (stress testing).

3. A validated stability-indicating assay method, described in full, should be used in these studies, unless the method for related substances is specific and quantitative, such as using the High Performance Liquid Chromatography (HPLC) technique.

4. Supporting chromatograms, where relevant, should be included in the methods or validation section.

5. Stability data on NCE APIs should be generated according to the stability guideline (refer to ICH Q1B); for well-known chemical entities, supporting literature may be submitted.

6. For biological medicines, stability of the primary production lot and all intermediates (if not used immediately) should be provided.

3.2.P Pharmaceutical Product (Name, Dosage Form)

3.2.P.1 Description and Composition of the Pharmaceutical Product (Name, Dosage Form)

1. The formulation should show the INN or approved names, generic, and/or chemical names of all APIs, and polymorph (if relevant), and approved names of IPIs, including those that do not remain in the final product after

manufacturing, for example, granulating agents and gases used for flushing. IPIs not present in the final product should be indicated.

The ingredients for in-situ preparations, pre-mixes, FPP intermediates, cores, coating, etc. should be listed/grouped together and identified accordingly.

2. The name and the quantity of the API and the name and quantity provided under “Composition” in the package insert and patient information leaflet (PIL) should correspond. The name and quantity of the API per dosage unit should also correspond to the final product specifications.

   Justification should be provided for deviations.

   The theoretical quantity of the base of the API should be indicated if a compound, for example, a hydrate, solvate, or salt, is used.

   If the moisture content or other characteristic of an API is relevant to the quantity of the IPIs used in the formulation, this should be mentioned in a footnote.

3. A product may contain more than one API provided that:

   a) Each API makes a contribution to the claimed indications
   b) The effect of combining the APIs in one product does not decrease the safety, efficacy, or quality (including stability) of the product significantly
   c) The product provides rational concurrent therapy for a significant proportion of the target population (e.g., tuberculostatic combinations).

4. Each pharmaceutical ingredient should be listed with its quantity per dosage unit. This would include the vehicle(s), solvent(s), or base(s) (excluding quantities of coating solvents). In the absence of an approved name (INN) or chemical name, a chemical description or characterization of the substance should be given. If so required and relevant, the proprietary name of the IPI may be included in addition to the approved name.

   The approved name for each ingredient should be standardized throughout the application.

   Where applicable, special characteristics of the IPI, for example, lyophilised, micronised, solubilised, emulsified, or form (e.g., anhydrous, monohydrate) and/or source (e.g., the botanical source of starch) should be indicated.

The grade of IPIs, also when a pharmacopoeia monograph covers more than one grade (e.g., viscosity of methyl cellulose), and the type of water (e.g., purified, water for injection), where relevant, should be indicated.

The use of IPIs that are not described in official pharmacopoeia is strongly discouraged and should be justified. This includes flavorant, fragrance, colorant, and ink.

5. The purpose of each IPI should be briefly described. If the IPI is used for multiple purposes in the formulation, each purpose should be mentioned.

   The name of each API and IPI should correspond and the quantities correlate with those reflected in the batch formulation submitted in section 3.2.P.3.2 of module 3, and the batch manufacturing record submitted or made available for inspection.

6. Some IPIs are single chemical entities, while others are combinations. Some are chemically transformed (e.g., modified starch). For excipients that are mixtures of chemically related or unrelated components, for example, polyol esters (mixture of mono, di, and tri esters), direct compression excipients, solutions, or film coating formulations, or excipients that are chemically modified, the nature and quantity of each such excipient should be specified.

   The qualitative composition of inks should be specified.

   The composition of these mixtures/combinations could be attached to the formulation information or included separately on the next page.

7. Any overages for the API should be given separately. The label claim quantity should be provided and the excess quantity indicated as the actual quantity or as a percentage. For example, 500 mg + 5 mg (= 1 %) overage.* (*Use the asterisk to indicate the justification for the overage.)

   The reason for the overage should be indicated/justified, for example, with reference to batch results, in section 3.2.P.2.2.2 of module 3.

8. If a potency adjustment for the API has to be made, a statement to the effect that the actual quantity of the API will depend on the potency and the IPI(s) that will be used to adjust the bulk quantity should be made. The manner in which the adjustment will be made should also be specified.

   If the moisture content or other characteristic of an IPI is relevant to the quantity of the IPI used in the formulation, this should be mentioned in a footnote.

9. Permitted flavoring and coloring agents (that comply with directives of the European Union [EU] or the register of the US Food and Drug Administration [USFDA]), in many instances because of their complexity, may be described in terms of their main constituents only, provided that a conclusive identification is given in the relevant section.

   The Color Index Numbers or the colorant reference number, in accordance with the EU or USFDA directive on colorants, should be included in the formulation.

   The use of dyes, printing ink, coating materials, flavorants, and organic solvents is subject to the same safety and quality requirements that apply to medicinal substances.

10. The content of alcohol, if included in medicines for oral administration, should comply with the requirements of the Alcohol Content of Medicines guideline (EMA or USFDA guidelines).

11. If a vehicle is added up to the required volume or mass of the product, the actual or estimated quantity of that vehicle may be indicated. Expressions such as “add up to” and “q.s.” are acceptable. Solutions added to adjust the pH should be described in terms of composition and strength (e.g., normality, molarity), but it is not necessary to state the actual quantity added as none or only minute quantities may be required.

12. In the case of capsules, the fill mass as well as the capsule size, composition, and mass should be indicated.

13. The theoretical mass should be indicated for uncoated tablets. In the case of coated dosage forms, the theoretical mass of the core, coating material, as well as the total mass of the dosage form/unit should be indicated and the IPIs used for each should be grouped separately.

14. For biological medicines, the details of any solution supplied by the manufacturer for the reconstitution before use of a dried biological medicine that is offered for sale in a dried form should be supplied.

15. Toxicity levels per dosage unit should be indicated for all solvents and for other ingredients when required by the DGDA. Levels should be indicated as per the most recent edition of The Complete Drug Reference by United States Pharmacopoeia or other related document.

3.2.P.2 Pharmaceutical Development (Name, Dosage Form)

A pharmaceutical development report (generally of not more than 25 pages on A4 paper) should be submitted with each application. It should include at least an overall conclusion and the following information:

3.2.P.2.1 Components of the Pharmaceutical Product (Name, Dosage Form)

3.2.P.2.1.1 Active Pharmaceutical Substance(s) (Name, Dosage Form)

- Comment on the synthesis of the API(s).
- Discussion of all the physicochemical properties, for example, solubility (in terms of BCS classification), water content, particle size distribution, crystal properties, polymorphs, chirality, isomers, and stability of the API that can influence the performance of the final product.
- The compatibility of the API with excipients listed in section 3.2.P.1 should be discussed.
- Provide studies (literature) on the proposed excipients. If the excipients are the same as those of the reference product, this information is not required.
- In the case of fixed-dose combination (FDC) products, extensive studies on API-API compatibility under various conditions (aqueous medium and solid state) should be provided. For well-established combinations, literature information may suffice, if available. In general, the pharmaceutical development and quality aspects of FDC products should be in accordance with the WHO Technical Report Series No. 929, "Guidelines for Registration of Fixed-dose Combination Medicinal Products" (2005)[9] or the most recent revision.

3.2.P.2.1.2 Inactive Pharmaceutical Ingredients or Excipients (Name, Dosage Form)

- Submit an explanation of the function of the excipients.
- For multisource products, state whether excipients are the same as in the reference product.
- Non-compendial excipients should be avoided in generic products. Safety/toxicity profile of the excipients should be submitted if it is non-compendial.
- All the excipients used during the development should be clearly listed in tabulated form (see the sample table below).

[9] http://apps.who.int/medicinedocs/en/d/Js19979en/.

List of Excipients Used

Inactive Ingredient Name(s)	Dosage Strength	Dosage Unit	Pharmacopoeia Reference	Maximum Potency Allowed

3.2.P.2.2 Final Pharmaceutical Product (Name, Dosage Form)

3.2.P.2.2.1 Formulation Development (Name, Dosage Form)

- Data or literature (including the qualitative composition of the innovator product) on any interactions likely to occur, or that may occur, under given circumstances between the API and excipients should be provided.
- For multisource products, include a tabulated comparison of the qualitative composition, appearance, physical parameters, impurity profiles, and other relevant parameters of the test and reference/innovator products.
- Discussion of the relevant physicochemical parameters (e.g., dissolution and choice of medium, effect of pH) should be provided. The dissolution conditions and acceptance criteria should be derived from the multipoint comparative data generated for the batch used in the bioequivalence/biowaiver studies.
- Provide information on tablet “scoring,”, if applicable

    - Functional scoring:

        - Provide data from a study on the uniformity of dosage units of the tablet halves in terms of United States Pharmacopoeia (USP) or European Pharmacopoeia (Ph Eur)/British Pharmacopoeia (BP) recommendations. The data generated should support and be in line with the dosage and directions outlined in the PI/PIL.

    - Non-functional scoring:

        - This should be explained/justified. It should be indicated as non-functional in the PI/PIL.

- Pre-formulation testing
- Clinical trial formulations
- Discussion or explanation of novel formulations and novel IPI composition, function, and safety

- Any differences in the formulation during the development should be indicated clearly in tabulated form
- Stability (may refer to section 3.2.P.8)
- Discussion of the stability of the final product formulation, the parameters and specifications used during stability, and to confirm quality for lot release
- Conclusion on stability and shelf-life allocation

3.2.P.2.2.2 Overages (Name, Dosage Form)

Provide the following information:

- A justification/explanation for overages.
- Overages for the sole purpose of extending the shelf-life of the FPP are generally not acceptable, unless justified.

3.2.P.2.2.3 Physicochemical and Biological Properties (Name, Dosage Form)

- Parameters relevant to the performance of the final product, such as pH, ionic strength, dissolution, redispersion, reconstitution, particle size distribution, aggregation, polymorphism, rheological properties, biological activity or potency, and/or immunological activity, should be addressed.
- Show that no precipitation will occur with poorly soluble APIs formulated at a non-physiological pH or formulated with co-solvents.

3.2.P.2.3 Manufacturing Process Development (Name, Dosage Form)

The selection and optimization of the manufacturing process described in 3.2.P.3.3, the critical aspects, in particular, should be explained. Where relevant, the method of sterilization should be explained and justified, and compatibility with production equipment (e.g., filter media).

Differences between the manufacturing process(es) used to produce pivotal clinical batches and the process described in 3.2.P.3.3 that can influence the performance of the product should be discussed.

3.2.P.2.4 Container Closure System (Name, Dosage Form)

The suitability of the container closure system described in 3.2.P.7 used for storage, transportation (shipping), and use of the final product should be discussed. This discussion should consider, for example, choice of materials; protection from moisture and light; compatibility of the construction materials with the dosage form (including sorption to container and leaching, injections with rubber closures); safety of construction materials; and performance, such as reproducibility of the dose

delivery from the device when presented as part of the FPP product (e.g., inhalers/aerosols).

3.2.P.2.5 Microbiological Attributes (Name, Dosage Form)

Where appropriate, the microbiological attributes of the dosage form should be discussed, including, for example: the rationale for not performing microbial limit testing for non-sterile products, and the selection and effectiveness of preservative systems in products containing antimicrobial preservatives. This should be determined on at least one stability batch (aging).

For sterile products, the integrity of the container closure system to prevent microbial contamination should be addressed, as well as in-use stability testing, whether there is a preservative or not, including eye drops. Also see 3.2.P.8.

3.2.P.2.6 Compatibility (Name, Dosage Form)

The compatibility of the FPP with:

- Reconstitution diluent(s)
- IV solutions: provide data or reference to primary references
- Dosage devices (e.g., precipitation of API in solution; sorption on injection administration sets; adsorption by in-line filters) should be addressed to provide appropriate and supportive information for the labeling

3.2.P.3 Manufacture (Name, Dosage Form)

3.2.P.3.1 Manufacturer(s) (Name, Dosage Form)

If more than one pharmaceutical manufacturing facility/site is involved in any of the manufacturing or packaging processes, the complete name and physical address of each site should be given, the various stages of manufacturing and packaging at each site clearly identified, and the declaration of similarity included in section 1.7.5. of module 1. If all the stages of manufacturing and packaging are performed at one site, a statement confirming this will suffice.

An inspection flow diagram, also of FPP intermediates, clearly indicating the sites and processes, including clear distinction between primary and secondary packers, should be included (section 1.7.10 of module 1).

3.2.P.3.2 Batch Formula (Name, Dosage Form)

The batch manufacturing formulation, also for FPP intermediates, and the batch size(s) (number of dosage units) should be included. If more than one batch size is indicated, the batch formulation for each of the batch sizes should be given.

3.2.P.3.3 Description of Manufacturing Process and Process Controls (Name, Dosage Form)

The following should be submitted:

- A comprehensive flow diagram, detailing the various stages of manufacturing.
- A comprehensive description of the manufacturing procedures, detailing the various stages of manufacturing, derived from the master manufacturing documents.
    - The type and size of manufacturing equipment (including sieve sizes in metric units), duration of treatment, temperature, light and humidity conditions, machine settings (e.g., rotation speed or rpm), and other relevant details should be indicated.
    - For sterile manufacturing, the grades of clean areas should also be indicated.
- A brief description of the packaging procedure:
    - A brief description of the packaging procedure reflecting the stages, temperature, humidity, and other conditions applicable for the packaging of specific dosage forms (e.g., effervescent tablets and granules) should be included.
    - For sterile manufacturing, the grades of clean areas should also be indicated.
    - The frequency of all in-process control tests (analytical, microbiological, physical, packaging, and labeling) should be shown in the flow diagram or specified in the description.
- Either a copy of the Master Batch Manufacturing and Packaging Document or Records for a batch or the Batch Records should be available for inspection, or be available on request.

3.2.P.3.4 Controls of Critical Steps and Intermediates (Name, Dosage Form)

The frequency of all in-process control tests (analytical, microbiological, physical, packaging, and labeling) should be shown in the flow diagram or specified in the description.

3.2.P.3.5 Process Validation and/or Evaluation (Name, Dosage Form)

A process validation protocol (VP) or validation report (VR) should be submitted

The validation of the maximum holding time of the final product before packaging and the holding time of FPP intermediates before further processing should also be addressed. The conditions during storage and/or shipping should be covered.

If different sterilization methods are used, validation of each method should be addressed in the VP or VR that is provided. This would include a description of the sterilization processes, aseptic manipulation, in-process controls, and grades of clean areas. Validation should include the validation of the maximum holding time before packing into the final container, and the holding time of FPP intermediates before further processing.

New Applications for Registration

A VP or a VR should be included in 3.2.P.3.5. If the VP is submitted, the VR should be submitted only if and when requested by the DGDA.

Applications for Change in Applicant/Manufacturer/Packer/Laboratory

A VP or VR should be submitted with each application for a change in manufacturer or laboratory, or a change in the applicant where it also involves a change in the manufacturer.

If the validation has already been done, it should be indicated as such in the application, and the VP and VR have to be submitted.

3.2.P.4 Control of Inactive Pharmaceutical Ingredients (Name, Dosage Form)

The approved name of each ingredient should concur with that reflected in the formulation in section 3.2.P.1.

3.2.P.4.1 Specifications (Name, Dosage Form)

Compendial and Non-Compendial

1. Specifications (titles and the limits) of all the IPIs and also the IPIs of FPP intermediates should be listed. Adherence to current pharmacopoeia requirements (BP, USP, and Ph Eur), where applicable, is recommended, in which case it is not necessary to list specifications. Any deviation from such specifications should be fully substantiated (e.g., non-inclusion of a specific impurity specification due to a different route of synthesis).

   Use of any other pharmacopoeia should be justified and acceptable to the DGDA. In the latter case, copies of the relevant monographs should be included.

   More than one pharmacopoeia may be used for the IPIs provided that each individual reference is used fully and not partially or selectively. For example:

   - The USP may be used for starch and the BP for lactose
   - An individual IPI may be referenced fully in two or more recognized pharmacopoeia simultaneously
   - An in-house specification consisting of all parameters and that includes the most stringent criteria of acceptance of two or more recognized pharmacopoeia

   For non-pharmacopoeia entities, the specifications should be at the pharmacopoeia level, i.e., based on current pharmacopoeia requirements for similar pharmacopoeia entities. (See ICH Q6A.)

2. Functionality specifications that confirm the IPI characteristics should be indicated.

3. Colorants and flavorants should comply with either one of the following:

   - At least a specification and control procedure regarding the chemical identification, a statement that the flavorants comply with the general requirements, and that the colorants comply with the purity criteria. At least a specification and control procedure regarding chemical identification and a statement that it complies with the directives of the EU or the register of the USFDA.

4. Microbial limits and control procedures for all organic ingredients of natural origin should be included (e.g., maize starch is an organic IPI of natural origin [test], but selenium dioxide is an inorganic IPI of natural origin [no test]).

5. Empty capsule specifications should include the description, moisture content, disintegration time, and microbial limits.

6. The absence of diethylene glycol should be specified for propylene glycol and glycerine if the dosage form is for oral or parenteral administration.

7. Specifications and control procedures should be included for intermediate preparations used as ingredients in the formulation as well as for each of the ingredients contained in the intermediate preparation. If stock preparations of the intermediate preparation are used, specification and control procedures to ensure the stability and confirm the identity should be included.

8. For biological medicines:

    a) Specifications for the primary production lot used in the manufacture of the final filling lot of a biological medicine and specifications for all ingredients for the diluent should be listed.
    b) Tests for a biological source material should include tests to confirm the identification, safety, and potency of the primary production or bulk lot used in the manufacture of the final filling lot.
    c) Parameters and criteria of acceptance to confirm the identification, safety, and potency of the product should be provided.

3.2.P.4.2 Analytical Procedures (Name, Dosage Form)

Control procedures for all IPIs should be fully described. These should include physicochemical tests, purity tests, solubility and assay, and any other relevant tests. When pharmacopoeia methods are used, they should be current and may be referred to.

3.2.P.4.3 Validation of analytical procedures (Name, Dosage Form)

Analytical validation information, including experimental data, for the analytical procedures used for testing the excipients should be provided, where appropriate. (Refer to ICH Guidelines Q2R1, Q6B.[10])

3.2.P.4.4 Justification for Specifications (Name, Dosage Form)

Justification for the proposed excipient specification should be provided, where appropriate. (Refer ICH Guidelines Q3C and Q6B.[10])

[10] http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html.

3.2.P.4.5 Excipients of Human or Animal Origin (Name, Dosage Form)

Refer to section 3.2.A.3 and ICH M4Q.

3.2.P.4.6 Novel Excipients (Name, Dosage Form)

For excipients(s) used for the first time in a FPP or by a new route of administration, full details of manufacture, characterization, and controls, with cross-references to supporting safety data (nonclinical and/or clinical) should be provided according to the API format. (Details may be found in section 3.2.A.3.)

3.2.P.5 Control of Pharmaceutical Product (Name, Dosage Form)

3.2.P.5.1 Specification(s) (Name, Dosage Form)

1. Specifications (titles and limits) should be listed for in-process controls, FPP intermediate controls, final product controls (batch release), stability controls, and the reconstituted or diluted final product (if applicable). (If the in-process controls are submitted in section 3.2.P.3.3 of module 3, a cross reference will suffice.) In-process controls should be clearly identified as such, including those performed on bulk (e.g., liquids and semi-solids prior to packaging).
   If a product is included in a recognized pharmacopoeia, any deviation from the relevant monograph should be justified.

2. The description of the final product and the description given under “Identification” in the package insert should correspond. The description should be such that visual identification of counterfeit medicines is facilitated, where possible.

3. If any specification is not appropriate for a particular product, an explanation should be included. Other parameters not appropriate for stability testing should also be included (e.g., a specification for residual organic solvents used during the coating procedure or sterility).

   The limits and acceptance criteria for each parameter (physical, chemical, and microbial, if applicable) should be fully described. To state "complies" for acceptance criteria is not acceptable.

Physical and Other Properties

4. At least the following physical and other properties additional to those listed in the Stability Guideline, should be specified, as appropriate, for the dosage form, unless the omission is justified:

a) Tablets, lozenges, capsules, suppositories

Theoretical mass, average mass and mass limits, uniformity of dosage units, divisibility of scored tablet with the relevant mass uniformity of the divided tablet.

Intactness of coating, in the case of coated tablets, if the coating has a protective purpose. If not appropriate for a particular product (e.g., film coat), an explanation should be included.

Microbial testing, as lot release requirement for capsules, is not a requirement if microbial testing of the empty capsules is performed and submitted in section 3.2.P.4 of module 3.

For soft gelatin capsules containing oily liquid, peroxide value/acid value/iodine value and any other appropriate parameter, suspension content uniformity of each should be provided.

b) Emulsions, suspensions, solutions:

Alcohol content, tonicity (eye and nasal preparations), fill volume or mass, deliverable volume. Peroxide value/acid value/iodine value and any other appropriate parameter for oily preparations should be included.

c) Powders, granules (including those for reconstitution), metered dose inhalation aerosols: Fill volume or mass.

d) Ointments, creams

Peroxide value/acid value/iodine value and any other appropriate parameter for oily preparations should be included.

e) Parenterals

Evaluation of FPP intermediates for parenterals should also include homogeneity, and FPP intermediate sterile powders should also include evaluation of sterility and bacterial endotoxin testing.

f) FPP intermediate (defined in the WHO Guideline to Good Manufacturing Practices as partially completed final product, pre-mixes, microspheres, granules, coated granules, sterile powders, etc.).

FPP intermediates should also include evaluation of homogeneity and other appropriate parameters relevant to the FPP intermediate product/dosage form.

Assay/Content

5. The limits of acceptance for the content of each active ingredient should be expressed as a percentage of the label claim. Limits greater than 5.0% of the label claim should be justified, except in the case of vitamins.

6. Uniformity of dosage units should be in accordance with the general requirements of the current editions of the official pharmacopoeia. Note that the uniformity has been harmonized in the ICH region (see ICH guideline Q4B Annex 6).[11]

   Also refer to the WHO Technical Report Series 929, "Guidelines for the Registration of Fixed-dose Combination Medicinal Products" (2005) or the most recent revision.

   FPP intermediates, including parenterals, should also be evaluated for homogeneity. (Refer to paragraph 4 above.)

Dissolution and Disintegration

7. Batch release and stability specifications for all solid oral dosage forms, including chewable tablets and suspensions, where applicable, should include a requirement for the dissolution of the API(s) (generally single point for immediate release, multipoint for modified release), unless otherwise determined by the DGDA.

8. Disintegration time, where relevant, for example, for chew tablets, matrix tablets, and soft gelatin capsules, should be determined on all batches on which dissolution is not determined as a requirement for lot release as well as for stability. Disintegration time may be used as a lot release requirement for preparations containing multivitamins and minerals, unless a dissolution requirement for a specific product is included in the USP, in which case dissolution should be done as a lot release requirement.

Preservative Efficacy

9. The preservative efficacy of relevant dosage forms and/or presentations (e.g., multi-dose vials, eye drops) should be specified in section 3.2.P.5.1 and

[11] http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q4B/Q4B_Annex_6_Step_4.pdf.

presented in section 3.2.P.8 of module 3. However, once established for the lowest limit of preservative content specification, it is not a routine batch test requirement.

Endotoxins

10. For a product from a non-biological origin that has endotoxin levels, the validation data, as required by the USP/BP/Ph Eur, should be submitted.

11. If the endotoxin levels are not determined according to the method in a recognized pharmacopoeia, the validation data should be submitted for evaluation.

3.2.P.5.2 Analytical Procedures (Name, Dosage Form)

All control procedures, other than those from a recognized pharmacopoeia, should be described in full, with calculations included, where relevant.
If an analysis is not technologically possible (e.g., complex extracts), an explanation and alternative quality criteria should be submitted.

3.2.P.5.3 Validation of Analytical Procedures (Name, Dosage Form)

1. The full validation data of the assay method of the API related to batch release should be submitted. Chromatograms confirming the separation of the API from the degradation products, if relevant, should be included.

2. It should be demonstrated that the assay method is stability-indicating, i.e., it should distinguish between the API(s) and the degradation product(s).

3. If the assay method used to determine the API content is not stability-indicating, it cannot be used for assaying after importation.

4. If the assay method (chromatographic) is taken from one of the latest recognized pharmacopoeias, other partial validation data (e.g., system suitability and specificity) should be submitted.

5. If an assay method different from the batch release method is used for stability testing, the validation of the assay method and a full description thereof should be submitted.

6. Supportive chromatograms for the validation should be submitted, if relevant.

7. All other quantitative assay methods (e.g., preservatives, degradation products, antioxidants, dissolution assay) should be validated and the validation data included.

   If not in accordance with the relevant pharmacopoeia, an explanation should be included for the deviation. All relevant limits should also be justified by stability or batch data.

3.2.P.5.4 Batch Analyses (Name, Dosage Form)

1. Complete batch analysis data for at least two batches (pilot or production) of the final product should be submitted with the application.

2. For imported products, at least the identification and assay of the API content should be performed by an approved laboratory (Finished Product Release Control [FPRC]) after importation. This is to verify that the product has not been affected adversely during transport.

3.2.P.5.5 Characterization of Impurities (Name, Dosage Form)

Information on the characterization of impurities should be provided, if not previously provided in section 3.2.S.3.2 (Impurities) (Refer to ICH Guidelines Q3B, Q5C, Q6A, Q6B.[10])

3.2.P.5.6 Justification for Specifications (Name, Dosage Form)

Justification for the proposed final product specifications should be provided. (Refer to ICH Guidelines Q3B, Q6A and Q6B.[10])

3.2.P.6 Reference Standards or Materials (Name, Dosage Form)

For NCEs and well-known non-compendial APIs, at least the following information on the primary reference standard should be provided:

- Purification method, if applicable
- Establishment of purity (potency)
- CoA, with a potency statement

If a pharmacopoeia monograph is claimed, the pharmacopoeia standard should be used.

Secondary standards should always be established against the pharmacopoeia/primary standard. For more details, refer to WHO Technical Report Series 943, Annex 3 (2007).[12]

3.2.P.7 Container Closure System (Name, Dosage Form)

1. The immediate container specifications (titles and limits), including the nature of the material, dimensions, and sketches, where applicable, as well as those of patient ready packs, the closure system, wadding, and any other component in direct contact with the product, where applicable, and a description of the control procedures, should be supplied.

   They should include:

   - The moisture and gas permeability of polyvinyl chloride (PVC), if not already supported by real time stability data of the product (not relevant for PVC forming a base layer of aluminum blisters)
   - Heat seal bond strength/intactness of the blister (integrity of the seal) – section 3.2.P.3.3 may be referred to for further details.

2. A description of the control procedures performed by the manufacturer of the final product should be given.

3. A brief description of the outer container, if any, should also be given. At least the nature of the material should be mentioned (e.g., outer cardboard carton).

4. The description of the container and that reflected in the package insert under "Presentation" and in the stability studies should correspond. To facilitate the visual identification of counterfeit medicines (also by the public), the description should include the type, color, and clarity of the container (e.g., clear plastic/silver aluminum blister).

5. If the product is packed in bulk containers, the type of material of the container should be described.

   The maximum period that the product may be stored (bulk) before final packaging should be given in section 3.2.P.3.3 of module 3. The nature of the container should be given in section 3.2.P.7 of module 3, with supporting data provided in section 3.2.P.8 of module 3.

[12] http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf.

6. The type of material and the dimensions, including sketches of ampoules, vials, aerosols, applicators, and administration sets should be given. Sketches of containers for oral dosage forms and blister packs are not required.

7. All pack sizes should be described in the submission.

8. If equivalent or more protective immediate container packaging material than that used in stability testing or approved (post-registration), is applied for, data to substantiate the claim should be submitted (e.g., USP permeation test).

9. Child-protective measures should be employed with regard to the retail sale of salicylates, paracetamol, and iron tablets or capsules. Smaller sales packs and blister packaging are regarded as suitable child protective measures.

3.2.P.8 Stability (Name, Dosage Form)

3.2.P.8.1 Stability Summary and Conclusion (Name, Dosage Form)

A tabulated summary of the data, clearly indicating the number and types /sizes (production, pilot, or experimental) of batches, packaging material, storage conditions and storage period, and manufacturer of the API with API batch numbers, should be included for each final product manufacturer.

3.2.P.8.2 Post-Approval Stability Protocol and Stability Commitment (Name, Dosage Form)

The post-approval stability protocol and stability commitment should be provided. Refer to ICH guidelines Q1A and Q5C.

3.2.P.8.3 Stability Data (Name, Dosage Form)

All applications for registration of a medicine should be submitted with stability data, in accordance with the minimum requirements given in the Stability guideline.

3.2.A Appendices

3.2.A.1 Facilities and Equipment (Name, Manufacturer)

For Biotech

A diagram should be provided illustrating the manufacturing flow, including movement of raw materials, personnel, waste, and intermediates in and out of the manufacturing areas. Information should be presented with respect to adjacent areas or rooms that may be of concern for maintaining integrity of the product.

Information on all developmental or approved products manufactured or manipulated in the same areas as the applicant's product should be included.

A summary description of product-contact equipment and its use (dedicated or multi-use) should be provided. Information on preparation, cleaning, sterilization, and storage of specified equipment and materials should be included, as appropriate.

Information should be included on procedures (e.g., cleaning and production scheduling) and design features of the facility (e.g., area classifications) to prevent contamination or cross-contamination of areas and equipment where operations for the preparation of cell banks and product manufacturing are performed.

3.2.A.2 Adventitious Agents Safety Evaluation (Name, Dosage Form, Manufacturer)

Information assessing the risk of potential contamination with adventitious agents should be provided in this section.

For Non-Viral Adventitious Agents

Detailed information should be provided on the avoidance and control of nonviral adventitious agents (e.g., transmissible spongiform encephalopathy agents, bacteria, mycoplasma, fungi). This information may include, for example, certification and/or testing of raw materials and excipients and control of the production process, as appropriate for the material, process, and agent.

Reference: ICH guidelines Q5A, Q5D, and Q6B.

For Viral Adventitious Agents

Detailed information from viral safety evaluation studies should be provided in this section.

Viral evaluation studies should demonstrate that the materials used in production are considered safe, and that the approaches used to test, evaluate, and eliminate the potential risks during manufacturing are suitable. The applicant should refer to ICH guidelines Q5A, Q5D, and Q6B for more details.

Information essential to evaluate the virological safety of materials of animal or human origin (e.g., biological fluids, tissue, organ, cell lines) should be provided. (See related information in sections 3.2.S.2.3, and 3.2.P.4.5.) For cell lines, information on the selection, testing, and safety assessment for potential viral

contamination of the cells and viral qualification of cell banks should also be provided. (See related information in section 3.2.S.2.3.)

The selection of virological tests that are conducted during manufacturing (e.g., cell substrate, unprocessed bulk, or postviral clearance testing) should be justified. The type of test, sensitivity and specificity of the test, if applicable, and frequency of testing should be included. Test results to confirm, at an appropriate stage of manufacture, that the product is free from viral contamination should be provided. (See related information in sections 3.2.S.2.4 and 3.2.P.3.4.) In accordance with ICH guidelines Q5A and Q6B, results for viral testing of unprocessed bulk should be included.

In accordance with ICH guideline Q5A, the rationale and action plan for assessing viral clearance and the results and evaluation of the viral clearance studies should be provided. Data may include those that demonstrate the validity of the scaled-down model compared to the commercial scale process, the adequacy of viral inactivation or removal procedures for manufacturing equipment and materials, and manufacturing steps that are capable of removing or inactivating viruses. (See related information in sections 3.2.S.2.5 and 3.2.P.3.5.) For details, refer to the ICH guidelines Q5A, Q5D, and Q6B.

3.2.A.3 Novel Excipients

For excipients(s) used for the first time in a FPP or by new route of administration, full details of manufacture, characterization and controls, with cross-references to supporting safety data (nonclinical and/or clinical) should be provided according to the API format.

3.2.R Regional Information

Any additional medicinal substance and/or medicine product information specific to each region, e.g., in Asia, should be provided in section R of the application. Applicants should consult the appropriate regional guidance and/or regulatory authorities for additional guidance.

MODULE 3.3 LITERATURE REFERENCES

Key literature referenced should be provided, if applicable.

REFERENCES

1. Department of Health, Republic of South Africa, Medicines Control Council. Pharmaceutical and Analytical CTD/eCTD. http://www.mccza.com/documents/1d9c57df2.01_General_information_Jul12_v8_showing_changes.pdfPublished June 2010.
2. International Conference on Harmonization. Quality Guidelines. http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html.
3. USFDA. International Conference on Harmonization – Quality. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm065005.htm.
4. European Medicines Agency. ICH: Topic M 4 Common Technical Document for the Registration of Pharmaceuticals for Human Use – Organization CTD. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002721.pdf. Effective February 2004.
5. WHO Technical Report Series 937. WHO Expert Committee on Specifications for Pharmaceutical Preparations. http://apps.who.int/iris/bitstream/10665/43443/1/WHO_TRS_937_eng.pdf. Published 2006.
6. WHO Technical Report Series 929. WHO Expert Committee on Specifications for Pharmaceutical Preparations. http://apps.who.int/prequal/info_general/documents/trs929/who_trs_929.pdf. Published 2005.
7. Technical Report Series: biological products: general recommendations. http://www.who.int/biologicals/publications/trs/areas/biological_products/en/. Published 2009.

添付資料 3

医薬品登録等の手数料に関する規制当局

（DGDA）の通達文書

（ベンガル語の仮英訳）

添付資料 3：医薬品登録等の手数料に関する規制当局の通達文書（ベンガル語の仮英訳）

Government of the People's Republic of Bangladesh
Ministry of Health and Family Welfare
Public Health-1 Unit

No-publichealth-1/drug-6/2007 (part)/ Date: 16-05-2013

Circular

In favor of DGDA 1-2715-0000-1863 Code, in order to determine/ re-determine tax rate on non taxable revenue items (new drug production license fee, drug production license renewal fee, sample Analyzing Fee, position/ post renewal fee, recipe evaluation fee including other fees), the following fees are revised/ re-fixed by the approval of Heath Ministry.

No	*Name of Fee*	Applicable particulars	Current Fee (Taka)	Redetermined Fee (Taka)
1	***2***	**3**	**4**	**5**
01	*New drug production license fee*	(a) Allopathic		
		1. Biological	7,500/- (1-30 posts) 15,000/- (31 & more)	1,00,000/-
		2. Non-biological	3,550/- (1-30 posts) 7,500/- (31 & more)	50,000/-
		(b) Unani, Ayurvedic, Homeopathic, Biochemic & Herbal	1,500/-	10,000/-
02	*Drug production license renewal fee (2 years interval)*	(a) Allopathic		
		1. Biological	7,500/-	30,000/-
		2. Non-biological	3,250/-	15,000/-
		(b) Unani, Ayurvedic, Homeopathic, Biochemic & Herbal	1,300/-	5,000/-
03	*Sample analyzing fee*	(a) Allopathic		
		1. BP/ under USP	1,500/-	5,000/-
		2. INN/ others	7,500/-	15,000/-
		(b) Unani, Ayurvedic, Homeopathic, Biochemic & Herbal	450/-	500/-
04	*Position renewal fee (5 years interval)*	(a) Allopathic	7,500/-	10,000/-
		(b) Unani, Ayurvedic, Homeopathic, Biochemic & Herbal	650/-	1,000/-
05	*Recipe evaluation fee*	(a) Allopathic	1,500/-	5,000/-
		(b) Unani, Ayurvedic, Homeopathic, Biochemic & Herbal	450/-	500/-
06	*Recipe re-evaluation fee*	(a) Allopathic		5,000/-
		(b) Unani, Ayurvedic,		1,000/-

添付資料 3：医薬品登録等の手数料に関する規制当局の通達文書（ベンガル語の仮英訳）

No	*Name of Fee*	Applicable particulars	Current Fee (Taka)	Redetermined Fee (Taka)
		Homeopathic, Biochemic & Herbal		
07	*New position inclusion fee*	(a) Allopathic	7,500/-	10,000/-
		(b) Unani, Ayurvedic, Homeopathic, Biochemic & Herbal	750/-	2,000/-
08	*Production license-Ownership changing fee (applicable for both Pvt. Owner & Ltd. company)*	(a) Allopathic		
		1. Biological	30,000/-	2,00,000/-
		2. Non-biological	15,000/-	1,00,000/-
		(b) Unani, Ayurvedic, Homeopathic, Biochemic & Herbal	3,000/-	50,000/-
09	*New retail drug license fee (Allopathic)*	(a) Inside Municipality	1,500/-	2,500/-
		(b) Outside Municipality	750/-	1,500/-
10	*New retail drug license fee (Unani, Ayurvedic, Homeopathic, Biochemical & Herbal)*	(a) Inside Municipality	1,500/-	2,000/-
		(b) Outside Municipality	750/-	1,000/-
11	*Retail drug license renewal fee (Allopathic)*	(a) Inside Municipality	1,300/-	1,800/-
		(b) Outside Municipality	650/-	700/-
12	*Retail drug license renewal fee (Unani, Ayurvedic, Homeopathic, Biochemic & Herbal)*	(a) Inside Municipality	1,300/-	1,500/-
		(b) Outside Municipality	650/-	700/-
13	*All kinds of new wholesale drug license fee*	All wholesale drug license	3,750/-	10,000/-
14	*Wholesale drug license renewal fee*		3,250/-	5,000/-
15	*Ownership changing fee for all retail drug license*	(a) Inside Municipality	3,000/-	3,000/-
		(b) Outside Municipality	1,500/-	1,500/-
16	*Registration fee for imported drugs*	All kinds of drugs	7,500/-	35,000/-
17	*Registration renewal fee for imported drugs*	All kinds of drugs	6,500/-	10,000/-
18	*Registration fee for source validation (3 years interval)*	Per source		8,000/-
19	*Source validation-each position inclusion/ Registration fee (3 years interval)*	Each position		1,000/-
20	*NOC fee for imported drugs*	All kinds of drugs	450/-	2,000/-
21	***Late fee***			

添付資料 3：医薬品登録等の手数料に関する規制当局の通達文書（ベンガル語の仮英訳）

No	*Name of Fee*	Applicable particulars	Current Fee (Taka)	Redetermined Fee (Taka)
	(a) For all kind of drug production license renewal	1.Late for one period/term		Equivalent to renewal fee
		2.Late for > 1 period/term		Multiple rate of renewal fee
	(b) For wholesale/ retail drug license renewal of all kinds of drugs	**1.Date of expiry from 1 month to 3 months:**		
		(a)Wholesale license		200/-
		(b)Retail license (inside of Municipality or Poura area)		100/-
		(c)Retail license (outside of Municipality)		50/-
		2. Date of expiry from 3 months above to 12 months:		
		(a)Wholesale license		500/-
		(b)Retail license (inside of Municipality or Poura area)		200/-
		(c)Retail license (outside of Municipality)		100/-
		3. Date of expiry from 12 months plus for next each year		
		(a)Wholesale license		1,000/-
		(b)Retail license (inside of Municipality or Poura area)		500/-
		(c)Retail license (outside of Municipality)		200/-
22	*All kinds of duplicate certificate*			500/-

2.This order is made for the interest of public and it will be effective from the date of order.

(Fatema Rahim Bhina)
Deputy Secretary
Phone: 9567252

No-publichealth-1/drug-6/2007 (part)/ 116 Date: 16-05-2013
Copy to for information and necessary action
1.Director General, DGDA, Motijeel C/A,
2.Deputy Secretary, DhakaNon Tax Revenue-3, Audhi Branch, Treasury & Credit management dept., Finance division, Ministry of Health.

(Fatema Rahim Bhina)

添付資料 3：医薬品登録等の手数料に関する規制当局の通達文書（ベンガル語の仮英訳）

Deputy

Secretary

Copy to for information;
1. APS to honorable Minister, Ministry of Health and Family Welfare
2. APS to honorable state Minister, Ministry of Health and Family Welfare
3. APS to honorable Secretary, Ministry of Health and Family Welfare

添付資料 4

薬局管理に関する規制当局（DGDA）の通達文書

（ベンガル語の仮英訳）

DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH
Oushad Bhavan, Mohakhali, Dhaka-1212
www.dgda.gov.bd

-:Pharmacy Management:-

1. **Drug License:**
   As per existing regulations, a valid pharmacy license which must be displayed in the appropriate place.

2. **Pharmacist:**
   a. Registered Pharmacist will run the pharmacy
   b. In absence of registered Pharmacist, no medicine will be sold and dispensed
   c. Registration Certificate of the Pharmacist should be displayed
   d. Pharmacist will be employed as per categorization (Model Pharmacy- Graduate Pharmacist and Model Medicine Shop- Any Certified Pharmacist)
   e. Notify DGDA for any changes in approved personnel (Pharmacist)

3. **Trade License:**
   As per existing regulations, a valid trade license as per license which must be displayed in the appropriate place

4. **Medicine Preservation Mechanism:**
   a. Pharmacy should have adequate air conditioner with a power back up source so that the ambient temperature does not exceed 30 degree centigrade
   b. Refrigerators used to store medicine and vaccines must be dedicated to the storage of the pharmaceuticals only
   c. Separate shelf for preserving OTC and prescription drugs
   d. Others health related products should be kept in separate shelf
   e. Status level should be included in the medicine kept shelf
   f. Unani, Ayurbedic, Herbal medicine should be kept in separate shelf

5. **Illegitimate Medicine:**
   a. Unregistered, Counterfeit, Copied and Misbranded medicine must not be kept in the pharmacy
   b. No Food Supplement will be allowed in the Pharmacy
   c. Damaged or expired medicines shall be recorded, sealed, quarantined and labeled with the statement in red ink “Expired/ Damaged Medicine – not for sale. Expired medicine must be returned to Pharmaceuticals company or destroyed within one month.
   d. Govt. provided medicine will not be allowed in the pharmacy
   e. Imported medicine should be marked DAR number and MRP and without DAR and MRP, the medicine would be treated as illegal and not kept in the pharmacy
   f. Over printing and Sticker of Pricing in the medicine pack is not acceptable

6. **Documents:**
   a. Purchasing documents should be kept
   b. Medicine sale record should be kept
   c. Sale cash memo will be provided

DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH
Oushad Bhavan, Mohakhali, Dhaka-1212
www.dgda.gov.bd

7. Dispensing and Counseling:

a. Without prescription only OTC medicine can be sold
b. The customer receives dosing instructions and drug information before he or she leaves the pharmacy
c. The customer understands and advice given regarding antibiotic full course as per prescription
d. Adverse drug reaction should notify through prescribed form

8. Pharmacy Audit:

Pharmacy Audit should be conducted at least once in week which will be recorded. Expired medicine should be removed from the shelf

9. Origin of Medicine:

Medicine should be procured from valid and legitimate source. Medicine should not be procured Unknown, floating or broker. If circumstances, should notify DGDA.

10. Unregistered Prescription:

If written unregistered medicine in the prescription, should notify DGDA with prescription

11. Corrective Inspection:

Corrective Inspection will be conducted by DGDA personnel, Chemist and Druggist Association in order to implement regulations. Any person who violates any provision of this standard shall be liable upon conviction to a warning, fine and /or imprisonment as specified under the existing acts, ordinance and rules.

Signed by Director General dated March 18, 2018

添付資料 5

医療機器の登録ガイドライン

Registration Guidelines for Medical Devices
Bangladesh
2015

Directorate General of Drug Administration
Ministry of Health and Family Welfare
Government of the People's Republic of Bangladesh

Message from DG, DGDA

It is my pleasure that the regulatory system of Medical Device in Bangladesh is standardized and harmonized by formulating and introducing this Medical Device Registration Guidelines" Registration Guidelines for Medical Device, Bangladesh 2015" which is based upon the guidelines of the Global Harmonization Task Force (GHTF). The GHTF is a voluntary group of international regulatory affairs experts for medical devices that was established to harmonize the regulation of medical devices internationally.

The Bangladesh Medical Device regulatory system has the following features:

- A classification scheme based on the level of risk
- Compliance with a set of essential principles to ensure that only safe, effectiveand quality medical devices are supplied
- Implementation of conformity assessment procedures, depending on the class ofthe medical device to demonstrate compliance with the essential principlesincluding an implemented quality management system in accordance to ISO13485:2003
- A recognition of international medical device reference standards in order todemonstrate compliance to the essential principles e.g. IEC 60601-1
- Implementation of regulatory controls for manufacturing processes
- Inclusion on the registration of Medical Devices of class B, C & D
- Implementation of post market surveillance systems, adverse incident reporting programs and vigilance activities.

Major General Md. Jahangir HossainMollik
Director General
Directorate General of Drug Administration,Bangladesh.

Members of Medical Device Registration Guidelines Committee

1. Major General Md. JahangirHossain Mollik, DG,DGDA Convener
2. Brigadier General Golam Mahiuddin Chowdhury, Member
   Adviser Specialist Dentistry, CMH, Dhaka
3. Director, National Institute of Kidney diseases &Urology Member
4. Head of the Dept. of ENT, DMCH Member
5. Head of the Dept. of Surgery, BSMMU Member
6. Prof. Dr. MahfujurRahman, Dept. of Radiology, BIRDEM Member
7. Prof. Dr. HumayunSattar, Dept. of Microbiology, BSMMU Member
8. Prof. Dr. Nazir Ahmed, National Heart Foundation Member
9. Prof. Dr. Ashrafunnesa, Dept. of Gynecology & Obs. Member
10. Prof. Dr.NiazAbdurRahman , Bangladesh Eye Hospital Member
11. Assoc.Prof.Dr.ShakeelAkhtar,dept.ofOrthopedics,UAMCH Member
12. Mr.Md. AbulKhairChowdhury, Deputy Chief, NCL Member
13. Mr. Md. GolamKibria, Director, DGDA, Member
14. Mr. Md. Ruhul Amin, Director(cc), DGDA Member
15. Ms. Nayer Sultana , DD, DGDA Member secretary

Members of Medical device Guideline Formulating working Committee:

1. Mr. Md. GolamKibria, Director, DGDA, Convener
2. Mr. Md. Ruhul Amin, Director(cc), DGDA Member
3. Ms. Nayer Sultana , DD, DGDA Member
4. Mr. Md. AltafHossain, DD, DGDA Member
5. Mr.Md. Salahuddin AD, DGDA Member Secretary

Registration Guidelines for Medical Devices , Bangladesh 2015

Preamble: Manufacturer and / or importer of medical devices are required to adhere to the regulatory controls in Bangladesh. This guideline will enable the DGDA Bangladesh and other stake holders to ensure that medical devices conforming to internationally acceptable standards of quality, safety and performance are available to the Bangladesh population.
All the relevant stake holders shall adhere to these guidelines for manufacture, import, distribution and sales of medical devices in Bangladesh.
Scope: This guideline shall be applicable to all medical devices as decided by Government of Bangladesh from time to time. The products which are already registered and are currently sold in Bangladesh market will automatically be covered and the registrations already granted will be deemed valid.
Timelines for Implementation: This guideline shall be implemented within short period of time.If an already existing manufacturer / importer, who is already manufacturing and / or importing their products into Bangladesh, submits an application for continuing of registration of these products as per this guideline, they can continue to manufacture and / or Import till such time DGDA takes a final decision on the application.

REQUIREMENTS FOR THE MANUFACTURE, IMPORT, DISTRBUTION AND SALES OF MEDICAL DEVICES IN BANGLADESH

1. General:

The manufacture, import and sale of Medical Devices, which are regulated under the Drugs Act 1940 and Drug (Control) Ordinance 1982 & Rules there under.

1.1 For the purposes of this Guideline:

'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such meansshall be deemed to be a Device under the meaning of Section (3)b (ii), (iii) and (v) of the Drugs Act 1940

Note 1: Accessories intended specifically by manufacturers to be used together with a 'parent' medical device to enable that medical device to achieve its intended purpose are subject to the same procedures as apply to the medical device itself. For example, an accessory will be classified as though it is a medical device in its own right. This may result in the accessory having a different classification than the 'parent' device. (eg. Dialysis Machine and kit)

Note 2: Components to medical devices are generally controlled through the manufacturer's quality management system and the conformity assessment procedures for the device.

Note 3: Semi-finished products, in specific processes performed by sub-contractors are to be generally controlled through the manufacturer's quality management system and the conformity assessment procedures for the device.

The products described in notes 1, 2, and 3 abovewill be regulated as per the regulation in their respective country/ies of origin.

Note 4: Products which may be considered to be medical devices in some jurisdictions but not in others**,** will be regulated as per the regulation in country of origin, include:

a. disinfection substances,
b. aids for persons with disabilities,
c. devices incorporating animal and/or human tissues,
d. devices forin-vitro fertilization or assisted reproduction technologies.

2. Definitions:

Accessory to a medical device: An article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use."

Active medical device: Any medical device, operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patients, without any significant change, are not considered to be active medical devices. Standalone software that fulfills the attributes of the definition of "medical device" above is deemed to be an active medical device. (eg. ECG Machine)

Active therapeutic device: Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap. (eg. Heart Valve)

Active device intended for diagnosis: Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or to support in treating physiological conditions, states of health, illnesses or congenital deformities. (eg. X-ray Machine, Ultrasonography Machine)

EXPLANATION FOR COMBINATION MEDICAL DEVICES: a. Where a device is intended to administer a medicinal product within the meaning of the Drugs Act relating to medicinal products for human use it shall be governed by this guideline. If, however, such a device is placed on the market in such a way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall not be governed by this guideline. The relevant essential requirements shall apply as per the internationally accepted standards, to that product as far as safety and performance related device features are concerned. (Eg : Prefilled Insulin Syringe)

b. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of the Drugs Act and which is liable to act upon the body with action ancillary to that of the device, that device shall be assessed and authorized in accordance with this guideline.(Eg : Drug Eluting Stent.)

c.Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma within the meaning of the Drugs Act and which is liable to act upon the human body with action ancillary to that of the device, hereinafter referred to as a 'human blood derivative', that device shall be assessed and authorized in accordance with this guideline.(Eg : .Cord blood coated stent)

d. This Guideline shall not apply to:

i. Medicinalproducts covered by the Drugs Act. In deciding whether a product falls under the drug category under the Drugs Act or Medical Devices under this Guideline, particular account shall be taken of the principal mode of action of the product;
ii. cosmetic products
iii. human blood, blood products, plasma or blood cells of human origin transplants or tissues or cells of human origin orto products incorporating or derived from tissues or cells of human origin,
iv. transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or human plasma.

Adverse Event: Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons, whether or not related to the medical device in Bangladesh.

NOTE 1: This definition includes events related to the investigational medical device or the comparator.

NOTE 2: This definition includes events related to the procedures involved.

NOTE 3: For users or other persons, this is restricted to events related to investigational medical devices

AuthorizedRepresentative: Anynaturalorlegalpersonestablishedwithinacountryor jurisdictionwhohasreceivedawrittenmandatefromthemanufacturertoactonhisbehalffor specifiedtaskswithregardtothelatter'sobligationsunderthatcountryorjurisdiction'slegislation.
GHTF/SG1/N055:2009

Distributor: Anynaturalorlegal person in thesupplychain who, on his own behalf, furthers the availabilityofamedicaldeviceto the end user.

Notes:

1. Morethan onedistributormaybeinvolved in thesupplychain.
2. Persons in thesupplychain involved in activities such as storageand transport on behalf ofthemanufacturer, importerordistributor, arenot distributors underthis definition. *GHTF/SG1/N055:2009*

Importer: Anynatural orlegal person in thesupplychain who is the first in asupplychain to makeamedical device,manufactured in anothercountryorjurisdiction, availablein the country orjurisdiction whereit is to bemarketed.
GHTF/SG1/N055:2009

Manufacturer: Anynatural orlegal person[1]with responsibilityfordesignand/ormanufacture ofamedical devicewiththeintention ofmakingthemedical device available foruse, underhis name; whetherornot such amedical deviceis designedand/ormanufactured bythat person himselforon his behalf byanotherperson(s). (GHTFSG1/N55:2009)
GHTF/SG3/N19:2012

([1]The term "Person" that appears here includes legal entities such a corporation, a partnership or an association.)

'Clinical data' means the safety and/or performance information that is generated from the use of a device. Clinical data are sourced from:

a. Clinical investigation(s) of the device concerned; or

b. Clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated; or

c. Published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated;

'Clinical Evaluation': The assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer.
'Clinical Evidence': The clinical data and the clinical evaluation report pertaining to a medical device.

'Clinical Investigation': Any systematic investigation or study in or one or more human subjects, undertaken to assess the safety and/or performance of a medical device.

'Clinical Performance': The ability of a medical device to achieve its intended purpose as claimed by the manufacturer.

'Clinical Safety': The absence of unacceptable clinical risks, when using the device according to the manufacturer's Instructions for Use.

'Conformity Assessment': Thesystematic examination of evidencegenerated and procedures undertaken bythemanufacturer, underrequirements established bytheNationalRegulatoryAuthority, to determinethat amedicaldeviceis safe and performs as intended bythemanufacturer
'**Conformity assessment body**': A body authorized or mandated for the systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the National Regulatory Authority, to determine that a medical device is safe and performs as intended by the manufacturer
'Custom-made device' means any device specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient.

Mass-produced devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be custom-made devices
'Device intended for clinical investigation' means any device intended for use by a duly qualified medical practitioner or by paramedical personnel when conducting investigations in an adequate human clinical environment. For the purpose of conducting clinical investigation, any other person who, by virtue of his professional qualifications, is authorized to carry out such investigation shall be accepted as equivalent to a duly qualified medical practitioner.
'Device subcategory' means a set of devices having common areas of intended use or common technology; (eg. Stents having sub-categories like bare metal stent and drug eluting stent)
'Generic device group' means a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics for the purpose of registration; (eg. Catheter)
'Intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the labeling, in the instructions and/or in promotional materials;

IN VITRO DIAGNOSTIC MEDICAL DEVICE

In Vitro Diagnostic (IVD) Medical Device:A medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.
Note 1: IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

Note 2: Products for general laboratory use are not *in vitro* diagnostic medical devices.

'Kits / System / Bundle / Procedure pack': Acollection ofmedical products, including medical devices,and otherproducts that arepackaged togethertoachieveastated intendeduse, beingdistributed asasinglemedical device. This includes procedural packs andconveniencekits.

Notified Body: A Notified Body is a third-party, accredited body which will be approved by DGDA for the purpose of verification, testing and certification of the manufacturer of medical devices in Bangladesh for the purpose of registration with DGDA.
'Quality Management System (QMS)': Management system to direct and control an organization with regard to quality.
Note: The organizational structure, responsibilities, procedures, processes and resources for implementing quality management. For the purpose of these guidelines 'implementing quality management' is taken to include both the establishment and maintenance of the system.
'Placing on the market' means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use in the market, regardless of whether it is new or fully/partly refurbished.

'Putting into service' means the stage at which a device is ready for use in the market for the first time for its intended purpose.
'Risk': Combination oftheprobabilityofoccurrenceofharm and theseverityofthat harm.

'RiskManagement': Systematic application ofmanagement policies, procedures and practices to thetasks ofanalysing,evaluating and controlling risk.

'SingleUseDevice' means themedical deviceis intended to beused on anindividual patient duringasingleprocedureand then disposed of. Itis not intended to be reprocessed and used again.

'Specimen receptacles' are considered to be *in vitro* diagnostic medical devices. 'Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

'Serious AdverseEvent': Adverseevent that:

- **a.** led to adeath;
- **b.** led to aserious deterioration in thehealth ofthesubject that either
  - i. resulted in alife-threateningillness orinjury, or
  - ii. resulted in apermanent impairment ofabodystructureorabodyfunction, or
  - iii. required in-patient hospitalization orprolongation of existinghospitalization, or
  - iv. resulted in medical orsurgical intervention to prevent lifethreateningillness or
- **c.** Lead to foetal distress, foetal death ora congenital abnormalityorbirth defect.

NOTE 1: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device.
NOTE 2: This definition includes any event resulting from use error or from intentional misuse of the investigational medical device.

3.

Classification:

Medical Devices shall be classified as per their risk level and intended use. They shall be divided into Classes A, B, C and D. Classification shall be carried out in accordance with ***Annexure 1: Classification Rules (procedures)***. In case the product does not follow the said classification, internationally accepted classification may be accepted by DGDA.

Whereas the classification rules are based on the intended use and vulnerability of the human body taking into account of the potential risks associated with the technical design and manufacture of the devices.

4. Placing on the market and putting into service:

4.1 Whereas medical devices should provide patients, users and third parties with a high level of protection and attain the performance levels attributed to them by the manufacturer; whereas, therefore, the maintenance or improvement of the level of protection attained in the country is one of the essential objectives of this Guideline.

4.2 Whereas, for the purpose of this Guideline, compliance with the essential principles of safety and performance required for a medical device, shall be presumed in presumed for those medical devices where the manufacturer relies on relevant current ISO, IEC, standard(s) or any other official standard(s) or the manufacturer's own validated standard(s).

4.3 Conformity assessment procedures shall be the responsibility of manufacturers and notified bodies for carrying out conformity assessment on the basis of the type of devices intended to be manufactured.

4.4 Whereas it is necessary, essentially for the purpose of the conformity assessment procedures, to group the devices into four product classes.

4.5 The conformity assessment procedures for Class A devices can be carried out, as a general rule, under the sole responsibility of the manufacturers in view of the low level of vulnerability associated with these products. The manufacturers are not required to obtain manufacturing license from DGDA. The manufacturer of a Class A device shall inform DGDA about compliance by way of Declaration of Conformity.

4.6 For device(s) falling under Classes B, C and Class D which constitute a medium to high risk potential, certification by a notified body with regard to QMS and in case of Class D certification for the design of the device(s) is required. The manufacturers and /or importers are required to apply for registration along with documents specified by DGDA. Based on these documents and inspection carried out, if required, the registration will be issued by DGDA.

4.7 The manufacturers who have already gone through Quality Management System (QMS) and product certification and/or marketing authorization issued by a National Regulatory Authority / Notified body outside Bangladesh need to produce those documents for DGDA's consideration of registration of the product for marketing in Bangladesh.

4.8 Any expenses incurred by an applicant for assessment and certification by the notified body shall be borne by the manufacturer only.

4.9 Wherever possible sampling of medical devices shall be carried out in accordance with the procedure laid down in Drugs Act, 1940. In case the nature of the devices is such that the above procedure cannot be adopted, DGDA may take any other measure to verify the claim of the manufacturer or importer and/or the conformity of the device with the regulatory requirements.

5. Post-Marketing Surveillance and Adverse Event (Vigilance) Reporting:

Once a Class B, C or D medical device is placed on the market in Bangladesh, the manufacturer or Importer shall adhere to requirements of post-marketing surveillance (PMS) to systematically monitor the performance of the device during use in Bangladesh. Serious Adverse events should be analyzed and reported to a designated authority in DGDA("vigilance reports"). As part of the manufacturer's Quality Management System, appropriate corrective and preventive actions may be applied to prevent or reduce the likelihood of the recurrence of adverse events. Medical device manufacturers should submit such vigilance reports within 10 working days from the date of incident being known to the manufacturer/importer.

6. Free movement, devices intended for special purposes:

6.1 Custom-made devices being placed on the market are allowed to be put into service, if they are accompanied by a statement, which shall be available to the particular patient or user identified by name, an acronym or a numerical code.

6.2 At trade fairs, exhibitions, demonstrations, etc. there shall not be any obstacle to the showing of devices which do not conform to this Guideline, provided that a visible sign clearly indicates that such devices cannot be marketed or put into service until they have been made to comply to the regulations and/or the manufacturer/importer has informed the DGDA as to the purpose of the Import. Such product imported can be re-exported back to the country of origin after its purpose (i.e. trade fairs, exhibitions, and demonstrations) has been served.

7. Reference to Standards:

7.1 Standards:

1. In order for the manufacturer/importer to demonstrate conformity with the relevant regulatory requirements, the DGDA shall adopt International Standard(s) like ISO 13485, Essential Principles of Safety and Performance of medical devices etc. in respect of the specifications to be followed for Quality Management Systems.

2. For the purposes of this Guideline, reference to harmonized standards also includes the monographs of the *US, European Pharmacopoeia wherever applicable or other established pharmacopoeia,* for surgical sutures, bandages, and combination of drugs and devices etc.

7.2 Labeling:

The packaging of medical devices shall be labeled as per relevant International / ISO standards and Global Harmonization Task Force guidance document GHTF/SG1/N70:2011.

Additionally relevant internationally accepted symbols denoting sterilization, single use etc. as per ISO 15223-1:2007shall also be depicted.

Note 1: Medical Devices shall either mention Date of manufacture or Date of Expiry or both, as the case may be on Labels.

Note 2: In case of medical devices sold in bulk packaging labeling shall be on the bulk package.

Note 3: In case of Medical Devices imported to the country, the importer can carry out further labeling of the product for conforming to the labeling rules, under quarantine, before release for sale in the market.

8. Expert Committees on Medical Devices:

Expert Committees, consisting of experts of relevant fields of the devices to be constituted by the Government and shall work as Technical Sub-committee of the Drug Control Committee.

9. Safeguard Clause:

Where DGDA ascertains that the devices,when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or, where

applicable, other persons, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service.

The DGDA shall immediately inform the manufacturer or importer of any such measures, indicating the reasons for its decision and, in particular, whether non-compliance is due to:

a. failure to meet the requirements laid down in Medical Device Guideline
b. Incorrect application of the prevailing International standards.
c. Shortcomings in standard themselves
d. Any other reason which may compromise the health of anyone.

10. Particular health monitoring measures:

Where DGDA considers in relation to a given product or group of products, that, in order to ensure protection of health and safety and/or to ensure that public health requirements are observed, such products should be withdrawn from the market, or their placing on the market and putting into service should be prohibited, restricted or subjected to particular requirements, it may take any necessary and justified transitional measures. DGDA shall then inform the, manufacturer/Importer and all other Stakeholders, giving the reasons for its decision. The DGDA shall, whenever possible, consult the interested Parties.

11. Procedure packs/Kits/Bundle:

Any manufacturer who places/combines devices for procedure packs/kits/bundles within their intended purpose and within the limits of use specified by their manufacturers, in order to place them on the Bangladesh market as a system or procedure pack, shall draw up a declaration to DGDA by which he states that:

a. he has verified the, mutual compatibility of the devices in accordance with the manufacturers' instructions and has carried out his operations in accordance with these instructions; and

b. he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers; and
c. the whole activity is subjected to appropriate methods of internal control and inspection.

d. Where the chosen combination of devices is not compatible in view of their original intended use, the system or procedure pack shall be treated as a device in its own right and subject to conformity assessment procedures appropriate to the classification of the kit (as determined through Annexure I).

12. Sale of Medical Devices

Sale of medical devices by way of wholesale and retail will be controlled as per the existing regulations of the Drugs Act and its Rules and Ordinances, as amended from time to time.

13. Clinical investigation/ Clinical Evaluation/Clinical Trial:

13.1 In the case of Class B, C and D devices which are intended for clinical investigations in Bangladesh, the manufacturer or the authorized representative of the manufacturer or Importer shall notify the DGDA before starting that investigation and follow the prevailing international accepted standard, i.e. ISO 14155 or equivalent standard.

13.2 The manufacturer or his authorized representative or sponsor shall notify the DGDA of the end of a clinical investigation carried out on Class B, C and D devices, with a justification in case of early termination.

13.3 The provisions of paragraphs 13.1 do not apply where the clinical investigations are conducted using devices which are products of Class B, C and D already authorized for marketing in Bangladesh unless the aim of these investigations is to use the devices for a purpose other than that approved earlier

14. Decision in respect of refusal or restriction:

Any decision taken pursuant to this guideline:

a. to refuse or restrict the placing on the market or the putting into service of a device or the carrying out of clinical investigations;

or

b. to withdraw devices from the market,

Shall state the exact grounds on which it is based. Such decisions shall be informed to the party concerned, who shall at the same time be informed of the remedies available to him under the Drugs Act in question and of the time limits to which such remedies are subject.

15. Confidentiality:

15.1 Without prejudice to the existing national provisions and practices on medical confidentiality, DGDA shall ensure that all the Parties involved in the application of this guideline are bound to observe confidentiality with regard to all information obtained in carrying out their tasks. This does not affect the obligation of DGDA with regard to mutual information and the dissemination of warnings, or the obligations of the persons concerned to provide information under criminal law.

15.2 The following information shall not be treated as confidential:

a. information on the registration of persons responsible for placing devices on the market in accordance with guideline;
b. information to users sent out by the manufacturer, authorized representative or distributor in relation to a measure according to guideline,
c. Information contained in certificates issued, modified, supplemented, suspended or withdrawn.

Annexures:

1. Medical Device Classification procedure
2. Procedure for Registration
3. Checklist
4. Medical Device List

Annexure-3

Application checklist for permission for Manufacture & import of Medical devices

Complete application has to fill in clear manner. If any data is not relevant and applicable,please enter N/A (not applicable) .
Annex details wherever required.

Sl. No	Details	comments	Supporting Documents
1	Name, address and communication details of the Manufacturer /Agent in Bangladesh		
2	Authorisation letter of the Authorised Agent		
3	Name address and communication details of the manufacturer		
4	Are the products already imported in Bangladesh, if so since when		
5	Name of the product, including its generic name, if any		
6	Device class and classification system followed. Attached conformity assessment certificate.		
7	Details of the Conformatory Assessment body		
8	Since how long the device is being used commercially? Has clinical evaluation and safety issues been addressed for the device?		
9	Principle use of the device		
10	Is it a drug-device combination?		
11	If the above is “yes”, is the drug a new drug		
12	Is it a kit comprising of more than one device?		
13	Sizes of the device		
14	Is Device Master File submitted		

15	Short description of the Manufacturing process		
16	Procedure for sterilization		
17	Procedure for release of the Device in the market		
18	Name and qualifications of technical personnel for manufacture and quality assurance		
19	Layout plan of the premises accompanied by the floor plan.		
20	Details of QMS and manual		
21	Is the product tested before release, if yes, submit details; if no, specify criteria for release		
22	Has the product been withdrawn due to any reasons? If yes please specify.		
23	Recall procedure to be followed in case the product has to be withdrawn		
24	Names of the countries where the device is exported.		

Annexure-2

Procedure for registration of Medical Devices for manufacture and import into Bangladesh

All Medical Devices of Class B, C and D, as per the below mentioned classification shall be registered before they are imported or manufactured into the country.

1. Application for registration of Medical devices which are already being importedor manufactured into the countryshall be made immediately from the issue of this guideline.
2. For Medical Devices which are to be imported or manufacturedfor the first time, the applicant has to apply for registration before such importor manufacture.
3. The application for registration has to be made by alocal authorized person of the manufacturer or foreign supplier or authorized agent to the DGDA.

Procedure for application.

1. Application for registration of a Medical Devices shall be made by theauthorizedperson orlocal authorized agentof the manufacturer, or foreign supplier in the prescribed form to the office of the DGDA.
2. Prescribed fees of Taka _____ shall be paid along with the application.
3. Separate application and fees are to be paid for separate applications, separate manufacturing premises and separate products. Similar type of Medical Devices if manufactured in the same premises can be applied in the same application form (Example – All Stents – Similar type, All Intra Ocular Lenses – Similar type, All Catheters – Similar type, All Orthopaedic Implants – Similar type, All Sutures – Similar type etc.). However an application shall not have more than 5 products and for more than5 products separate applications shall be made. (To consider company placing product as a manufacturer)

Details to be submitted in the application

1. Name, address, telephone number and email of the local authorised agent,
2. Authorisation letter, in original, from the manufacturer authorising the local agent to be the applicant. This will not be required if the application is made by the manufacturers own office in Bangladesh.
3. Name, address, telephone number and email id of the company/person responsible for placing the product in the market, if not the same as the manufacturer. Certified by a company's legally authorised person.
4. Details of the local manufacturer in case part processing is planned to be carried out in Bangladesh.(Exclusivity for local part manufacture and which part of manufacture considered as "Manufacturer" status)

Product Details

1. Name of the Device, including brand name and generic name, if any.
2. Device Class as per GHTF classification,
3. Device details and description,
4. Device sizes,
5. Principle use of the device,
6. Device Master File, (required only in cases where the CE/US FDA approvals are not available) should include material of construction and details of quantitative analysis, if required
7. Short description of the manufacturing process. Multi-facility manufacturing details may be given,(Brief description of manufacturing process and accompanied with flow diagram)
8. Labelling and Packaging details,
9. Details of accessories required for using the product,if applicable
10. Details of any predicate/ substantially equivalent product, if applicable,
11. Standard of the product,(Prevailing International standards like ISO(International Organization for Standardization)/ASTM(American Society for Testing and Materials)/IEC(International Electrotechnical Commission)/AAMI(Association for Advancement of Medical Instrumentation)
12. Device user's manual /Direction for use , e labeling if any (Example : e Instruction For Use) (IFU),)

Marketing and Regulatory details

1. Regulatory status in the country of manufacture and in other developed economies : (a) For class B Devices, FSC from country of origin,

(b) For class C and D Medical Devices , FSC from any one of the countries – EU, USA, Canada,Australia and Japan and FSC from country of origin.

(c) Conformityassessment certificate or equivalent certificate has to be submitted.

2. List of countries where the device is marketed,
3. Details regarding any withdrawal / market recall initiated by the regulatory authority fromthe market for any reasons in the last two years,

Combination devices

1. The medical benefits of Drug-device combination products should be described in detail.

2. Drugs which are incorporated with the device and have action ancillary to device, data on the drug's safety has to be given,

3. Clinical trial data of devices containing new drugs have to be submitted. (Refer New Drug definition under Drug Act and Rules Bangladesh and make amendment if necessary)

Sales and post marketing process details :

1. Sales, Service and Distribution model details of the product, (Example : Direct marketing/ Channel partners; Service support etc), procedure by applicant/ manufacturer
2. Post Marketing : Adverse report handling, Field Action , product recalls including re-export of the product and complaint management procedure by applicant/ manufacturer

1. Introduction:

The purpose of this document is to provide for the classification of Medical Devices and IVDs. Its purpose is to assist manufacturer & importer to allocate its medical device to an appropriate risk class using a set of harmonized principles.

2. Definitions:

2.1 Duration of use:

Transient: Normally intended for continuous use for less than 60 minutes.

Short term: Normally intended for continuous use for between 60 minutes and 30 days.

Long term: Normally intended for continuous use for more than 30 days

NOTE: For the purpose of this document, continuous use means:

a) The entire duration of use of the device without regard to temporary interruption of use during a procedure or, temporary removal for purposes such as cleaning or disinfection of the device.

b) The accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.

2.2 Invasive devices:

Invasive device: A device, which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body,

Body orifice: Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy.

Surgically invasive device: An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

NOTE*: Devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, should be treated as surgically invasive devices.*

2.3. Reusable surgical instrument: Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or other surgical procedures, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures for cleaning and/or sterilization have been carried out.

3. Proposed General Classification System for Medical Devices:

Regulatory controls are intended to safeguard the health and safety of patients, users and other persons by ensuring that manufacturers of medical devices follow specified procedures during design, manufacture and marketing.

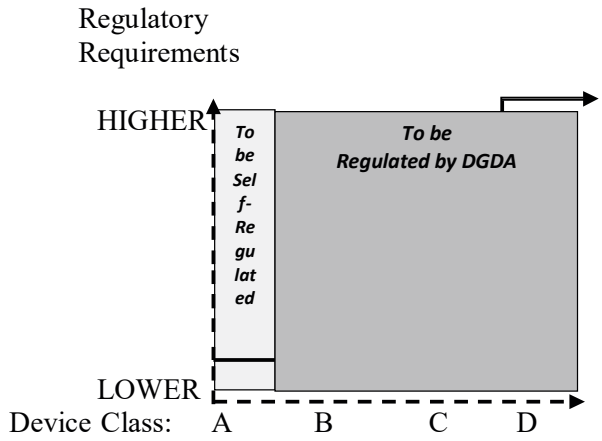
Regulatory controls should be proportional to the level of risk associated with a medical device. In general, the classification rules are intended to accommodate new technologies.

Figure 1 indicates the four risk classes of devices. The examples given are for illustration only and the manufacturer must apply the classification rules to each medical device according to its intended purpose.

Figure 1: Proposed general classification system for medical devices

CLASS	RISK LEVEL	DEVICE EXAMPLES
A	Low Risk	Surgical retractors / tongue depressors
B	Low-moderate Risk	Hypodermic Needles / suction equipment
C	Moderate-high Risk	Lung ventilator / bone fixation plate
D	High Risk	Heart valves / implantable defibrillator

Figure 2: Conceptual illustration of regulatory controls increasing with device risk class



4. Determination of Device Class using this Rules-based System:

The manufacturer should:

1. Decide if the product concerned is a medical device, using the appropriate definition.

   NOTE: Medical devices that are used for the *in vitro* examination of specimens derived from the human body are not covered by the classification rules within this document.

2. Document the intended use of the medical device.

3. Take into consideration all the rules that follow in order to establish the proper classification for the device, noting that **where a medical device has features that place it into more than one class, classification and conformity assessment should be based on the highest class indicated.**

NOTES:

1. Once a rules-based system has been adopted, modifications **may occasionally be required**. For example, where through post-market experience, a level of risk for a type of medical device, classified using the criteria found in this guidance document is no longer appropriate, consideration should be given to re-classification of the device type by a change to the rules.

2. Similarly, the historical knowledge of a device may necessitate a different class than the one assigned by the initial classification. Unlike the principle of reclassification after post-market experience with a device, this principle of historical knowledge should be applied immediately when the initial classification yields an inappropriate result.

3. Where special national rules are applied, resulting in a device class other than that suggested by the present rules, then a different conformity assessment procedure may be indicated. This may have an effect on the acceptability of such devices for free movement in countries where these present rules have been adopted unless other, or additional, conformity assessment procedures are carried out.

2. Classification Rules:

The actual classification of each device depends on the claims made by the manufacturer and on its intended use. While the provision of illustrative examples in the table that follows is helpful when interpreting the purpose of each rule, it must be emphasized that the actual classification of a particular device must be considered individually, taking account of its design and intended use.

Rule	Illustrative examples of devices that may conform with a rule
Non-Invasive Devices	
Rule 1. All non-invasive devices which come into contact with injured skin: - are in Class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates only, i.e. they heal by primary intent; - are in Class B if they are intended to be used principally with wounds which have breached the dermis, including devices principally intended to manage the microenvironment of a wound. **unless** they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, in which case they are in Class C.	Devices covered by this rule are extremely claim sensitive. Examples: simple wound dressings; cotton wool. Examples: non-medicated impregnated gauze dressings. Devices used to treat wounds where the subcutaneous tissue is as least partially exposed and the edges of the wound are not sufficiently close to be pulled together. To close the wound, new tissue must be formed within the wound prior to external closure. The device manufacturer claims that they promote healing through physical methods other than 'primary intent'. Examples: dressings for chronic ulcerated wounds; dressings for severe burns.

Rule 2(i). All non-invasive devices intended for channeling or storing • liquids, or • gases for the purpose of eventual infusion, administration or introduction into the body are in Class A,	Such devices are 'indirectly invasive' in that they channel or store liquids that will eventually be delivered into the body. Examples: administration sets for gravity infusion; syringes without needles.
unless they may be connected to an active medical device in Class B or a higher class, in which case they are Class B;	Examples: syringes and administration sets for infusion pumps; anesthesia breathing circuits. **NOTE**: "Connection" to an active device covers those circumstances where the safety and performance of the active device is influenced by the non-active device and vice versa.
Rule 2(ii). All non-invasive devices intended to be used for channeling blood, or storing or channeling other body liquids, or storing organs, parts of organs or body tissues, for the purpose of eventual infusion, administration or introduction into the body are Class B.	Examples: tubes used for blood transfusion, organ storage containers.
unless they are blood bags, in which case they are Class C.	Examples: Blood bags that do not incorporate an anti-coagulant. **NOTE**: In some jurisdictions, blood bags have a special rule that places them within a different class.
Rule 3. All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids, or other liquids, intended for infusion into the body are in Class C,	Such devices are 'indirectly invasive' in that they treat or modify substances that will eventually be delivered into the body. They are normally used in conjunction with an active device within the scope of either Rule 9 or 11. Examples: haemodializers; devices to remove white blood cells from whole blood.

	NOTE: For the purpose of this part of the rule, 'modification' does not include simple, mechanical filtration or centrifuging which are covered below.
unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class B.	Examples: devices to remove carbon dioxide; particulate filters in an extra-corporeal circulation system.
Rule 4. All other non-invasive devices are in Class A.	These devices either do not touch the patient or contact intact skin only. Examples: urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds.
Rule	**Illustrative examples of devices that may conform with a rule**
Non-Invasive Devices	
Rule 5. All invasive devices with respect to body orifices (other than those which are surgically invasive) and which: • are not intended for connection to an active medical device, or • are intended for connection to a Class A medical device only.	Such devices are invasive in body orifices and are not surgically invasive (refer to definition in Section 4). Devices tend to be diagnostic and therapeutic instruments used in ENT, ophthalmology, dentistry, proctology, urology and gynecology. Classification depends on the duration of use and the sensitivity (or vulnerability) of the orifice to such invasion.
- are in Class A if they are intended for transient use;	Examples: examination gloves; enema devices.
- are in Class B if they are intended for short-term use;	Examples: urinary catheters, tracheal tubes.
unless they are intended for short-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class A,	Examples: dressings for nose bleeds.
- are in Class C if they are intended for long-term use;	Example: urethral stent; contact lenses for long-term continuous use (for this device, removal of the lens for cleaning is considered as part of the continuous use).
unless they are intended for long-	

term use in the oral cavity as far as the pharynx, in an ear canal up to the ear-drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class B.	Examples: orthodontic materials, removable dental prosthesis.
All invasive devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to an active medical device in Class B or a higher class, are in Class B.	Examples: tracheal tubes connected to a ventilator; suction catheters for stomach drainage; dental aspirator tips. NOTE: Independent of the time for which they are invasive.
Rule 6. All surgically invasive devices intended for transient use are in Class B,	A majority of such devices fall into several major groups: those that create a conduit through the skin (e.g. syringe needles; lancets), surgical instruments (e.g. single-use scalpels; surgical staplers; single-use aortic punch); surgical gloves; and various types of catheter/sucker etc.
unless they are reusable surgical instruments, in which case they are in Class A; or	Examples: Manually operated surgical drill bits and saws. NOTE: A surgical instrument connected to an active device is in a higher class than A.
unless intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or	Example: catheter containing sealed radioisotopes.
unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class C; or	**NOTES**: (a) The 'biological effect' referred to is an intended one rather than unintentional. The term 'absorption' refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body. (b) This part of the rule does not apply to those substances that are excreted without modification from the body. Example: Insufflation gases for the abdominal cavity.

unless intended to administer medicinal products by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class C; or	Example: insulin pen for self-administration. NOTE: The term 'administration of medicines' implies storage and/or influencing the rate/volume of medicine delivered not just channeling. The term 'potentially hazardous manner' refers to the characteristics of the device and not the competence of the user.
unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D; or	Example: spinal needle.
unless intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.	Examples: angioplasty balloon, catheters and related guide wires; dedicated disposable cardiovascular surgical instruments.
Rule 7. All surgically invasive devices intended for short-term use are in Class B,	Such devices are mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types. Examples: infusion cannula; temporary filling materials; non-absorbable skin closure devices; tissue stabilizers used in cardiac surgery. **NOTE**: Includes devices that are used during cardiac surgery but do not monitor or correct a defect.
unless they are intended to administer medicinal products, in which case they are in Class C; or	**NOTE**: The term 'administration of medicines' implies storage and/or influencing the rate/volume of medicine delivered not just channeling.
unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class C; or	Example: surgical adhesive.

unless they are intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or	Example: brachytherapy device.
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or	Example: absorbable suture; biological adhesive. **NOTE**: The 'biological effect' referred to is an intended one rather than unintentional. The term 'absorption' refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body.
unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D;	Example: neurological catheter.
unless they are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.	Examples: cardiovascular catheters; temporary pacemaker leads; carotid artery shunts.
Rule 8. All implantable devices, and long-term surgically invasive devices, are in Class C,	Most of the devices covered by this rule are implants used in the orthopedic, dental, ophthalmic, and cardiovascular fields. Example: maxilla-facial implants; bone plates and screws; bone cement; non-absorbable internal sutures; posts to secure teeth to the mandibular bone (without a bioactive coating).
unless they are intended to be placed into the teeth or on prepared tooth structure, in which case they are in Class B; or	Examples: materials for inlays, crowns, and bridges; dental filling materials.

unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D; or	Examples: prosthetic heart valves; cardiovascular stents; pacemaker leads and electrodes; deep brain stimulation electrodes; cerebrospinal catheter.
unless they are intended to be life supporting or life sustaining, in which case they are in Class D; or	
unless they are intended to be active implantable medical devices, in which case they are Class D; or	Example: pacemakers; implantable defibrillators.
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or	Example: implants claimed to be bioactive. NOTE: Hydroxy-apatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer.
unless they are intended to administer medicinal products, in which case they are in Class D; or	Example: subcutaneous infusion ports for long-term use.
unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class D; or	Example: surgical adhesives intended for long term use. NOTE: Bone cement is not within the scope of the term 'chemical change in the body' since any change takes place in the short rather than long term.
unless they are breast implants, in which case they are in Class D.	

Rule	Illustrative examples of devices that may conform with a rule
Active Devices	
Rule 9(i). All active therapeutic devices intended to administer or exchange energy are in Class B,	Such devices are mostly electrically powered equipment used in surgery; devices for specialized treatment and some stimulators. Examples: muscle stimulators; powered dental hand pieces; hearing aids; neonatal phototherapy equipment; ultrasound equipment for physiotherapy.
unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionizing radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class C.	Examples: lung ventilators; baby incubators; electrosurgical generators; external pacemakers and defibrillators; surgical lasers; lithotriptors; therapeutic X-ray and other sources of ionizing radiation. **NOTE**: The term 'potentially hazardous' refers to the type of technology involved and the intended application.
Rule 9(ii). All active devices intended to control or monitor the performance of active therapeutic devices in Class C, or intended directly to influence the performance of such devices, are in Class C.	Examples: external feedback systems for active therapeutic devices.
Rule 10(i). Active devices intended for diagnosis are in Class B:	Such devices include equipment for ultrasonic diagnosis/imaging, capture of physiological signals.
- if they are intended to supply energy which will be absorbed by the human body (except for devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, in which case they are Class A), or	Examples: magnetic resonance equipment; diagnostic ultrasound in non-critical applications; evoked response stimulators.
- if they are intended to image in vivo distribution of radiopharmaceuticals, or	Example: gamma/nuclear cameras.
- if they are intended to allow direct diagnosis or monitoring of vital physiological processes,	Example: electronic thermometers, stethoscopes and blood pressure monitors; electrocardiographs.
unless they are specifically intended for: a) monitoring of vital physiological	Example: monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnea

parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system, or b) diagnosing in clinical situations where the patient is in immediate danger, in which case they are in Class C.	monitors. Example: ultrasound equipment for use in interventional cardiac procedures.
Rule 10(ii). Active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including devices which control or monitor such devices, or those which directly influence their performance, are in Class C.	Example: devices for the control, monitoring or influencing of the emission of ionizing radiation.
Rule 11. All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are in Class B,	Such devices are mostly drug delivery systems or anesthesia equipment. Examples: suction equipment; feeding pumps; jet injectors for vaccination; nebulizer to be used on conscious and spontaneously breathing patients where failure to deliver the appropriate dosage characteristics is not potentially hazardous.
unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode and route of administration, in which case they are in Class C.	Examples: infusion pumps; anesthesia equipment; dialysis equipment; hyperbaric chambers; nebulizer where the failure to deliver the appropriate dosage characteristics could be hazardous.
Rule 12. All other active devices are in Class A.	Examples: examination lamps; surgical microscopes; powered hospital beds & wheelchairs; powered equipment for the recording, processing, viewing of diagnostic images; dental curing lights.

Rule	Illustrative examples of devices that may conform with a rule
Additional Rules	
Rule 13. All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices, are in Class D.	These medical devices incorporate medicinal substances in an ancillary role. Examples: antibiotic bone cements; heparin-coated catheters; wound dressings incorporating antimicrobial agents to provide ancillary action on the wound; blood bags incorporating an anti-coagulant. **NOTE:** In some jurisdictions such products: - are considered to be outside the scope of the medical device definition; - may be subject to different controls.
Rule 14. All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are in Class D,	Example: porcine heart valves. **NOTE:** In some jurisdictions such products: - are considered to be outside the scope of the medical device definition; - may be subject to different controls.
unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only in which case they are in Class A.	Examples: leather components of orthopaedic appliances.
Rule 15. All devices intended specifically to be used for sterilizing or disinfecting medical devices are in Class B.	Example: desk-top sterilisers for use with dental instruments.
unless they are disinfectant solutions or washer-disinfectors intended specifically for invasive medical devices, as the end point of processing, in which case they are in Class C; or	Examples: solutions intended to be used for the disinfection of medical devices without further processing (for example in a steriliser) including those where the infective agent is a prion; Washer-disinfector equipment specifically for disinfecting an endoscope or another invasive device.
unless they are intended to clean medical devices by means of physical action only, in which case they are in Class A.	

Rule 16. All devices that are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class C.	**NOTE:** In some jurisdictions such products: - are considered to be outside the scope of the medical device definition; - may be subject to different controls.
Rule 17. All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class C,	Examples: condoms; contraceptive diaphragms.
unless they are implantable or long-term invasive devices, in which case they are in Class D.	Example: intrauterine contraceptive device.

3. Rationale for the inclusion of the Additional Rules within this document

There are a small number of products that fall within the scope of the definition of a medical device and which may need to be classified to take account of factors other than those covered by the general rules (Rules 1 to 12). While GHTF continues to support and encourage regulatory harmonization, it recognizes that a particular RA may have to reflect different local needs or social considerations when it introduces regulations on the classification of a minority of medical devices. Additional rules 13 to 17 provide examples of where this may occur.

For the understanding of those countries that are not Founding Members of GHTF, it is felt important to offer guidance on the classification of such devices. Therefore, five Additional Rules are provided (Rules 13 to 17).

Matters that may need to be considered are:

Rule 13: Devices incorporating a medicinal substance

- The regulations applying to medicinal products require different acceptance procedures to those for medical devices.
- The behavior of a medicinal substance used in conjunction with a medical device may differ from that covered by its approved use as a medicinal product alone.

Rule 14: Devices incorporating animal or human tissues

- There is an absence of global regulatory controls for such devices.
- Classification needs to acknowledge the diversity of opinions on such devices, globally.
- The possible transmission of infectious agents to human beings by the use of devices incorporating animal or human tissues (e.g. Bovine Spongiform Encephalopathy (BSE) and Creutzfeldt-Jacob disease (CJD)) demands classification at a higher level.

Rule 15: Disinfection as the end point of processing

- Classification of disinfection solutions and washer-disinfector equipment intended for the treatment of invasive devices **as the end point of**

processing rather than as an intermediate step before sterilization.

Rule 16: Fluids used with contact lenses

- The particular concerns relating to disinfectant solutions and other fluids that are used with contact lenses, due to sensitivity and vulnerability of the eye.

Rule 17: Contraceptive devices

- The hazard associated with unwanted pregnancy if caused by mechanical failure of the device.
- The need to safeguard public health through the use of condoms to reduce the prevalence of sexually transmitted diseases.
- User expectation that contraceptive devices are perfectly reliable and safe despite published data to the contrary.

4. General Classification System for IVDs:

The Classification of an IVD medical device is based on the following criteria:

- The intended use and indications for use as specified by the manufacturer (including but not limited to specific disorder, populations, condition or risk factor for which the test is intended)
- The technical/scientific/medical expertise of the intended user (lay person or healthcare professional)
- The importance of the information to the diagnosis (sole determinant or one of several), taking into consideration the natural history of the disease or disorder including presenting signs and symptoms which may guide a physician
- The impact of the result (true or false) to the individual and/or to public health

Certain jurisdictions may lower the classification of IVD medical devices for which traceability is established through the use of reference measurement procedures and/or available reference materials.

A four class system is proposed.

Figure 1 indicates the four risk classes of devices. The examples given are for illustration only; the manufacturer must apply the classification rules to each IVD medical device according to its intended use.

Figure 1: Proposed general classification system for IVDs

CLASS	RISK LEVEL	EXAMPLES
A	Low Individual Risk and Low Public Health Risk	Clinical Chemistry Analyzer , prepared selective culture media
B	Moderate Individual Risk and/or Low Public Health Risk	Vitamin B12, Pregnancy self testing, Anti-Nuclear Antibody, Urine test strips
C	High Individual Risk and/or Moderate Public Health Risk	Blood glucose self testing, HLA typing, PSA screening, Rubella
D	High Individual Risk and High Public Health Risk	HIV Blood donor screening, HIV Blood diagnostic

5. **Determination of Class of IVD:**

The manufacturer should:

1. Decide if the product concerned is an IVD medical device based on the intended use and the indications for use using the definition in section 4.0 of this document.

2. Take into consideration all the rules as listed in section 9.0 in order to establish the proper classification for the device. Where an IVD medical device has multiple intended uses as specified by the manufacturer, which place the device into more than one class, it will be classified in the higher class.

3. Where more than one of the classification rules applies to the IVD medical device, it should be allocated to the highest class indicated, e.g. a self-testing for HIV would be a class D under rule 1 and not a class C under rule 4.

4. Determine that the device is not subject to special national rules that apply within a particular jurisdiction.

NOTE: Where special national rules are applied, resulting in a device class other than that suggested by the present rules, then a different conformity assessment

procedure may be indicated. This may have an effect on the acceptability of such devices for free movement in a global context unless other, or additional, conformity assessment procedures are carried out. For example, where such special national rules result in the lower classification of a particular IVD medical device than that indicated in the rules indicated below, and as a consequence, a less vigorous conformity assessment procedure is carried out, this may be unacceptable to other jurisdictions.

6. **Classification Rules for IVD**

Rule 1: IVD medical devices intended for the following purposes are classified as Class D:

- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, cells, tissues or organs in order to assess their suitability for transfusion or transplantation, or
- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening, often incurable, disease with a high risk of propagation

Rationale: The application of this rule as defined above should be in accordance with the rationale that follows: Devices in this Class are intended to be used to ensure the safety of blood and blood components for transfusion and/or cells, tissues and organs for transplantation. In most cases, the result of the test is the major determinant as to whether the donation/product will be used. Serious diseases are those that result in death or long-term disability, that are often incurable or require major therapeutic interventions and where an accurate diagnosis is vital to mitigate the public health impact of the condition.

Examples: Tests to detect infection by HIV, HCV, HBV, HTLV. This Rule applies to first-line assays, confirmatory assays and supplemental assays.

Rule 2: IVD medical devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation, are classified as Class C, except for ABO system [A (ABO1), B (ABO2), AB (ABO3)], rhesus system [RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e)], Kell system [Kel1 (K)], Kidd system [JK1 (Jka), JK2 (Jkb)] and Duffy system [FY1 (Fya), FY2 (Fyb)] determinations which are classified as Class D.

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: A high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation places the device into Class D. The rule divides blood

grouping devices into two subsets, Class C or D, depending on the nature of the blood group antigen the IVD medical device is designed to detect, and its importance in a transfusion setting.

Examples: HLA, Duffy system (other Duffy systems except those listed in the rule as Class D are in Class C).

Rule 3: IVD medical devices are classified as Class C if they are intended for use:

- In detecting the presence of, or exposure to, a sexually transmitted agent. Examples: Sexually transmitted diseases, such as *Chlamydia trachomatis*, *Neisseria gonorrhea*.

- In detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation. Examples: *Neisseria meningitides* or *Cryptococcus neoformans.*

- In detecting the presence of an infectious agent where there is a significant risk that an erroneous result would cause death or severe disability to the individual or fetus being tested. Examples: diagnostic assay for CMV, *Chlamydia pneumoniae,* Methicillin Resistant *Staphylococcus aureus*.

- In pre-natal screening of women in order to determine their immune status towards transmissible agents. Examples: Immune status tests for Rubella or Toxoplasmosis.

- In determining infective disease status or immune status, and where there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient. Examples: Enter viruses, CMV and HSV in transplant patients.

- In screening for selection of patients for selective therapy and management, or for or for disease staging, or in the diagnosis of cancer. Example: personalized medicine. NOTE: those IVD medical devices where the therapy decision would usually be made only after further investigation and those used for monitoring would fall into class B under rule 6.

- In human genetic testing. Examples: Huntington' Disease, Cystic Fibrosis.

- To monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient. Examples: Cardiac markers, Cyclosporine, Prothrombin time testing.

- In the management of patients suffering from a life-threatening infectious disease.
  Examples: HCV viral load, HIV Viral Load and HIV and HCV genome and subtyping.

- In screening for congenital disorders in the fetus. Examples: Spinal Bifida or Down Syndrome.

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: Devices in this Class present a moderate public health risk, or a high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation, or would have a major negative impact on outcome. The devices provide the critical, or sole, determinant for the correct diagnosis. They may also present a high individual risk because of the stress and anxiety resulting from the information and the nature of the possible follow-up measures.

Rule 4: IVD medical devices intended for self-testing are classified as Class C, except those devices from which the result is not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test in which case they are Class B.

IVD medical devices intended for blood gases and blood glucose determinations for near-patient testing would be Class C. Other IVD medical devices that are intended for near-patient should be classified in their own right using the classification rules.

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: In general, these devices are used by individuals with no technical expertise and thus the labelling and instructions for use are critical to the proper outcome of the test.

Example for self-testing class C: Blood glucose monitoring,

Example for self-testing class B: Pregnancy self test, Fertility testing, Urine test-strips.

Rule 5: The following IVD medical devices are classified as Class A:

- Reagents or other articles which possess specific characteristics, intended by the manufacturer to make them suitable for in vitro diagnostic procedures related to a specific examination.

- Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures

- Specimen receptacles

Note: Any product for general laboratory use not manufactured, sold or represented for use in specified in vitro diagnostic applications are not deemed to be IVD medical devices, as defined in this document. However, in certain jurisdictions products for general laboratory use are considered to be IVD medical devices.

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: These devices present a low individual risk and no or minimal public health risk.

Examples: Selective/differential microbiological media (excluding the dehydrated powders which are considered not to be a finished IVD medical device), identification kits for cultured microorganisms, wash solutions, instruments and plain urine cup.

Note 1: In certain jurisdictions there may be differences as to whether a device classified in this rule is considered an IVD medical device.

Note 2: The performance of software or an instrument that is specifically required to perform a particular test will be assessed at the same time as the test kit.

Note 3: The interdependence of the instrument and the test methodology prevents the instrument from being assessed separately, even though the instrument itself is still classified as Class A.

Rule 6: IVD medical devices not covered in Rules 1 through 5 are classified as Class B.

Rationale: The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: These devices present a moderate individual risk as they are not likely to lead to an erroneous result that would cause death or severe disability, have a major negative impact on patient outcome or put the individual in immediate danger. The devices give results that are usually one of several determinants. If the test result is the sole determinant however other information is available, such as presenting signs and symptoms or other clinical information which may guide a physician, such that classification into Class B may be justified. Other appropriate controls may also be in place to validate the results. This Class also includes those devices that present a low public health risk because they detect infectious agents that are not easily propagated in a population.

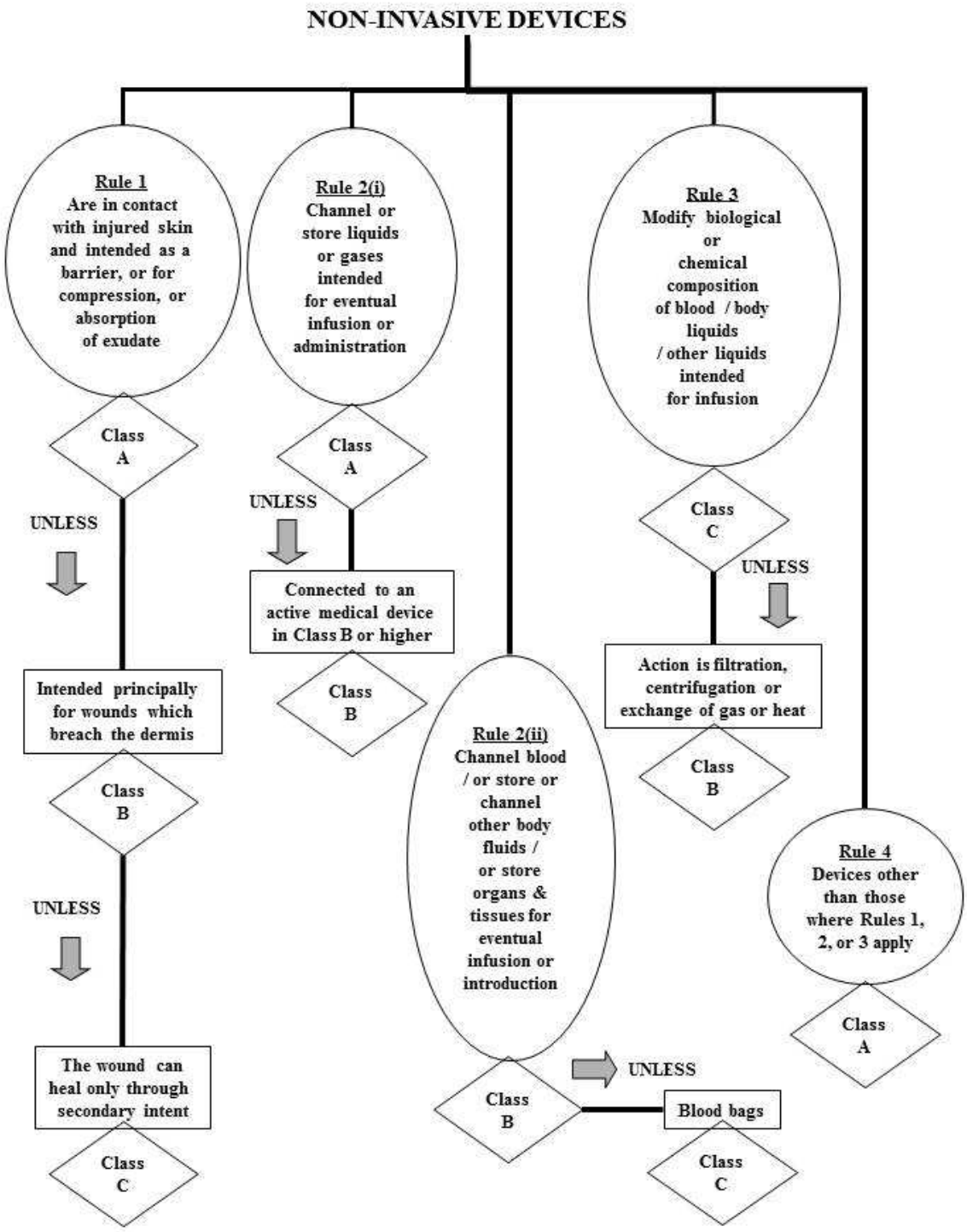
Examples: Blood gases, *H. pylori* and physiological markers such as hormones, vitamins, enzymes, metabolic markers, specific IgE assays and celiac disease markers.

Rule 7: IVD medical devices that are controls without a quantitative or qualitative assigned value will be classified as Class B.

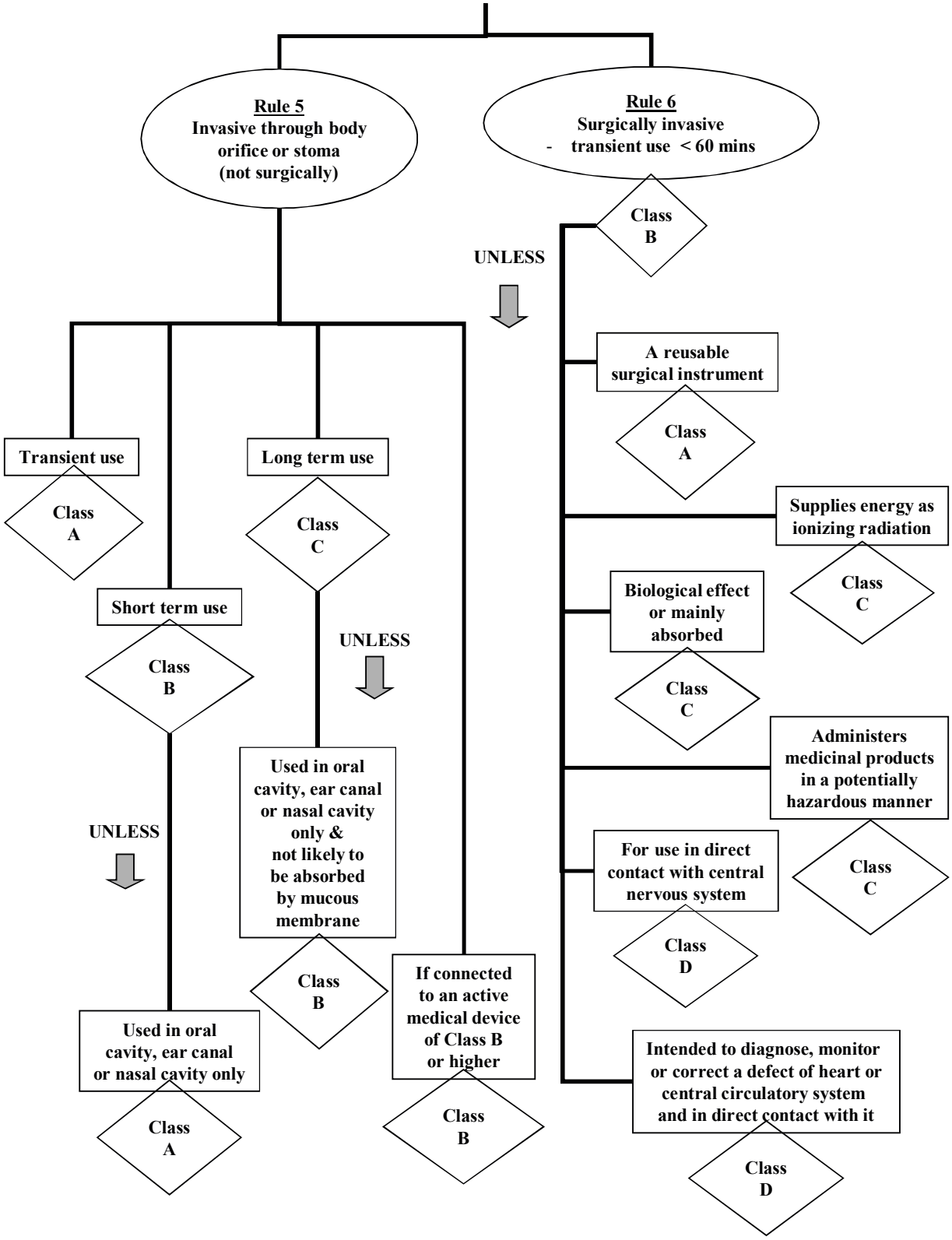
Rationale: For such controls, the qualitative or quantitative value is assigned by the user and not the manufacturer.

Appendix A: Decision trees to illustrate how the rules may be used to classify specific devices.

NOTE: The diagrams in this appendix are for illustrative purposes only and the determination of class for a particular device should be made by referring to the rules themselves and not the decision trees. Where a medical device has features that place it into more than one class, conformity assessment should be based on the highest class indicated.


NON-INVASIVE DEVICES
Rule 1
Are in contact with injured skin and intended as a barrier, or for compression, or absorption of exudate
Class A
UNLESS
Intended principally for wounds which breach the dermis
Class B
UNLESS
The wound can heal only through secondary intent
Class C
Rule 2(i)
Channel or store liquids or gases intended for eventual infusion or administration
Class A
UNLESS
Connected to an active medical device in Class B or higher
Class B
Rule 2(ii)
Channel blood / or store or channel other body fluids / or store organs & tissues for eventual infusion or introduction
Class B
UNLESS
Blood bags
Class C
Rule 3
Modify biological or chemical composition of blood / body liquids / other liquids intended for infusion
Class C
UNLESS
Action is filtration, centrifugation or exchange of gas or heat
Class B
Rule 4
Devices other than those where Rules 1, 2, or 3 apply
Class A

INVASIVE DEVICES (1 of 2)



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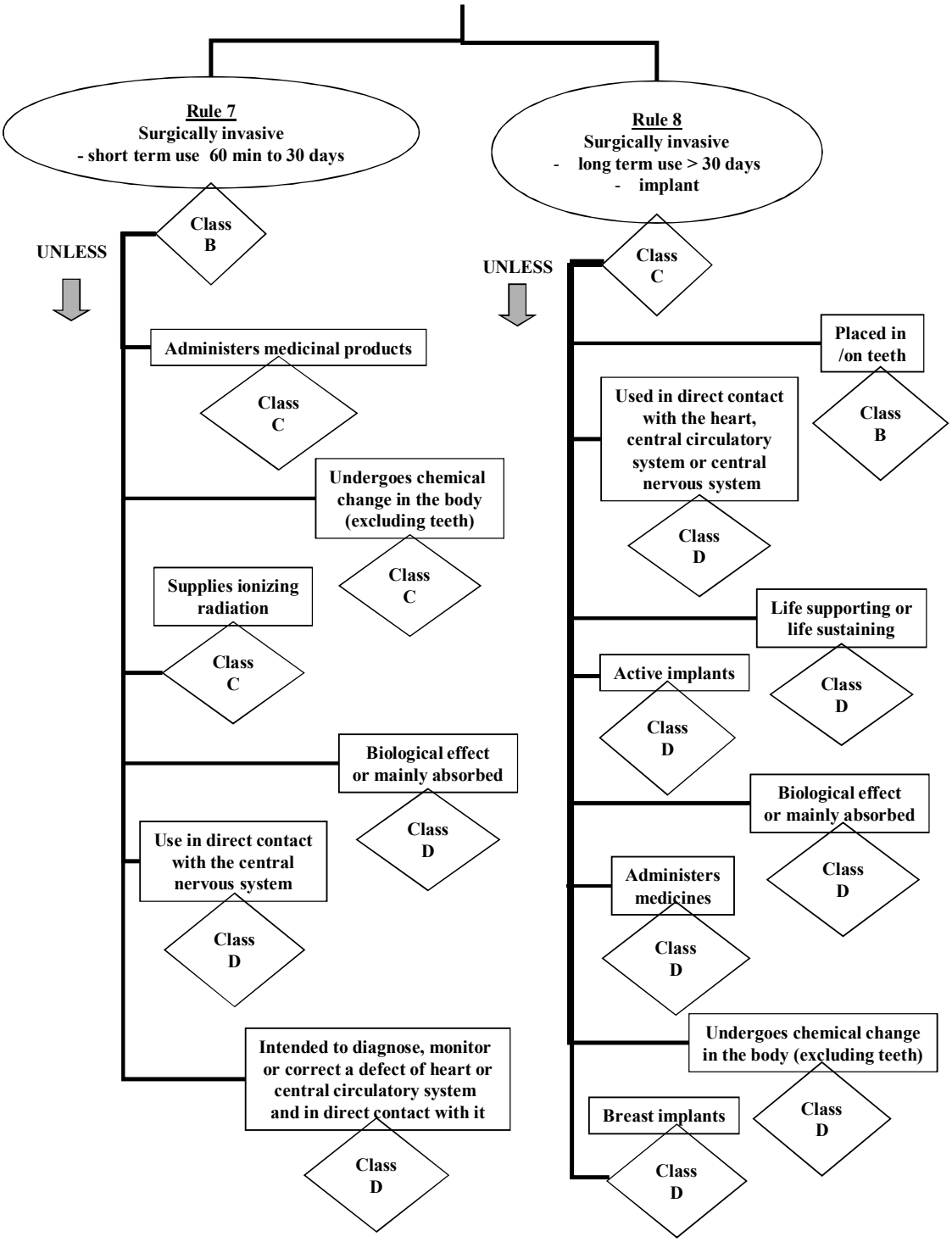
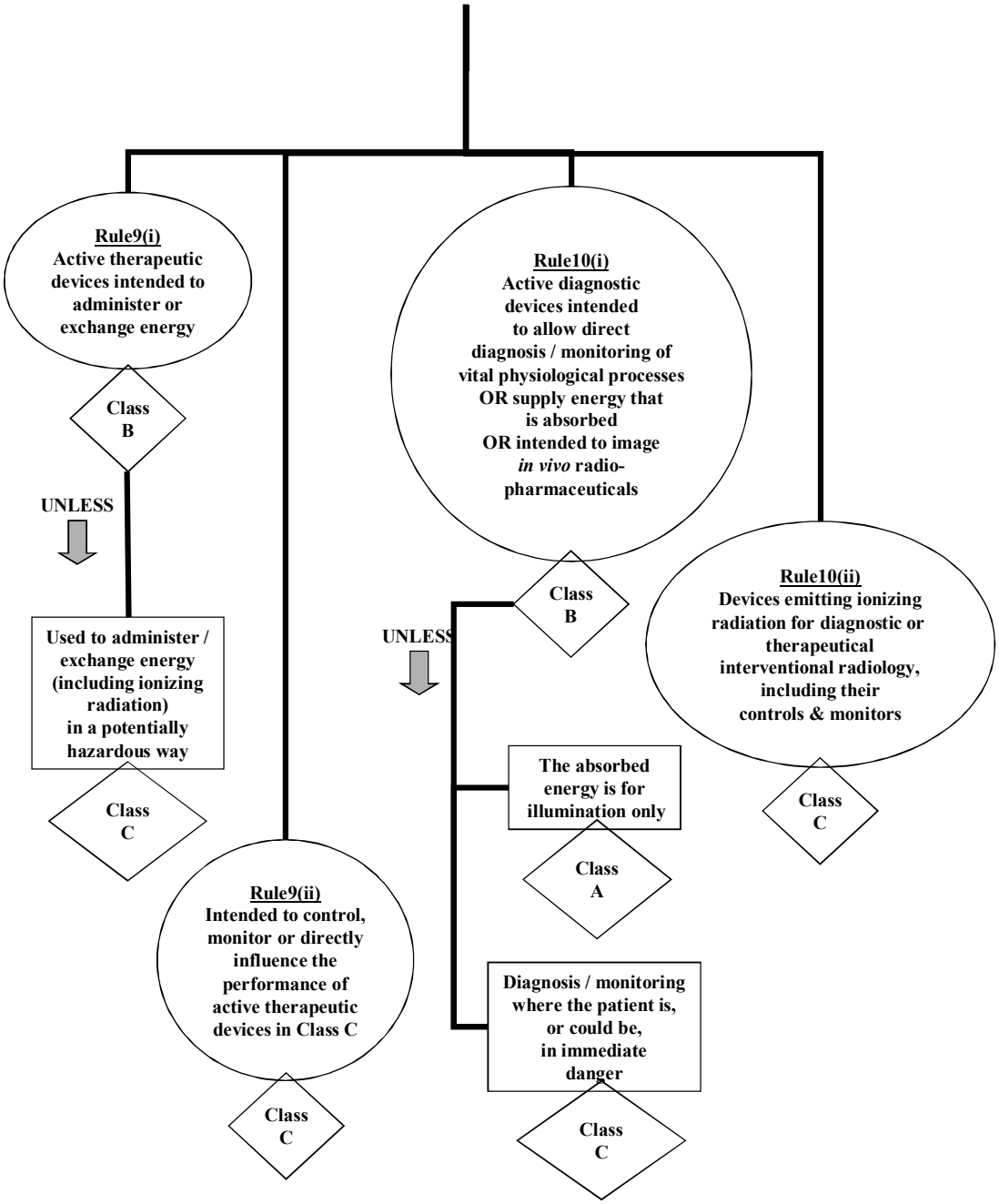
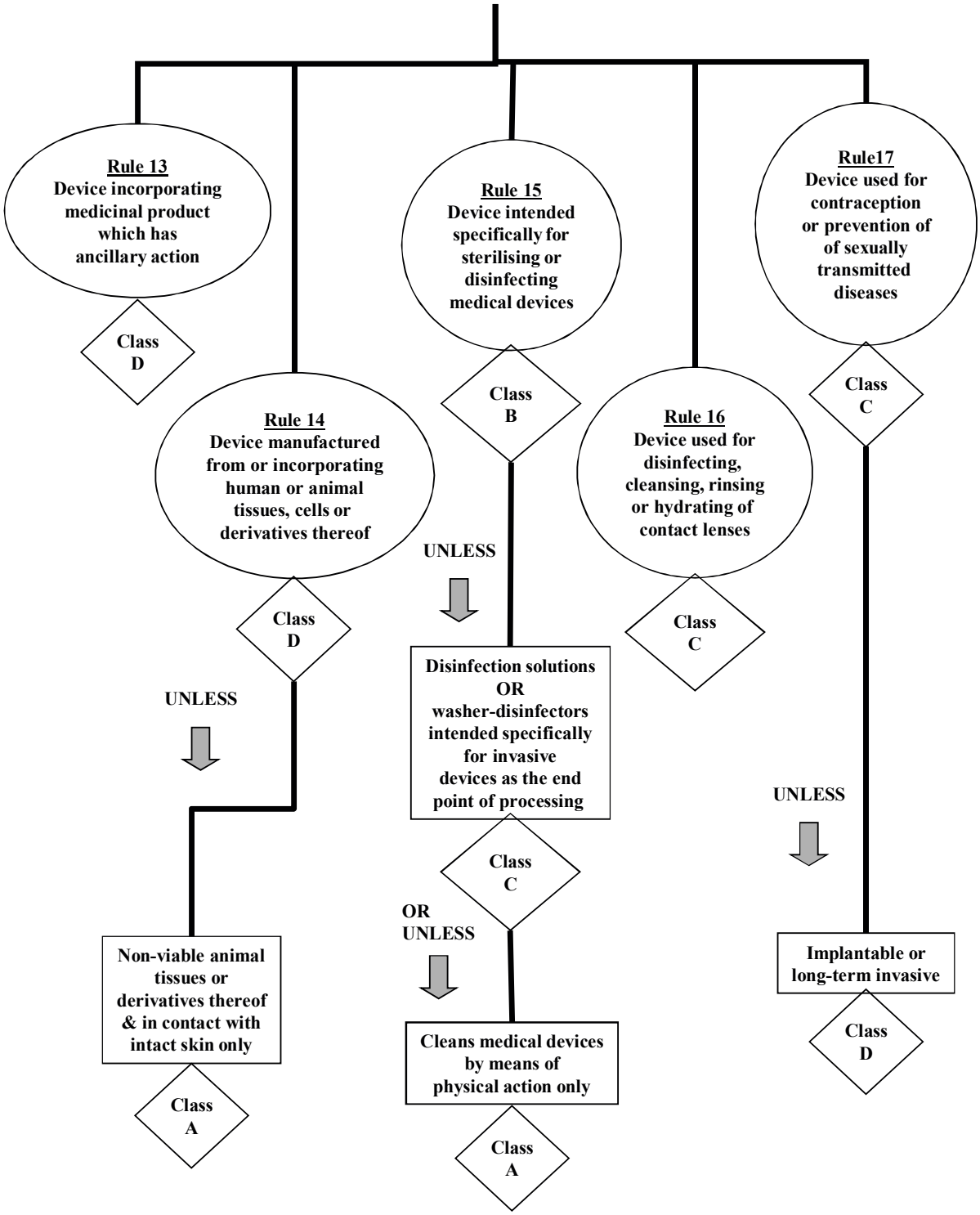


ACTIVE DEVICES (1 of 2)



ADDITIONAL RULES



Annexure- 4

Medical specialty / Therapeutic code (Therapeutic Class)

Two numbers represent medical specialty as follows –

73 – Anesthesiology
74 – Cardiovascular
76 – Dental
77 – Ear, Nose & Throat
78 – Gastroenterology & Urology
79 – General & Plastic Surgery
80 – General Hospital & Personal Use
84 – Neurology
85 – Obstetrics & Gynecology
86 – Ophthalmology
87 – Orthopedics
89 – Physical Medicine
90 – Radiology

Medical device list:

This list of Medical Devices is hereby adopted by DGDA, Bangladesh on the basis of risk categories such as – Class A (Low risk), Class B (Low moderate risk), Class C (Moderate high risk), Class D (High risk). The list comprises four columns- (1) Key word, (2) Therapeutic code, (3) class and (4) description.

Medical device list:

Keyword	Therapeutic Code	Class	Description
ABERROMETER	86	B	ABERROMETER, OPHTHALMIC
ABLATION	74	B	DEVICE, ABLATION, VARICOSE VEIN
	85 78	C	DEVICE, ABLATION, THERMAL, ENDOMETRIAL SYSTEM, GALLBLADDER THERMAL ABLATION
	74 74 74	D	ELECTRODE, PERCUTANEOUS CONDUCTION TISSUE ABLATION SUCTION ABLATION CATHETER SYSTEM (SAC) SYSTEM, ABLATION, RADIOFREQUENCY
ABORTION	85	A	INSTRUMENT, DESTRUCTIVE, FETAL, OBSTETRIC
	85	B	SYSTEM, ABORTION, VACUUM
ABSORBENT	80	A	FIBER, MEDICAL, ABSORBENT
	73	B	ABSORBENT, CARBON-DIOXIDE
ABSORBER	73	B	ABSORBER, CARBON-DIOXIDE

ABUTMENT	76	C	ABUTMENT, IMPLANT, DENTAL ENDOSSEOUS
ACCELERAT OR	90	C	ACCELERATOR, LINEAR, MEDICAL
ACID	78	B	ELECTRODE, PH, STOMACH
ACRYLIC	76 76	B C	MATERIALS, FABRICATING PROSTHODONTIC APPLIANCES, DENTAL LAB. MATERIAL, ACRYLIC, DENTAL
ACTIVATOR	76	A	ACTIVATOR, ULTRAVIOLET, FOR POLYMERIZATION
ACTUATOR	74	C	ACTUATOR, SYRINGE, INJECTOR TYPE
	74	D	CATHETER, OXIMETER, FIBEROPTIC
ACUPRESSURE	89 80	A	AID, SLEEP, ACUPRESSURE (NON-POWERED) DEVICE, ACUPRESSURE (NON-POWERED)
ACUPUNCTURE	80	B	ACUPUNCTURE, DIAGNOSTIC, ELECTRIC AL RESISTANCE
ADAPTOR	78 73 73 73 78 80 79 79 74 74 74 80 78 74 80	B	ADAPTER, A-V SHUNT OR FISTULA ADAPTER, ANESTHESIA ADAPTER, TRACHEAL TUBE ADAPTER, TRACHEOSTOMY TUBE ADAPTOR, BULB, MISCELLANEOUS, FOR ENDOSCOPE ADAPTOR, CABLE, EQUIPMENT ADAPTOR, CATHETER ADAPTOR, ELECTROSURGICAL UNIT CABLE ADAPTOR, LEAD SWITCHING, ELECTROCARDIOGRAPH ADAPTOR, NEEDLE ADAPTOR, STOPCOCK, MANIFOLD, FITTING, CARDIOPULMONARY BYPASS ADAPTOR, SYRINGE ADAPTOR, Y CABLE AND ADAPTER, DEFIBRILLATOR TUBING, CONNECTOR/ADAPTOR
	74	D	ADAPTOR, LEAD, PACEMAKER
ADENOTOME	77	A	ADENOTOME
	79	B	BLADE, OSTEOTOME AND OTHER CUTTING INSTRUMENTS (DISPOSABLE)
ADHESIVE	80 76 80 79 79	A	ADHESIVE STRIP ADHESIVE, DENTURE, OTC ADHESIVE, LIQUID CLOSURE, SKIN, ADHESIVE STRIP PROSTHESIS, ADHESIVE, EXTERNAL
	76 74	B	ADHESIVE, BRACKET AND TOOTH CONDITIONER, RESIN ELECTRODE, GEL
	76 76 79	C	CEMENT, DENTAL DENTAL ADHESIVE SYSTEM (ETCHANT, PRIMER, ADHESIVE) GLUE, SURGICAL TISSUE
	84	D	TISSUE ADHESIVE FOR ANEURSMORRHAPHY

AEROSOL	80	A	SPRAY, PRE-TAPE
	73 73	B	ATOMIZER AND TIP, ENT MASK, OXYGEN
	73	C	KIT, DIAGNOSTIC, PULMONARY, RADIO AEROSOL
AEROSOLIZER	73	B	NEBULIZER (DIRECT PATIENT INTERFACE)
AESTHESIOMETER	86	B	OCULAR ESTHESIOMETER
AIRWAY	73 80 73	A	AIRWAY, NASOPHARYNGEAL AIRWAY, OBSTRUCTION REMOVAL (CHOKE SAVER) RESUSCITATOR, EMERGENCY, PROTECTIVE, INFECTION
	73 73 73 73 73	B	AIRWAY, ESOPHAGEAL (OBTURATOR) AIRWAY, OROPHARYNGEAL, ANESTHESIOLOGY KIT, CRICOTHYROTOMY KIT, SUCTION, AIRWAY UNIT, CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP, CPPB)
ALARM	78 74 73 78	B	ALARM, ENURESIS, CONDITIONED RESPONSE ALARM, LEAKAGE CURRENT, PORTABLE MONITOR (APNEA DETECTOR), VENTILATORY EFFORT SYSTEM, ALARM, ELECTROSURGICAL
	74 73 74	C	ALARM, BLOOD PRESSURE ALARM, BREATHING CIRCUIT DETECTOR AND ALARM, ARRHYTHMIA
ALGESIMETER	73	A	ALGESIMETER, MANUAL
	73	B	ALGESIMETER, POWERED
ALIGNER	76 76	A	ALIGNER, BEAM, X-RAY ALIGNER, BRACKET, ORTHODONTIC
ALIGNMENT	87 89	A	APPARATUS, FRACTURE ALIGNMENT DEVICE, PROSTHESIS ALIGNMENT
	76	B	ALIGNMENT SYSTEM, ORTHODONTIC
ALIMENTATION	80	B	PUMP, INFUSION, ENTERAL
ALLOGEN	79	C	SKIN EXPANDER, INFLATABLE
ALLOY	76	B	CERAMIC, PROSTHODONTIC APPLIANCES
	76 76	C	ALLOY, AMALGAM ALLOY, PRECIOUS METAL, FOR CLINICAL USE
AMALGAM	76	A	CAPSULE, DENTAL, AMALGAM
	76	C	ALLOY, AMALGAM
AMALGAMATOR	76	A	AMALGAMATOR, DENTAL, AC -POWERED

AMNIOCENTESIS	85	B	SAMPLER, AMNIOTIC FLUID (AMNIOCENTESIS TRAY)
AMNIOSCOPE	85	B	ENDOSCOPE, TRANSCERVICAL (AMNIOSCOPE), AND ACCESSORIES
	85	D	AMNIOSCOPE, TRANSABDOMINAL (FETOSCOPE) (AND ACCESSORIES)
AMNIOTOME	85	B	AMNIOTOME (DISPOSABLE)
AMPLIFIER	74 74 80 84 90	B	AMPLIFIER AND SIGNAL CONDITIONER, BIOPOTENTIAL AMPLIFIER AND SIGNAL CONDITI ONER, TRANSDUCER SIGNAL AMPLIFIER, MICROELECTRODE AMPLIFIER, PHYSIOLOGICAL SIGNAL TUBE, IMAGE AMPLIFIER, X-RAY
ANALGESIA	73	B	GAS-MACHINE, ANALGESIA
ANALYSIS	77	B	SYSTEM, HEARING- AID ANALYSIS
	74	C	SYSTEM, ECG ANALYSIS
ANALYZER	86 87 87 84	A	ANALYSER, VISUAL FUNCTION ANALYZER, DISTRIBUTION, WEIGHT, PODIATRIC ANALYZER, GAIT ANALYZER, SPECTRUM, ELECTROENCEPHALOGRAM (EEG) SIGNAL
	74 80	B	ANALYZER, BODY COMPOSITION ANALYZER, DOPPLER SPECTRUM

Keyword	Therapeutic Code	Class	Description
	79		ANALYZER, ELECTROSURGICAL UNIT
	73		ANALYZER, METABOLISM
	74		ANALYZER, PACEMAKER, GENERATOR FUNCTION
	73		ANALYZER, PULMONARY FUNCTION
	78		SYSTEM, GASTROINTESTINAL MOTILITY (ELECTRICAL)
	85	C	ANALYZER, DATA, OBSTETRIC
	73		ANALYZER, GAS, CARBON-DIOXIDE, GASEOUS PHASE
	73		ANALYZER, GAS, CARBON-MONOXIDE, GASEOUS PHASE
	73		ANALYZER, GAS, HALOTHANE, GASEOUS PHASE (ANESTHETIC CONC.)
	73		ANALYZER, GAS, MULTIPLE, GASEOUS PHASE (ANESTHETIC CONC.)
	73		ANALYZER, GAS, NITROGEN, GASEOUS PHASE
	73		ANALYZER, GAS, NITROUS-OXIDE, GASEOUS PHASE (ANESTHETIC CONC.)
	73		ANALYZER, GAS, OXYGEN, CONTINUOUS MONITOR
	73		ANALYZER, GAS, OXYGEN, GASEOUS PHASE
	73		ANALYZER, OXYHEMOGLOBIN CONCENTRATION, BLOOD PHASE, INDWELLING
ANASTOMOSIS	78	C	ANASTOMOSIS DEVICE FOR GASTROENTEROLOGY-UROLOGY USE
	74		ANASTOMOSIS DEVICE FOR MICROVASCULAR SURGERY
ANASTOMOTIC	74	B	DEVICE, ANASTOMOTIC, MICROVASCULAR
ANCHOR	76	B	ANCHOR, PREFORMED
ANESTHESIA	73	B	ABSORBENT, CARBON-DIOXIDE
	85		ANESTHESIA SET, PUDENDAL
	73		APPARATUS, GAS-SCAVENGING
	73		CALIBRATOR ANESTHESIA UNIT
	76		DEVICE, ELECTRICAL DENTAL ANESTHESIA
	73		KIT, ANESTHESIA, BRACHIAL PLEXUS
	73		KIT, ANESTHESIA, EPIDURAL
	73		KIT, ANESTHESIA, SPINAL
	85		SET, ANESTHESIA, PARACERVICAL
	73		STIMULATOR, NERVE, PERIPHERAL, ELECTRIC
	73	C	APPARATUS, ELECTRONANESTHESIA
	73		GAS-MACHINE, ANESTHESIA
ANESTHETIC	73	C	KIT, CONDUCTION ANESTHETIC
ANGIODYNOGRAPH	90	B	ANGIODYNOGRAPH

ANGIOGRAPHIC	74	B	WIRE, GUIDE, ANGIOGRAPHIC AND ACCESSORIES
	90	D	KIT, ANGIOGRAPHIC, DIGITAL
ANGIOGRAPHY	74	D	KIT, CATHETERIZATION, CARDIAC
ANGIOPLASTY	74	B	DILATOR, VESSEL, FOR PERCUTANEOUS CATHETERIZATION
ANGIOSCOPE	74	B	ANGIOSCOPE
ANKLE	89	A	ASSEMBLY, THIGH/KNEE/SHANK/ANKLE/FOOT, EXTERNAL
	89		COMPONENT, EXTERNAL, LIMB, ANKLE/FOOT
	87	C	PROSTHESIS, ANKLE, SEMI-CONSTRAINED, CEMENTED, METAL/POLYMER
	87		PROSTHESIS, ANKLE, TALAR COMPONENT
	87		PROSTHESIS, ANKLE, TIBIAL COMPONENT
ANOMALOSCOPE	86	A	ANOMALOSCOPE
ANOSCOPE	78	B	ANOSCOPE, NON-POWERED
ANTI -EMBOLIC	80	A	STOCKING, MEDICAL SUPPORT
ANTI -SNORING	77	A	ANTI-SNORING DEVICE
ANTICHOKE	80	A	AIRWAY, OBSTRUCTION REMOVAL (CHOKE SAVER)
	77	B	DEVICE, ANTICHOKE, TONGS
	77	C	DEVICE, ANTICHOKE, SUCTION
ANTISPASMODIC	80	A	FABRIC, PAIN RELIEF
ANVIL	84	A	ANVIL, SKULL PLATE
AORTOGRAPHY	79	B	NEEDLE, ASPIRATION AND INJECTION, DISPOSABLE

Keyword	Therapeutic Code	Class	Description
APNEA	73 73 73	B	EQUIPMENT, THERAPY, APNEA MONITOR (APNEA DETECTOR), VENTILATORY EFFORT MONITOR, BREATHING FREQUENCY
APPLICATOR	76 77 86	A	APPLICATOR, RAPID WAX, DENTAL ENT DRUG APPLICATOR OCULAR PRESSURE APPLICATOR
	73 76 90	B	APPLICATOR (LARYNGO-TRACHEAL), TOPICAL ANESTHESIA APPLICATOR, RESIN SYSTEM, APPLICATOR, RADIONUCLIDE, MANUAL
	90	C	SYSTEM, APPLICATOR, RADIONUCLIDE, REMOTE-CONTROLLED
	74	D	PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE
APPLIER	87 79	A	APPLIER, CERCLAGE APPLIER, SURGICAL, STAPLE
	84 79	B	APPLIER, ANEURYSM CLIP APPLIER, SURGICAL, CLIP
APPROXIMATOR APRON	79 79 90 90	A A	APPROXIMATOR, SURGICAL APRON, CONDUCTIVE APRON, LEADED APRON, PROTECTIVE
ARCHIVING	90	B	RADIOGRAPHIC PICTURE ARCHIVING/COMMUNICATION SYSTEM (PACS)
ARGON	86	C	OPHTHALMIC LASER
	74	D	DEVICE, LASER, ANGIOPLASTY, CORONARY
ARM	87	A	PROSTHESIS, ARM
ARTHROGRAM	87	B	ARTHROGRAM KIT
ARTHROSCOPE	87	B	ARTHROSCOPE AND ACCESSORIES
ARTICULATORS	76	A	ARTICULATORS
ASPIRATING	73	B	CATHETER, SUCTION, TRACHEOBRONCHIAL
ASPIRATION	77	A	TUBE, EAR SUCTION

	78 85	B	ELECTRODE, FLEXIBLE SUCTION COAGULATOR SYSTEM, ABORTION, VACUUM
	77 86	C	DEVICE, ANTICHOKE, SUCTION INSTRUMENT, VITREOUS ASPIRATION AND CUTTING, AC - POWERED
	84	D	DEVICE, NEUROSURGICAL, FRAGMENTATION AND ASPIRATION
ASPIRATOR	77 76 74 85 85 80 78 86 79 77 85 80 78 85	A B	ASPIRATOR, NASAL EVACUATOR, ORAL CAVITY APPARATUS, SUCTION, PATIENT CARE ASPIRATOR, ENDOCERVICAL ASPIRATOR, ENDOMETRIAL ASPIRATOR, INFANT ASPIRATOR, LOW VOLUME (GASTRIC SUCTION) - UROLOGY USE ASPIRATOR, OPHTHALMIC ASPIRATOR, SURGICAL ASPIRATOR, TRACHEAL ASPIRATOR, ULTRASONIC ASPIRATOR, WOUND SUCTION PUMP EVACUATOR, BLADDER, MANUALLY OPERATED EXTRACTOR, VACUUM, FETAL
ATOMIZER	73 73	B	ATOMIZER AND TIP, ENT NEBULIZER, MEDICINAL, NON-VENTILATORY (ATOMIZER)
AUDIOMETER	77	B	AUDIOMETER
AUGMENTATION	76	C	MATERIAL, PERIODONTAL TISSUE AUGMENTATION/REGENERATION
AUSCULTOSCOPE	74	B	STETHOSCOPE, ELECTRONIC
AUTOCLAVE	80	B	STERILIZER, STEAM (AUTOCLAVE)

Keyword	Therapeutic Code	Class	Description
AUTOTRANSFUSION	73 74	B	APPARATUS, AUTOTRANSFUSION HEMOCONCENTRATOR
AVERSIVE	84	B	DEVICE, AVERSIVE CONDITIONING
AWL	87	B	AWL
BAG	78 78 80 78 80 78 78	A	BAG, BILE COLLECTING BAG, DRAINAGE, WITH ADHESIVE, OSTOMY BAG, ENEMA BAG, STOMAL BAG, URINARY COLLECTION BAG, URINARY, ILEOSTOMY BAG, URINE COLLECTION, LEG, FOR EXTERNAL USE
	73 80 78 77 80 80	B	BAG, BREATHING BAG, ENTERAL FEEDING BAG, HEMOSTATIC BAG, POLITZER, BAG AND ACCESSORIES CONTAINER, I.V. DEVICE, MEDICATION RECONSTITUTION/TRANSER
	74	C	BAG, POLYMERIC MESH, PACEMAKER
BALLISTOCARDIOGRAPH	74	B	BALLISTOCARDIOGRAPH
BALLOON	77	A	BALLOON, EPISTAXIS
	78 74 74	B	BALLOON, RECTAL DEVICE, PERCUTANEOUS RETRIEVAL OCCLUDER, VASCULAR
	78	C	INTRAGASTRIC IMPLANT FOR MORBID OBESITY
	84 74	D	BALLOON FOR CEREBROVASCULAR OCCLUSION SYSTEM, BALLOON, INTRA-AORTIC AND CONTROL
BAND	89 76	A	BAND OR BELT, PELVIC SUPPORT MATRIX, DENTAL
	76 76 76	B	BAND, ELASTIC, ORTHODONTIC BAND, MATERIAL, ORTHODONTIC BAND, PREFORMED, ORTHODONTIC
	78 85 86	C	BAND, GASTRIC, IMPLANTED DEVICE, OCCLUSION, TUBAL (TOD), CONTRACEPTIVE EXPANSION BANDS, SCLERAL

BANDAGE	74 80 79 80 89 80 80 80 80 80	D A	BAND, PULMONARY ARTERY ADHESIVE STRIP ADHESIVE TAPE AND ADHESIVE BANDAGE BANDAGE, BINDER, ELASTIC BANDAGE, CAST BANDAGE, GAUZE BANDAGE, PRESSURE BANDAGE, TRACTION FIBER, MEDICAL, ABSORBENT POST-SURGICAL COMPRESSION GARMENTS/BANDAGES
	79	B	BANDAGE, LIQUID
BAR	76	B	BAR, PREFORMED
BARRIER	85 77	C	BARRIER, ABSORBABLE, ADHESION BARRIER, STD, ORAL SEX
BASKET	78	B	BASKET, BILIARY STONE RETRIEVAL
BASSINET	80	A	BASSINET (INFANT BED)
BATH	89 80	A	BATH, HYDRO-MASSAGE BATH, SITZ
	89	B	BATH, PARAFFIN

Keyword	Therapeutic Code	Class	Description
BATTERY	79	B	BATTERY, REPLACEMENT, RECHARGEABLE
	74	D	BATTERY, PACEMAKER
BEAD	79	A	BEADS, HYDROPHILIC, FOR WOUND EXUDATE ABSORPTION
	76	B	STERILIZER, GLASS BEAD
BEAM -LIMITING	90	B	DEVICE, BEAM -LIMITING, X-RAY, DIAGNOSTIC
	90		DEVICE, BEAM -LIMITING, X-RAY, THERAPEUTIC
BED	80	A	BASSINET (INFANT BED)
	80		BED, AC -POWERED ADJUSTABLE HOSPITAL
	80		BED, BIRTHING
	80		BED, HYDRAULIC, ADJUSTABLE HOSPITAL
	80		BED, MANUAL
	89		BED, PATIENT, ROTATION, MANUAL
	80		BED, PEDIATRIC OPEN HOSPITAL
	80		BEDRAIL
	87		UNIT, TRACTION, STATIC BED
	89	B	BED, AIR FLUIDIZED
	89		BED, FLOTATION THERAPY, POWERED
	89		BED, PATIENT, ROTATION, POWERED
	73	C	BED, ROCKING, BREATHING ASSIST
BELL	85	A	BELL, CIRCUMCISION
BELT	89	A	BAND OR BELT, PELVIC SUPPORT
	89		BELT, ABDOMINAL
	87		BELT, LUMBOSACRAL
	89		BELT, PELVIC, TRACTION
	87		BELT, RIB (SUPPORT)
	78		SUPPORT, HERNIA
	78		TRUSS, UMBILICAL
BENDER	87	A	BENDER
BENDING	87	A	INSTRUMENT, BENDING OR CONTOURING
BIFOCAL	86	B	LENS, CONTACT (OTHER MATERIAL) - DAILY
	86		LENS, CONTACT, BIFOCAL
BILIRUBINOMETER	80	B	BILIRUBINOMETER, CUTANEOUS (JAUNDICE METER)
BINDER	80	A	BANDAGE, BINDER, ELASTIC
	80		BINDER, ABDOMINAL

	80 80 87 87		BINDER, BREAST BINDER, PERINEAL BINDER, T BINDER, WRIST
BIOFEEDBACK	84	B	DEVICE, BIOFEEDBACK
BIOMICROSCOPE	86	A	BIOMICROSCOPE, SLIT-LAMP, AC -POWERED
BIOPSY	85 74 78 78 80	B	CURETTE, SUCTION, ENDOMETRIAL (AND ACCESSORIES) DEVICE, BIOPSY, ENDOMYOCARDIAL INSTRUMENT, BIOPSY INSTRUMENT, BIOPSY, MECHANICAL, GASTROINTESTINAL KIT, BIOPSY
BISTOURI	77	B	KNIFE, MYRINGOTOMY (DISPOSABLE)
BISTOURY	77	A	BISTOURY, TRACHEAL
BIT	87 79 76 79 87	B	BIT, DRILL BIT, SURGICAL BUR, DENTAL BUR, SURGICAL, GENERAL & PLASTIC SURGERY BURR, ORTHOPEDIC
BITE	84	A	BLOCK, BITE

Keyword	Therapeutic Code	Class	Description
	76		WAX, DENTAL, INTRAORAL
BLADE	80	A	BLADE, TONGUE (SEE 77KBL)
	87	B	BLADE, BONE CUTTING
	73		BLADE, LARYNGOSCOPE
	79		BLADE, OSTEOTOME AND OTHER CUTTING INSTRUMENTS (DISPOSABLE)
	79		BLADE, SCALPEL (DISPOSABLE)
	79		BLADE, SURGICAL, SAW, GENERAL & PLASTIC SURGERY
	79		RETRACTOR BLADES (DISPOSABLE)
BLANKET	80	A	BLANKET, RESCUE, ALUMINIZED
	80	B	BLANKET, HYPO/HYPERTHERMIA
	74		DEVICE, HYPOTHERMIA (BLANKET, PLUMBING & HEAT EXCHANGER)
BLENDER	73	B	CONTROLLER, OXYGEN (BLENDER)
BLOCK	84	A	BLOCK, BITE
	90	B	BLOCK, BEAM -SHAPING, RADIATION THERAPY
	79	C	RECONSTRUCTION BLOCK, PLASTIC SURGERY
BLOOD	73	B	APPARATUS, AUTOTRANSFUSION
	80		KIT, ADMINISTRATION, BLOOD
	73		KIT, SAMPLING, ARTERIAL BLOOD
	80		KIT, SAMPLING, BLOOD
	74		RESERVOIR, BLOOD, CARDIOPULMONARY BYPASS
	74	D	DEVICE, EMBOLIZATION, ARTERIAL
BLOWER	77	A	BLOWER, POWDER, ENT
BLUE	76	A	ACTIVATOR, ULTRAVIOLET, FOR POLYMERIZATION
BMR	73	B	ANALYZER, METABOLISM
BOARD	79	A	BOARD, ARM (WITH COVER)
	80		BOARD, CARDIOPULMONARY RESUSCITATION
	87		BOARD, SPINE
BOLSTER	79	A	BOLSTER, SUTURE (BUMPER)
BOLT	87	C	WASHER, BOLT, NUT
BONDING	76	B	ADHESIVE, BRACKET AND TOOTH CONDITIONER, RESIN

	76	C	AGENT, TOOTH BONDING, RESIN
BONE	80 87	B	BONE MARROW COLLECTION/TRANSFUSION KIT STIMULATOR, BONE GROWTH, NON -INVASIVE
	89 87 87 76 76 87	C	BONE GRAFT, SUBSTITUTE CAP, BONE CEMENT, BONE GRANULES, TRICALCIUM PHOSPHATE FOR DENTAL BONE REPAIR IMPLANT, ENDOSSEOUS FOR BONE FILLING AND/OR AUGMENTATION STIMULATOR, OSTEOGENESIS, ELECTRIC, BATTERY-OPERATED, INVASIVE
	87	D	GRAFT, BONE
BOTTLE	80 73 80	A	BOTTLE COLLECTION, VACUUM BOTTLE, BLOW BOTTLE, COLLECTION AND TRAP, BREATHING SYSTEM (UNCALIBRATED)
BOUGIE	78 77 77 78	B	BOUGIE, ESOPHAGEAL, AND GASTROINTESTINAL, GASTRO-UROLOGY BOUGIE, ESOPHAGEAL, ENT BOUGIE, EUSTACHIAN DILATOR, URETHRAL
BOW	76	B	FACE BOW
BRACE	87 84 89 89 89	A	BRACE, DRILL HANDPIECE (BRACE), DRILL JOINT, ANKLE, EXTERNAL BRACE JOINT, HIP, EXTERNAL BRACE JOINT, KNEE, EXTERNAL BRACE

Keyword	Therapeutic Code	Class	Description
	89		STIRRUP, EXTERNAL BRACE COMPONENT
BRACKET	76	B	BRACKET, METAL, ORTHODONTIC
	76		BRACKET, ORTHODONTIC, OTHER
	76		BRACKET, PLASTIC, ORTHODONTIC
BREAST	85	A	KIT, BREAST CANCER DETECTION
	85	C	SYSTEM, THERMOGRAPHIC, LIQUID CRYSTAL
	85		THERMOGRAPHIC DEVICE, INFRARED
	79	D	PROSTHESIS, BREAST, INFLATABLE, INTERNAL, SALINE
	79		PROSTHESIS, BREAST, NONINFLATABLE, INTERNAL, SALINE
	79		PROSTHESIS, BREAST, NONINFLATABLE, INTERNAL, SILICONE GEL-FILLED
BREATHING	73	B	ATTACHMENT, BREATHING, POSITIVE END EXPIRATORY PRESSURE
	73		CIRCUIT, BREATHING (W CONNECTOR, ADAPTOR, Y PIECE)
	73		CIRCUIT, BREATHING, VENTILATOR
	73		MONITOR (APNEA DETECTOR), VENTILATORY EFFORT
	73		TUBE, TRACHEOSTOMY
BRIDGE	76	B	CROWN AND BRIDGE, TEMPORARY, RESIN
BROACH	87	A	BROACH
BRONCHOSCOPE	77	A	CLAW, FOREIGN BODY, BRONCHOSCOPE (NON-RIGID)
	77	B	BRONCHOSCOPE (FLEXIBLE OR RIGID)
	77		BRONCHOSCOPE, FLEXIBLE
BRUSH	76	A	BRUSH, DENTAL PLATE (DENTURE)
	76		BRUSH, GUM (GINGIVAL)
	86		BRUSH, HAIDINGER, (INCLUDING MACULAR INTEGRITY)
	87		BRUSH, INTRAMEDULLARY
	79	B	BRUSH, BIOPSY, GENERAL & PLASTIC SURGERY
	78		BRUSH, CYTOLOGY, FOR ENDOSCOPE
	85		BRUSH, ENDOMETRIAL
	86		BRUSH, OPHTHALMIC
BUBBLE	78	C	DETECTOR, AIR OR FOAM
	78		INTRAGASTRIC IMPLANT FOR MORBID OBESITY
BUCKY	90	A	TABLE, RADIOGRAPHIC, TILTING
	90	B	GRID, RADIOGRAPHIC
BULB	78	B	BULB, INFLATION, FOR ENDOSCOPE

	80		IRRIGATING SYRINGE
BULKING	78	C	INJECTABLE BULKING AGENT FOR GASTROENTEROLOGY
BUMPER	79	A	BOLSTER, SUTURE (BUMPER)
BUNDLE	74	D	SUCTION ABLATION CATHETER SYSTEM (SAC)
BURN	79	A	SHEET, BURN
	80	B	BURN KIT
BURNISHER	76	A	BURNISHER, OPERATIVE
BURR	86	A	BURR, CORNEAL, MANUAL
	76	B	BUR, DENTAL
	79		BUR, SURGICAL, GENERAL & PLASTIC SURGERY
	86		BURR, CORNEAL, AC -POWERED
	86		BURR, CORNEAL, BATTERY-POWERED
	87		BURR, ORTHOPEDIC
	76		DRILL, DENTAL, INTRAORAL
	84		POWERED COMPOUND DRILLS, BURRS, TREPHINES & ACCESSORIES
	84		POWERED SIMPLE DRILLS, BURRS, TREPHINES & ACCESSORIES
BUTTON	79	A	BUTTON, SURGICAL
	77	B	BUTTON, NASAL SEPTUM
	73		BUTTON, TRACHEOSTOMY TUBE
BUTTRESS	79	A	RETENTION DEVICE, SUTURE

Keyword	Therapeutic Code	Class	Description
CABINET	89	B	CABINET, MOIST STEAM
CABLE	89	B	CABLE
	74		CABLE AND ADAPTER, DEFIBRILLATOR
	80		CABLE, ELECTRIC
	89		CABLE, ELECTRODE
	79		CABLE, ELECTROSURGICAL UNIT
	74		CABLE, TRANSDUCER AND ELECTRODE, PATIENT, (INCLUDING CONNECTOR)
	84		CABLE/LEAD, EEG
	84		CABLE/LEAD, EMG
	84		CABLE/LEAD, TENS
	76		CONTROLLER, FOOT, HANDPIECE AND CORD
CAGE	89	A	CAGE, KNEE
CALCULATOR	73	B	CALCULATOR, PULMONARY FUNCTION DATA
	73		CALCULATOR, PULMONARY FUNCTION INTERPRETATOR (DIAGNOSTIC)
CALIBRATION	73	B	GAS, CALIBRATION (SPECIFIED CONCENTRATION)
	90		SOURCE, CALIBRATION, SEALED, NUCLEAR
CALIBRATOR	73	B	CALIBRATOR ANESTHESIA UNIT
	80		CALIBRATOR, BLOOD GAS
	90		CALIBRATOR, DOSE, RADIONUCLIDE
	73		CALIBRATOR, PRESSURE TRANSDUCER
	73		CALIBRATOR, PRESSURE, GAS
	73		CALIBRATOR, RESPIRATORY THERAPY UNIT
	86		CALIBRATOR, TONOMETER
	73		CALIBRATOR, VENTILATOR
CALIPER	86	A	CALIPER, OPHTHALMIC
	87		CALIPER, ORTHOPEDIC
	80		CALIPER, SKINFOLD
	79		TAPE, MEASURING, RULERS AND CALIPERS
CAMERA	79	A	CAMERA, STILL, ENDOSCOPIC
	79		CAMERA, STILL, SURGICAL
	79		CAMERA, TELEVISION, MICROSURGICAL, WITHOUT AUDIO
	79		CAMERA, TELEVISION, SURGICAL, WITHOUT AUDIO
	80		CAMERA, VIDEO
	79		SURGICAL CAMERAS AND ACCESSORIES
	79	B	CAMERA, CINE, ENDOSCOPIC, WITHOUT AUDIO (INVASIVE)
	90		CAMERA, FOCAL SPOT, RADIOGRAPHIC

	86 90 79 90		CAMERA, OPHTHALMIC, AC -POWERED CAMERA, SCINTILLATION (GAMMA) CAMERA, TELEVISION, ENDOSCOPIC, WITHOUT AUDIO (INVASIVE) CAMERA, X -RAY, FLUOROGRAPHIC, CINE OR SPOT
	90	C	CAMERA, MULTI-IMAGE
CAMPIMETER	86 86 86	A	CAMPIMETER, STEREO, BATTERY-POWERED SCREEN, TANGENT, AC -POWERED (CAMPIMETER) SCREEN, TANGENT, FELT (CAMPIMETER)
CANALICULUS	86	B	SYSTEM, INTUBATION, LACRIMAL
CANE	89	A	CANE
CANNULA	79 86	A	CANNULA, EAR CANNULA, EYE, CYCLODIALYSIS
	78 74 74 74 74	B	CANNULA AND TROCAR, SUPRAPUBLIC, NON-DISPOSABLE CANNULA, AORTIC CANNULA, ARTERIAL CANNULA, CATHETER CANNULA, CORONARY ARTERY

Keyword	Therapeutic code	Class	Description
	87		CANNULA, DRAINAGE, ARTHROSCOPY
	86		CANNULA, EYE, LACRIMAL
	78		CANNULA, HEMODIALYSIS
	79		CANNULA, INJECTION
	85		CANNULA, INSUFFLATION, UTERINE (AND ACCESSORIES)
	73		CANNULA, NASAL OXYGEN, CONTINUOUS POSITIVE AIRWAY PRESSURE
	73		CANNULA, NASAL, OXYGEN
	86		CANNULA, OPHTHALMIC
	79		CANNULA, SINUS
	85		CANNULA, SUCTION, UTERINE
	79		CANNULA, SURGICAL, GENERAL & PLASTIC SURGERY
	74		CANNULA, VENA CAVA
	74		CANNULA, VENOUS
	84		CANNULA, VENTRICULAR
	79		CANNULAE, BRONCHIAL
	79		INSTRUMENT, SURGICAL, ENDOSCOPIC/LAPAROSCOPIC (NON-POWERED)
	79		SURGICAL INSTRUMENT WITH SUCTION CANNULA
	85		SYSTEM, CANNULA, INTRAFALLOPIAN
	78	C	CANNULA, A-V SHUNT
	74	D	CATHETER, CORONARY PERFUSION
CANNULATOR	79	B	CANNULAT OR, LYMPH DUCT
CAP	79	A	CAP, SURGICAL
	80		CAP, TIP, SYRINGE
	85	B	CONTRACEPTIVE CERVICAL CAP
	80		SITE, SAMPLING/INJECTION, ASEPTIC
	87	C	CAP, BONE
	74		CAP, LEAD, PACEMAKER
CAPNOGRAPH	73	C	ANALYZER, GAS, CARBON-DIOXIDE, GASEOUS PHASE
CAPSULE	76	A	CAPSULE, DENTAL, AMALGAM
CARDIAC	74	C	CARDIAC OUTPUT UNIT, DIRECT FICK
	74		CARDIAC OUTPUT UNIT, DYE DILUTION
	74		CARDIAC OUTPUT UNIT, INDICATOR DILUTION (THERMAL)
	90		RADIOGRAPHIC/FLUROSCOPIC UNIT, ANGIOGRAPHIC, DIGITAL
CARDIOGRAPH	74	B	PLETHYSMOGRAPH, IMPEDANCE

CARDIOTACHOMETER	85 74	C	CARDIOTACHOMETER, FETAL, WITH SENSORS MONITOR, CARDIAC (INCL. CARDIOTACHOMETER & RATE ALARM)
CARRIER	76 79 78 77	A	CARRIER, AMALGAM, OPERATIVE CARRIER, LIGATURE CARRIER, SPONGE, ENDOSCOPIC SOURCE, CARRIER, FIBREOPTIC LIGHT
CARTILAGE	87	C	IMPLANT, CARTILAGE, FOR ARTICULAR CARTILAGE REPAIR
CARTON	86	A	GRID, AMSLER
CARVER	76 76	A	CARVER, DENTAL AMALGAM, OPERATIVE CARVER, WAX, DENTAL
CASSETTE	90	A	CASSETTE, RADIOGRAPHIC FILM
CAST	89 87 87 87	A	BANDAGE, CAST CAST COMPONENT, CAST STOCKINETTE
CASTING	76	A	RING, DENTAL (CASTING)
CAT	90	C	SCANNER, COMPUTED TOMOGRAPH Y, X-RAY
CATHETER	77 78	A	CATHETER, NASOPHARYNGEAL DEVICE, INCONTINENCE, UROSHEATH TYPE

Keyword	Therapeutic Code	Class	Description
	87		CANNULA, DRAINAGE, ARTHROSCOPY
	86		CANNULA, EYE, LACRIMAL
	78		CANNULA, HEMODIALYSIS
	79		CANNULA, INJECTION
	85		CANNULA, INSUFFLATION, UTERINE (AND ACCESSORIES)
	73		CANNULA, NASAL OXYGEN, CONTINUOUS POSITIVE AIRWAY PRESSURE
	73		CANNULA, NASAL, OXYGEN
	86		CANNULA, OPHTHALMIC
	79		CANNULA, SINUS
	85		CANNULA, SUCTION, UTERINE
	79		CANNULA, SURGICAL, GENERAL & PLASTIC SURGERY
	74		CANNULA, VENA CAVA
	74		CANNULA, VENOUS
	84		CANNULA, VENTRICULAR
	79		CANNULAE, BRONCHIAL
	79		INSTRUMENT, SURGICAL, ENDOSCOPIC/LAPAROSCOPIC (NON-POWERED)
	79		SURGICAL INSTRUMENT WITH SUCTION CANNULA
	85		SYSTEM, CANNULA, INTRAFALLOPIAN
	78	C	CANNULA, A-V SHUNT
	74	D	CATHETER, CORONARY PERFUSION
CANNULATOR	79	B	CANNULAT OR, LYMPH DUCT
CAP	79	A	CAP, SURGICAL
	80		CAP, TIP, SYRINGE
	85	B	CONTRACEPTIVE CERVICAL CAP
	80		SITE, SAMPLING/INJECTION, ASEPTIC
	87	C	CAP, BONE
	74		CAP, LEAD, PACEMAKER
CAPNOGRAPH	73	C	ANALYZER, GAS, CARBON-DIOXIDE, GASEOUS PHASE
CAPSULE	76	A	CAPSULE, DENTAL, AMALGAM
CARDIAC	74	C	CARDIAC OUTPUT UNIT, DIRECT FICK
	74		CARDIAC OUTPUT UNIT, DYE DILUTION
	74		CARDIAC OUTPUT UNIT, INDICATOR DILUTION (THERMAL)
	90		RADIOGRAPHIC/FLUROSCOPIC UNIT, ANGIOGRAPHIC, DIGITAL
CARDIOGRAPH	74	B	PLETHYSMOGRAPH, IMPEDANCE

CARDIOTACHOMETER	85 74	C	CARDIOTACHOMETER, FETAL, WITH SENSORS MONITOR, CARDIAC (INCL. CARDIOTACHOMETER & RATE ALARM)
CARRIER	76 79 78 77	A	CARRIER, AMALGAM, OPERATIVE CARRIER, LIGATURE CARRIER, SPONGE, ENDOSCOPIC SOURCE, CARRIER, FIBREOPTIC LIGHT
CARTILAGE	87	C	IMPLANT, CARTILAGE, FOR ARTICULAR CARTILAGE REPAIR
CARTON	86	A	GRID, AMSLER
CARVER	76 76	A	CARVER, DENTAL AMALGAM, OPERATIVE CARVER, WAX, DENTAL
CASSETTE	90	A	CASSETTE, RADIOGRAPHIC FILM
CAST	89 87 87 87	A	BANDAGE, CAST CAST COMPONENT, CAST STOCKINETTE
CASTING	76	A	RING, DENTAL (CASTING)
CAT	90	C	SCANNER, COMPUTED TOMOGRAPH Y, X-RAY
CATHETER	77 78	A	CATHETER, NASOPHARYNGEAL DEVICE, INCONTINENCE, UROSHEATH TYPE

Keyword	Therapeutic Code	Class	Description
	78 77		INSTRUMENT, CATHETER, PUNCH SET, FILLIFORM, ESTACHIAN
	86 74 78 80 74 74 79 78 78 78 73 74	B	BALLOON CATHETER FOR RETINAL REATTACHMENT CANNULA, CATHETER CATHETER (GASTRIC, COLONIC, ETC.), IRRIGATION AND ASPIRATION CATHETER AND TIP, SUCTION CATHETER, ANGIOGRAPHIC CATHETER, ARTERIAL CATHETER, BALLOON TYPE CATHETER, BALLOON, DILATATION, VESSEL CATHETER, BARTHOLIN GLAND CATHETER, BILIARY, GENERAL & PLASTIC SURGERY (SHORT-TERM) CATHETER, BRONCHOGRAPHY CATHETER, CANNULA AND TUBING, VASCULAR, CARDIOPULMONARY BYPASS

	79		CATHETER, CHOLANGIOGRAPHY
	73		CATHETER, CONDUCTION, ANESTHETIC
	74		CATHETER, CONTINUOUS FLUSH
	79		CATHETER, CONTINUOUS IRRIGATION
	78		CATHETER, COUDE
	78		CATHETER, DEPEZZER
	78		CATHETER, DOUBLE LUMEN FEMALE URETHROGRAPHIC
	85		CATHETER, EPIDURAL
	77Q		CATHETER, ESOPHAGEAL BALLOON
	79		CATHETER, EUSTACHIAN, GENERAL & PLASTIC SURGERY
	74		CATHETER, GUIDING
	78		CATHETER, HEMODIALYSIS, NON-IMPLANTED
	78		CATHETER, HEMOSTATIC
	79		CATHETER, INFUSION
	80		CATHETER, INTRAMUSCULAR, PRESSURE-MONITORING
	85		CATHETER, INTRAUTERINE AND INTRODUCER
	74		CATHETER, INTRAVASCULAR, OCCLUDING, TEMPORARY
	80		CATHETER, INTRAVASCULAR, SHORT TERM
	74		CATHETER, INTRAVENOUS
	79		CATHETER, IRRIGATION
	78		CATHETER, JEJUNOSTOMY
	78		CATHETER, LIGHT, FIBEROPTIC, GLASS, URETERAL
	78		CATHETER, MALECOT
	79		CATHETER, MULTIPLE LUMEN
	73		CATHETER, NASAL, OXYGEN
	78		CATHETER, NEPHROSTOMY
	73		CATHETER, OXYGEN, TRACHEAL
	78		CATHETER, PERITONEAL DIALYSIS, SINGLE USE
	90		CATHETER, RADIOGRAPHIC (NON-VASCULAR)
	78		CATHETER, RECTAL
	78		CATHETER, RETENTION TYPE
	78		CATHETER, RETENTION TYPE, BALLOON
	78		CATHETER, RETENTION, BARIUM ENEMA WITH BAG
	85		CATHETER, SALPINGOGRAPHY
	78		CATHETER, SINGLE NEEDLE HEMODIALYSIS
	78		CATHETER, STRAIGHT
	78		CATHETER, SUBCLAVIAN
	73		CATHETER, SUCTION, TRACHEOBRONCHIAL
	78		CATHETER, SUPRAPUBIC (AND ACCESSORIES)

Keyword	Therapeutic Code	Class	Description
	80		CATHETER, UMBILICAL ARTERY

	78		CATHETER, UPPER URINARY TRACT
	78		CATHETER, URETERAL DISPOSABLE (X-RAY)
	78		CATHETER, URETERAL, GASTRO-UROLOGY
	78		CATHETER, URETHRAL
	78		CATHETER, URETHRAL, DIAGNOSTIC
	78		CATHETER, URETHROGRAPHIC, MALE
	85		CHORIONIC VILLUS SAMPLING CATHETER
	74		DEVICE, PERCUTANEOUS RETRIEVAL
	79		SCLEROTHERAPY NEEDLE/CATHETER
	78		SYSTEM, WATER JET CATHETER, RENAL
	78	C	CATHETER, HEMODIALYSIS (LONG-TERM)
	80		CATHETER, PERCUTANEOUS, INTRAVASCULAR, LONG TERM
	80		CATHETER, PERCUTANEOUS, LONG -TERM, INTRASPINAL
	78		CATHETER, PERITONEAL, LONG-TERM INDWELLING
	80		PORT & CATHETER, IMPLANTED, SUBCUTANEOUS, INTRAVASCULAR
	80		PORT & CATHETER, SUBCUTANEOUS, INTRASPINAL
	80		PORT AND CATHETER, INFUSION, IMPLANTED, SUBCUTANEOUS,
	74		SYSTEM, CATHETER CONTROL, STEERABLE
	74	D	CATHETER, ANGIOPLASTY, PERIPHERAL, TRANSLUMINAL
	74		CATHETER, CARDIAC THERMODILUTION
	74		CATHETER, CARDIOVASCULAR
	74		CATHETER, CARDIOVASCULAR, BALLOON TYPE
	84		CATHETER, CEREBROSPINAL
	74		CATHETER, CORONARY PERFUSION
	74		CATHETER, CORONARY, ATHERECTOMY
	74		CATHETER, ELECTRODE RECORDING, OR PROBE, ELECTRODE RECORDING
	74		CATHETER, EMBOLECTOMY
	74		CATHETER, FLOW D IRECTED
	90		CATHETER, IMAGING, ULTRASONIC
	74		CATHETER, INTRA- AORTIC BALLOON
	74		CATHETER, INTRACARDIAC MAPPING, HIGH DENSITY ARRAY
	84		CATHETER, INTRAVASCULAR OCCLUDING
	74		CATHETER, INTRAVASCULAR, DIAGNOSTIC
	74		CATHETER, INTRAVENOUS, CENTRAL
	74		CATHETER, LASER, MYOPLASTY, CORONARY
	74		CATHETER, OCCLUDING, CARDIOVASCULAR, IMPLANTABLE
	74		CATHETER, OCCLUSION
	74		CATHETER, OXIMETER, FIBEROPTIC
	7D4		CATHETER, PERCUTANEOUS
	74		CATHETER, PERCUTANEOUS (VALVULOPLASTY)
	74		CATHETER, PERFUSION
	74		CATHETER, PERICARDIUM DRAINAGE
	74		CATHETER, PERIPHERAL, ATHERECTOMY
	74		CATHETER, SEPTOSTOMY
	74		CATHETER, STEERABLE
	74		CATHETER, THROMBECTOMY
	74		CATHETER, TRANSLUMINAL, CORONARY ANGIOPLASTY, PERCUTANEOUS
	84		CATHETER, VENTRICULAR
	74		KIT, BALLOON REPAIR, CATHETER
	74		LEAD, PACEMAKER (CATHETER)
	84		SHUNT, CENTRAL NERVOUS SYSTEM AND COMPONENTS
	74		SUCTION ABLATION CATHETER SYSTEM (SAC)

Keyword	Therapeutic Code	Class	Description
CATHETERIZATION	74	B	INJECTOR AND SYRINGE, ANGIOGRAPHIC
	78		TRAY, CATHETERIZATION, STERILE URETHRAL, WITH OR WITHOUT CATHETER
	74	D	KIT, CATHETERIZATION, CARDIAC
CELL	73	B	APPARATUS, AUTOTRANSFUSION
	73		SENSOR, OXYGEN
CEMENT	78	A	CEMENT, STOMAL APPLIANCE, OSTOMY
	87	C	CEMENT, BONE
	76		CEMENT, DENTAL
CEPHALOMETER	76	A	CEPHALOMETER
CERAMIC	76	B	CERAMIC, PROSTHODONTIC APPLIANCES
CHAIR	85	A	CHAIR, BIRTHING
	76		CHAIR, DENTAL
	76		CHAIR, DEN TAL, WITH OPERATIVE UNIT
	78		CHAIR, DIALYSIS, POWERED, WITHOUT SCALES
	78		CHAIR, DIALYSIS, UNPOWERED, WITHOUT SCALES
	80		CHAIR, EXAMINATION AND TREATMENT
	80		CHAIR, GERIATRIC
	84		CHAIR, NEUROSURGICAL
	76		CHAIR, OPERATIVE, WITHOUT UNIT
	86		CHAIR, OPHTHALMIC, AC -POWERED
	86		CHAIR, OPHTHALMIC, MANUAL
	90		CHAIR, PNEUMOENCEPHALOGRAPHIC, RADIOGRAPHIC
	87		CHAIR, PODIATRIC
	73		CHAIR, POSTURE, FOR CARDIAC AND PULMONARY TREATMENT
	80		CHAIR, REHABILITATION
CHAMBER	85	C	CHAMBER, DECOMPRESSION, ABDOMINAL
	73		CHAMBER, HYPERBARIC
CHANGER	90	A	CHANGER, RADIOGRAPHIC FILM/CASSETTE
CHARGER	74	C	CHARGER, PACEMAKER
CHART	86	A	CHART, VISUAL ACUITY
CHIN	79	C	PROSTHESIS, CHIN, INTERNAL
CHISEL	79	A	CHISEL (OSTEOTOME)
	76		CHISEL, BONE, SURGICAL

	79 77 79 87 79		CHISEL, MASTOID CHISEL, MIDDLE-EAR CHISEL, NASAL CHISEL, ORTHOPEDIC CHISEL, SURGICAL, MANUAL
CHLORIDIMETER	78	B	CHLORIDIMETER
CHOLEDOCHOSCOPE	78	B	CHOLEDOCHOSCOPE, FLEXIBLE OR RIGID
CHRONAXIMETER	89	B	CHRONAXIMETER
CIRCUIT	73 73 73	B	CIRCUIT, BREATHING (W CONNECTOR, ADAPTOR, Y PIECE) CIRCUIT, BREATHING, VENTILATOR YOKE ASSEMBLY, MEDICAL GAS
CIRCULATOR	73	B	CIRCULATOR, BREATHING CIRCUIT
CIRCULATORY	74	D	DEVICE, BYPASS, VENTRICULAR (ASSIST)
CIRCUMCISION	85	B	KIT, CIRCUMCISION, DISPOSABLE TRAY
CLAMP	79 74 79 77 79 78	A	CLAMP, ANASTOMOSIS CLAMP, AORTA CLAMP, BONE CLAMP, BRONCHUS CLAMP, BULLDOG CLAMP, CANNULA
Keyword	Therapeutic Code	Class	Description
	85 86 78 78 78 86 78 77 79 78 76 79 80 85 85 78 79 84		CLAMP, CIRCUMCISION CLAMP, EYELID, OPHTHALMIC CLAMP, HEMORRHOIDAL CLAMP, INTESTINAL CLAMP, LINE CLAMP, MUSCLE, OPHTHALMIC CLAMP, NON-ELECTRICAL CLAMP, OSSICLE HOLDING CLAMP, PATENT DUCTUS CLAMP, PENILE CLAMP, RUBBER DAM CLAMP, SURGICAL, GENERAL & PLASTIC SURGERY CLAMP, TUBING CLAMP, UMBILICAL CLAMP, UTERINE FORCEPS, INTESTINAL (CLAMPS) HEMOSTAT HOLDER, HEAD, NEUROSURGICAL (SKULL CLAMP)
	74 76	B	CLAMP, VASCULAR CLAMP, WIRE, ORTHODONTIC

	79		INSTRUMENT GUARD
	78	C	CLAMP, TUBING, BLOOD, AUTOMATIC
CLASP	76 76	B	CLASP, PREFORMED CLASP, WIRE
CLAW	77	A	CLAW, FOREIGN BODY, BRONCHOSCOPE (NON-RIGID)
CLEANER	86	B	CLEANER, ULTRASONIC, CONTACT LENS
CLEANING	86	B	ACCESSORIES TO CONTACT LENSES - CLEANING AND WETTING AGENTS
CLEIDOCLAST	85	A	INSTRUMENT, DESTRUCTIVE, FETAL, OBSTETRIC
CLIP	86 73	A	CLIP, LENS, TRIAL, OPHTHALMIC CLIP, NOSE
	79 84 79	B	CLIP, REMOVABLE (SKIN) CLIP, SCALP CLIP, WOUND
	79 79 79 79 86 85	C	CLIP, HEMOSTATIC CLIP, IMPLANTABLE CLIP, LIGATING ABSORBABLE CLIP, SUTURE CLIP, TANTALUM, OPHTHALMIC DEVICE, OCCLUSION, TUBAL (TOD), CONTRACEPTIVE
	84 84 74 74	D	CLIP, ANEURYSM CLIP, IMPLANTED MALLEABLE CLIP, VASCULAR CLIP, VENA CAVA
CLIPPER	80	A	KIT, PREP
COAGULATION	79	C	ELECTROSURGICAL CUTTING & COAGULATION DEVICE & ACCESSORIES
COAGULATOR	85 85 85 78	B	COAGULATOR, LAPAROSCOPIC, UNIPOLAR (AND ACCESSORIES) COAGULATOR-CUTTER, ENDOSCOPIC, BIPOLAR (AND ACCESSORIES) COAGULATOR-CUTTER, ENDOSCOPIC, UNIPOLAR (AND ACCESSORIES) ELECTRODE, FLEXIBLE SUCTION COAGULATOR
COATING	76	B	COATING, DENTURE HYDROPHILIC, RESIN
	76	C	COATING, FILLING MATERIAL, RESIN
COCHLEAR	77	C	COCHLEAR IMPLANT
COLD	89	A	PACK, COLD, CHEMICAL

Keyword	Therapeutic Code	Class	Description
	89 89		PACK, HOT OR COLD, DISPOSABLE PACK, HOT OR COLD, REUSABLE
	89	B	DEVICE, CRYOTHERAPY/COMPRESSION
	86	C	UNIT, CRYOTHERAPY, OPHTHALMIC
COLIC	80	B	DEVICE, COLIC TREATMENT
COLLAGEN	78 76	C	INJECTABLE BULKING AGENT FOR GASTROENTEROLOGY PASTE, INJECTABLE FOR VOCAL CORD AUGMENTATION
	79 89	D	COLLAGEN IMPLANTS FOR NON- AESTHETIC USE IMPLANT, RESORBABLE BOVINE COLLAGEN, MENISCAL REPAIR
COLLAR	80 76 89	A	COLLAR, EXTRICATION COLLAR, GINGIVAL ORTHOSIS, CERVICAL
COLLECTION	80 78	A	KIT, MID -STREAM COLLECTION KIT, URINARY DRAINAGE COLLECTION, FOR INDWELLING CATHETER
	80 74	B	BONE MARROW COLLECTION/TRANSFUSION KIT KIT, BLOOD COLLECTION, PHLEBOTOMY
COLLECTOR	78 78	A	COLLECTOR, OSTOMY COLLECTOR, URINE, PEDIATRIC, FOR INDWELLING CATHETER
COLLIMATOR	76	A	ALIGNER, BEAM, X-RAY
	90 90 90	B	COLLIMATOR, AUTOMATIC, RADIOGRAPHIC COLLIMATOR, MANUAL, RADIOGRAPHIC COLLIMATOR, THERAUPEUTIC X-RAY, OTHER
COLONOSCOPE	78 78	B	COLONOSCOPE, GASTRO-UROLOGY COLONOSCOPE, GENERAL & PLASTIC SURGERY
COLOSTOMY	78	A	OSTOMY APPLIANCE (ILEOSTOMY, COLOSTOMY)

	78 78		PROTECTOR, OSTOMY ROD, COLOSTOMY
COLPOMICCROSCOPE	85	B	COLPOSCOPE (AND COLPOMICROSCOPE)
COLUMN	80	B	COLUMN, LIFE SUPPORT (ELECTRICAL/GAS)
	84	D	TOTALLY IMPLANTED SPINAL CORD STIMULATOR FOR PAIN RELIEF
COMMUNICATION	90	B	RADIOGRAPHIC PICTURE ARCHIVING/COMMUNICATION SYSTEM (PACS)
COMPOSITE	76	C	MATERIAL, TOOTH SHADE, RESIN
COMPRESSION	74 87	A	DEVICE, COMPRESSION, ANTIHEMATOMA INSTRUMENT, COMPRESSION
	74 89	B	COMPRESSION UNIT, INTERMITTENT (ANTI-EMBOLISM PUMP) DEVICE, CRYOTHERAPY/COMPRESSION
COMPRESSOR	86 74	A	COMPRESSOR, ORBITAL RESUSCITATOR, CARDIAC, MECHANICAL
	73	B	COMPRESSOR, AIR, PORTABLE
COMPUTER	77 74 74 90 73 80 73 90 74	B	COMPUTER, AUDIOMETRY COMPUTER, DIAGNOSTIC, PRE-PROGRAMMED, SINGLE FUNCTION COMPUTER, DIAGNOSTIC, PROGRAMMABLE COMPUTER, NUCLEAR MEDICINE COMPUTER, OXYGEN -UPTAKE COMPUTER, PATIENT DATA MANAGEMENT COMPUTER, PULMONARY FUNCTION LABORATORY COMPUTER, RADIOGRAPHIC IMAGE ANALYSIS COMPUTER, STRESS EXERCISE
	74 74 74 84 74	C	CARDIAC OUTPUT UNIT, DYE DILUTION CARDIAC OUTPUT UNIT, INDICATOR DILUTION (THERMAL) COMPUTER, BLOOD PRESSURE COMPUTER, BRAIN MAPPING COMPUTER, CARDIAC CATHETERIZATION
Keyword	Therapeutic Code	Class	Description
	90 90		COMPUTER, ULTRASOUND SYSTEM, MANAGEMENT, RADIOTHERAPY
CONDENSER	76	A	CONDENSER, AMALGAM AND FOIL, OPERATIVE
	73	B	CONDENSER, HEAT AND MOISTURE (ARTIFICIAL NOSE)

	90	C	GENERATOR, RADIOGRAPHIC, CAPACITOR DISCHARGE
CONDITIONER	76 74 74 84	B	ADHESIVE, BRACKET AND TOOTH CONDITIONER, RESIN AMPLIFIER AND SIGNAL CONDITIONER, BIOPOTENTIAL AMPLIFIER AND SIGNAL CONDITIONER, TRANSDUCER SIGNAL CONDITIONER, SIGNAL, PHYSIOLOGICAL
	76	C	SEALANT, PIT AND FISSURE, AND CONDITIONER, RESIN
CONDOM	85 85 85 80	B	CONDOMWITH NONOXYNOL-9 MICRO-CONDOM PROPHYLACTIC (CONDOM) - LATEX SHEATH, SEMINAL COLLECTION
	85 85 85	C D	CONDOM, NON-LATEX POUCH, INTRAVAGINAL (FEMALE CONDOM) CONDOM - NATURAL MEMBRANE
CONDUCTIVITY	78	B	SOLUTION-TEST STANDARD CONDUCTIVITY, DIALYSIS
CONE	90	B	CONE, RADIOGRAPHIC
CONFORMER	86	B	CONFORMER, OPHTHALMIC
CONNECTOR	78	A	CONNECTOR, URETERAL CATHETER
	73 78 79 78 74 80 78	B	CONNECTOR, AIRWAY (EXTENSION) CONNECTOR, BLOOD TUBING, INFUSION "T" CONNECTOR, CATHETER CONNECTOR, SHUNT CONNECTOR, TUBING, BLOOD TUBING, CONNECTOR/ADAPTOR TUBING, DIALYSATE (AND CONNECTOR)
CONSOLE	74	C	CONSOLE, HEART LUNG MACHINE, CARDIOPULMONARY BYPASS
CONTAINER	80 80	B	CONTAINER, EVACUATED CONTAINER, I.V.
CONTOURING	87 76	A	INSTRUMENT, BENDING OR CONTOURING INSTRUMENT, CONTOURING, MATRIX, OPERATIVE
CONTRACEPTIVE	85 85 85 85 85	B	CONTRACEPTIVE CERVICAL CAP CONTRACEPTIVE SPONGE CONTRACEPTIVE, VAGINAL (FOAM, GEL, SUPPOSITORY) DIAPHRAGM, CONTRACEPTIVE (AND ACCESSORIES) PESSARY, VAGINAL
	85 85	C	DEVICE, OCCLUSION, TUBAL (TOD), CONTRACEPTIVE INTRAUTERINE DEVICE, CONTRACEPTIVE (IUD) AND INTRODUCER
CONTRACTOR	79	A	CONTRACTOR, SURGICAL
CONTROLLER	80 74	B	APPARATUS, INFUSION, MANUAL CONTROL, PUMP SPEED, CARDIOPULMONARY BYPASS

	76		CONTROLLER, FOOT, HANDPIECE AND CORD
	78		CONTROLLER, HEMODIALYSIS UNIT, SINGLE NEEDLE
	80		CONTROLLER, INTRAVASCULAR, INFUSION, ELECTRONIC
	73		CONTROLLER, OXYGEN (BLENDER)
	74		CONTROLLER, TEMPERATURE, CARDIOPULMONARY BYPASS
	74		DEVICE, INFLATION CONTROL FOR DILATION BALLOONS
	74		GAS CONTROL UNIT, CARDIOPULMONARY BYPASS
	74		SUCTION CONTROL, INTRACARDIAC, CARDIOPULMONARY BYPASS
	80	D	CLOSED -LOOP BLOOD GLUCOSE CONTROLLER
CONVERTER	78	C	CONVERTER, HEMODIALYSIS UNIT, SINGLE PASS

Keyword	Therapeutic Code	Class	Description
COOLING	74	B	UNIT, COOLING, CARDIAC
CORD	78	B	CORD, ELECTRIC, FOR ENDOSCOPE
CORKSCREW	87	A	CORKSCREW
	87	B	INSTRUMENT, SURGICAL, ORTHOPEDIC, AC -POWERED MOTOR AND ACCESSORY/ATTACHMENT
CORRECTOR	90	B	RESPIRATORY MOTION CORRECTOR
COT	80	B	FINGER COT
COTTON	80	A	COTTON BALL
	76		COTTON, ROLL
	80		SWABS, COTTON
	80		TAPE, COTTON
	84	B	PADDIE, COTTONOID
COUNTER	90	B	COUNTER, WHOLE BODY, NUCLEAR
	86		PROBE AND COUNTER, ISOTOPE, FOR PHOSPHORUS CB
COUNTER -PULSATING	74	B	COUNTER-PULSATING DEVICE, EXTERNAL
COUNTERBORE	87	A	COUNTERBORE, ORTHOPEDIC
COUNTERSINK	87	A	COUNTERSINK
COUPLER	74	C	ANASTOMOSIS DEVICE FOR MICROVASCULAR SURGERY
COVER	89	A	COVER, LIMB
	80		COVER, MATTRESS (MEDICAL PURPOSES)
	79		COVER, SHOE, OPERATING ROOM

	79		SHOE AND SHOE COVER, CONDUCTIVE
	79 79	B	INSTRUMENT GUARD PROTECTOR, TISSUE, HYDROPHILIC POLYMER
	84 74	C	COVER, BURR HOLE PACEMAKER COVER
CPM	89	B	EXERCISER, PASSIVE, NON-MEASURING
CPR	74 80	A	AID, CARDIOPULMONARY RESUSCITATION BOARD, CARDIOPULMONARY RESUSCITATION
CRANIOCLAST	85	A	INSTRUMENT, DESTRUCTIVE, FETAL, OBSTETRIC
CRANIOTOME	84	A	CRANIOTOME
CRANIOTRIBE	85	A	INSTRUMENT, DESTRUCTIVE, FETAL, OBSTETRIC
CRIB	80	A	BED, PEDIATRIC OPEN HOSPITAL
CRICO THYROTOMY	73	B	KIT, CRICOTHYROTOMY
CRIMPER	87 77	A	CRIMPER, PIN CRIMPER, WIRE, ENT
CROCHETS	79	A	HOOK, SKIN
CROWN	76 76	B	CERAMIC, PROSTHODONTIC APPLIANCES CROWN AND BRIDGE, TEMPORARY, RESIN
	76	C	CROWN, PREFORMED
CRUSHER	79 78	A	CRUSHER, CARTILAGE CRUSHER, SPUR, COLOSTOMY
CRUTCH	89	A	CRUTCH
CRYOSURGICAL	86	A	EXTRACTOR, CATARACT
	86 79	C	CRYOPHTHALMIC UNIT CRYOSURGICAL UNIT & ACCESSORIES
CRYOTHERAPY	89	B	DEVICE, CRYOTHERAPY/COMPRESSION
	86	C	UNIT, CRYOTHERAPY, OPHTHALMIC
CSF	84	D	CATHETER, CEREBROSPINAL
CUFF	74 80 74 73 74	B	CUFF, BLOOD PRESSURE CUFF, CATHETER, ANTIMICROBIAL CUFF, INFLATION CUFF, TRACHEAL TUBE, INFLATABLE SYSTEM, MEASUREMENT, BLOOD PRESSURE, NON-INVASIVE

Keyword	Therapeutic Code	Class	Description

	84	C	CUFF, NERVE
CUIRASS	73	C	VENTILATOR, EXTERNAL BODY, NEGATIVE PRESSURE, ADULT (CUIRASS)
CULDOSCOPE	85	B	CULDOSCOPE (AND ACCESSORIES)
CUP	76	A	CUP, PROPHYLAXIS
	85	B	CUP, MENSTRUAL
CURETTE	79	B	CURETTE (DISPOSABLE)
	77		CURETTE, ADENOID (DISPOSABLE)
	79		CURETTE, DERMAL (DISPOSABLE)
	77		CURETTE, EAR (DISPOSABLE)
	77		CURETTE, ETHMOID (DISPOSABLE)
	77		CURETTE, NASAL (DISPOSABLE)
	76		CURETTE, OPERATIVE (DISPOSABLE)
	86		CURETTE, OPHTHALMIC (DISPOSABLE)
	77		CURETTE, SALPINGEAL (DISPOSABLE)
	85		CURETTE, SUCTION, ENDOMETRIAL (AND ACCESSORIES)
	79		CURETTE, SURGICAL (DISPOSABLE)
	85		CURETTE, UTERINE (DISPOSABLE)
CURING	76	A	ACTIVATOR, ULTRAVIOLET, FOR POLYMERIZATION
CURRENT	89	B	DEVICE, THERAPY, DIRECT CURRENT, LOW INTENSITY
	84		THERAPY, INTERFERENTIAL CURRENT
CUSHION	89	A	CUSHION, FLOTATION
CUTTER	77	A	ADENOTOME
	79		CUTTER, SKIN GRAFT
	87		CUTTER, WIRE
	77		GUILLOTINE, TONSIL
	87		INSTRUMENT, CAST REMOVAL, AC-POWERED
	77		NIPPER, MALLEUS
	79		OSTEOTOME, MANUAL
	77		RONGEUR, NASAL
	86		SCLEROTOME
	77		TONSILLECTOME
	86		TRABECULOTOME
	85	B	AMNIOTOME (DISPOSABLE)
	85		COAGULATOR-CUTTER, ENDOSCOPIC, BIPOLAR (AND ACCESSORIES)
	85		COAGULATOR-CUTTER, ENDOSCOPIC, UNIPOLAR (AND ACCESSORIES)
	87		CUTTER, BONE
	79		CUTTER, SURGICAL
	79		CUTTER, SUTURE
	86		CYSTOTOME (DISPOSABLE)
	79		DERMATOME
	86		KERATOME, AC -POWERED

	86 79 74		KERATOME, BATTERY-POWERED PAPILLOTOME/SPHINCTEROTOME VALVULOTOME
	86	C	CUTTER, VITREOUS INFUSION SUCTION
CUTTING	84 84 76	A	DOWEL CUTTING INSTRUMENT INSTRUMENT, CLIP FORMING/CUTT ING INSTRUMENT, CUTTING, OPERATIVE
	79 79	B	INSTRUMENT, CUTTING, ORTHOPEDIC SAW
	79 86 86	C	ELECTROSURGICAL CUTTING & COAGULATION DEVICE & ACCESSORIES INSTRUMENT, VITREOUS ASPIRATION AND CUTTING, AC - POWERED LASER, NEODYMIUM:YAG, OPHTHALMIC FOR POSTERIOR CAPSULOTOMY

Keyword	Therapeutic Code	Class	Description
CYCLODESTRUCTIVE	86	C	DEVICE, CYCLODESTRUCTIVE ULTRASOUND
CYSTIC-FIBROSIS	78	B	SYSTEM, DIAGNOSTIC, CYSTIC FIBROSIS
CYSTO-URETROSCOPE	78	B	CYSTOURETHROSCOPE
CYSTOMETER	78	B	CYSTOMETER, ELECTRICAL RECORDING
CYSTOMETRIC	78 78	B	CYSTOMETRIC GAS (CARBON-DIOXIDE) ON HYDRAULIC DEVICE DEVICE, CYSTOMETRIC, AIR
CYSTOSCOPE	78	B	CYSTOSCOPE, DIAGNOSTIC
CYSTOTOME	86	B	CYSTOTOME (DISPOSABLE)
CYSTOURETHROSCOPE	78	B	CYSTOURETHROSCOPE
DACRON	79	C	SUTURE, NONABSORBABLE, SYNTHETIC, POLYESTER
	74	D	PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE
DAM	76	A	DAM, RUBBER
	77	C	BARRIER, STD, ORAL SEX
DCI	90	C	RADIOGRAPHIC/FLUROSCOPIC UNIT, ANGIOGRAPHIC, DIGITAL
DECANTER	80	B	SET, I.V. FLUID TRANSFER

DECLOTTING	78	B	TRAY, DECLOTTING (INCLUDING CONTENTS)
DECOMPRESSION	73	C	CHAMBER, HYPERBARIC
DECONGESTION	73	B	RHINOANEMOMETER (MEASUREMENT OF NASAL DECONGESTION)
DECUBITUS	89	B	BED, AIR FLUIDIZED
	89		BED, FLOTATION THERAPY, POWERED
DEFIBRILLATOR	74	C	DC-DEFIBRILLATOR, HIGH ENERGY, (INCLUDING PADDLES)
	74		DEFIBRILLATOR, BATTERY POWERED
	74		DEFIBRILLATOR, TRANSTELEPHONIC
	74		DEFIBRILLATOR/MONITOR, BATTERY POWERED
	74		DEFIBRILLATOR/MONITOR, LINE POWERED
	74	D	DEFIBRILLATOR, AUTOMATIC IMPLANTABLE CARDIOVERTER
	74		DEFIBRILLATOR, EXTERNAL, AUTOMATIC
	74		LEAD, ELECTRODE, CARDIOVERTER, DEFIBRILLATOR, PERMANENT
DEFOAMER	74	B	DEFOAMER, CARDIOPULMONARY BYPASS
DELIVERY	73	C	APPARATUS, NITRIC OXIDE DELIVERY
DENSITOMETER	74	B	DENSITOMETER
	90		DENSITOMETER, RADIOGRAPHIC
	90	C	DENSITOMETER, BONE
	90		DENSITOMETER, BONE, DUAL PHOTON
	90		SONOMETER, BONE
DENT AL	76	B	UNIT, OPERATIVE DENTAL
	76	C	UNIT, ELECTROSURGICAL, AND ACCESSORIES
DENTOSCOPE	76	B	DENTOSCOPE
DENTURE	76	B	DENTURE PREFORMED (PARTIALLY PREFABRICATED DENTURE)
	76		DENTURE, PLASTIC, TEETH
	76		KIT, DENTURE REPAIR
	76		KIT, DENTURE REPAIR, OTC
	76		MATERIALS, FABRICATING PROSTHODONTIC APPLIANCES, DENTAL LAB.
	76		RELINER, DENTURE, OTC
	76		RESIN, DENTURE, RELINING, REPAIRING, REBASING
	76		TEETH, ARTIFICIAL, BACKING AND FACING
	76		TEETH, ARTIFICIAL, POSTERIOR WITH METAL INSERT
	76		TEETH, PORCELAIN
	76		TEETH, PREFORMED GOLD DENTURE
DEPILATION	79	C	INSTRUMENT, SURGICAL, POWERED, LASER
DEPRESSION	80	B	LIGHT, THERAPY, SEASONAL AFFECTIVE DISORDER (SAD)
DEPRESSOR	86	A	DEPRESSOR, ORBITAL
	80		DEPRESSOR, TONGUE

Keyword	Therapeutic Code	Class	Description
	77 85		DEPRESSOR, TONGUE, METAL, ENT DEPRESSOR, UTERINE
DERMABRASION	79	B	UNIT, DERMABRASION
DERMAL	79	C	IMPLANT, DERMAL, OTHER, FOR AESTHETIC USE
	79 79	D	DERMAL IMPLANTS OF COLLAGEN FOR AESTHETIC USE DEVICE, DERMAL REPLACEMENT
DERMATOME	79 79	B	BLADE, OSTEOTOME AND OTHER CUTTING INSTRUMENTS (DISPOSABLE) DERMATOME
DESENSITIZER	73	C	DESENSITIZER, TOOTH
DETECTION	85	A	KIT, BREAST CANCER DETECTION
	76 76	B	DEVICE, CARIES DETECTION LASER, FLUORESCENCE CARIES DETECTION
DETECTOR	86	A	DETECTOR, METAL, MAGNETIC
	74 73	B	DETECTOR, DEEP VEIN THROMBOSIS MONITOR (APNEA DETECTOR), VENTILATORY EFFORT
	74 78 74 78 78 85	C	DETECTOR AND ALARM, ARRHYTHMIA DETECTOR, AIR OR FOAM DETECTOR, BLOOD FLOW, ULTRASONIC (DOPPLER) DETECTOR, BLOOD LEAK DETECTOR, BLOOD LEVEL DETECTOR, FETAL HEART, ULTRASONIC (DOPPLER)
	74	D	DETECTOR, HIS BUNDLE
DIALYSATE	78	B	TUBING, DIALYSATE (AND CONNECTOR)
	78 78 78 78 78	C	SEMI-AUTOMATIC PERITONEAL DIALYSATE DELIVERY SYSTEM SYSTEM, DIALYSATE DELIVERY, CENTRAL MULTIPLE PATIENT SYSTEM, DIALYSATE DELIVERY, SINGLE PATIENT SYSTEM, DIALYSATE DELIVERY, SORBENT REGENER ATED SYSTEM, PERITONEAL, AUTOMATIC DELIVERY
DIALYSIS	78 78 78	B	SET, ADMINISTRATION, FOR PERITONEAL DIALYSIS, DISPOSABLE SET, DIALYSIS, SINGLE NEEDLE WITH UNI-DIRECTIONAL PUMP SET, TUBING, BLOOD WITH AND WITHOUT ANTI-REGURGITATION VALVE

	78		UNIT, DIALYSIS, PERITONEAL (CAPD)
DIALYZER	78 78 78 78	C B	STATION, DIALYSIS CONTROL, NEGATIVE PRESSURE TYPE SUBSYSTEM, WATER PURIFICATION SYSTEM, PERITONEAL, AUTOMATIC DELIVERY REPROCESSING UNIT, DIALYZER
	78 78 78 78 78 78	C 	DIALYZER, CAPILLARY, HOLLOW FIBER DIALYZER, COMPOSITE, HEMODIALYSIS/HEMOPERFUSION DIALYZER, DISPOSABLE DIALYZER, HIGH PERMEABILITY WITH OR WITHOUT SEALED DIALYSATE DIALYZER, PARALLEL FLOW DIALYZER, SINGLE COIL
DIAPHRAGM	85	B	DIAPHRAGM, CONTRACEPTIVE (AND ACCESSORIES)
DIATHERMY	89 89 89 89	B 	DIATHERMY, MICROWAVE, FOR USE IN APPLYING THERAPEUTIC DEEP HEAT DIATHERMY, MICROWAVE, FOR USE OTHER THAN APPLYING THERAPEUTIC DEEP HEAT DIATHERMY, SHORTWAVE, FOR USE IN APPLYING THERAPEUTIC DEEP HEAT DIATHERMY, ULTRASONIC, FOR USE IN APPLYING THERAPEUTIC DEEP HEAT
	89	C	DIATHERMY ULTRASONIC, FOR USE OTHER THAN APPLYING THERAPEUTIC DEEP HEAT
DIE	77	A	DIE, WIRE BENDING, ENT
DILATOR	77 77 77 85	A 	DILATOR, NASAL DILATOR, SALIVARY DUCT DILATOR, TRACHEAL DILATOR, UTERINE

Keyword	Therapeutic Code	Class	Description
	78 77 79 78 85 85 78 78 77 86 78	B 	BOUGIE, ESOPHAGEAL, AND GASTROINTESTINAL, GASTRO-UROLOGY BOUGIE, ESOPHAGEAL, ENT DILATOR, CATHETER DILATOR, CATHETER, URETERAL DILATOR, CERVICAL, FIXED SIZE DILATOR, CERVICAL, HYGROSCOPIC -LAMINARIA DILATOR, COMMON DUCT DILATOR, ESOPHAGEAL DILATOR, ESOPHAGEAL, ENT DILATOR, LACHRYMAL DILATOR, RECTAL

	78		DILATOR, URETHRAL
	85		DILATOR, VAGINAL
	74		DILATOR, VESSEL, FOR PERCUTANEOUS CATHETERIZATION
	74		DILATOR, VESSEL, SURGICAL
	78		FILLIFORM AND FILIFORM FOLLOWER
DIRECTOR	78	A	PROBE AND DIRECTOR, GASTRO-UROLOGY
	79	B	GUIDE, SURGICAL, NEEDLE
DISCRIMINATOR	84	A	DISCRIMINATOR, TWO-POINT
DISINFECTOR	80	B	WASHER/DISINFECTOR
DISK	76	A	DISK, ABRASIVE
	86		KERATOSCOPE
	74		RECORDER, MAGNETIC TAPE, MEDICAL
DISLODGER	78	B	DISLODGER, STONE, BASKET, URETERAL, METAL
	78		DISLODGER, STONE, BILIARY
	78		DISLODGER, STONE, FLEXIBLE
DISPENSER	76	A	DISPENSER, MERCURY AND/OR ALLOY
	80		LIQUID MEDICATION DISPENSER
	80		SYRINGE, ORAL (MEDICATION DISPENSER)
	87	B	DISPENSER, CEMENT
DISPENSING	80	B	DEVICE, MEDICATION RECONSITITUTION/TRANSER DEVICE
DISPLAY	74	B	DISPLAY, CATHODE-RAY TUBE, MEDICAL
DISSECTOR	79	B	DISSECTOR, SURGICAL, GENERAL & PLASTIC SURGERY
	77		DISSECTOR, TONSIL
DISTOMETER	86	A	DISTOMETER
DISTRACTOR	76	C	EXTERNAL MANDIBULAR FIXATOR AND/OR DISTRACTOR
DOPPLER	85	C	DOPPLER ULTRASOUND FOR FETAL EVALUATION
	74		DOPPLER, BLOOD FLOW, TRANSCRANIAL
	90		MONITOR, ULTRASONIC, NON-FETAL
DOSIMETER	77	B	NEBULIZER PUMP, ELECTRICALLY POWERED
	90	C	DOSIMETER, RADIATION
DOUCHE	85	B	DOUCHE, UTERINE
	85		DOUCHE-APPARATUS, VAGINAL, THERAPEUTIC
	85		NOZZLE, DOUCHE
DRAIN	85	B	DRAIN, CERVICAL
	78		DRAIN, PENROSE
	78		DRAIN, SUMP
	78		DRAIN, T
	73		DRAIN, TEE (WATER TRAP)
	73		DRAIN, THORACIC (CHEST)
	78		DRAIN, VENT
DRAINAGE	80	A	DRAINAGE UNIT, URINARY
	80		SYSTEM, DRAINAGE, THORACIC, WATER SEAL

Keyword	Therapeutic Code	Class	Description
	78		SYSTEM, URINE DRAINAGE, CLOSED, FOR NONINDWELLING CATHETER
	80	B	KIT, CHEST DRAINAGE (THORACENTESIS TRAY)
	79		KIT, INCISION AND DRAINAGE
	80		KIT, WOUND DRAINAGE
	8D		KIT, WOUND DRAINAGE, CLOSED, CRANIOTOMY
	80		TUBING, RUBBER
	77	C	TUBE, TYMPANOSTOMY
	8D	D	DEVICE, INTRACRANIAL PRESSURE MONITORING
DRAPE	79	A	DRAPE, MICROSCOPE, OPHTHALMIC
	79		DRAPE, PATIENT, OPHTHALMIC
	79		DRAPE, SURGICAL
	79		DRAPE, SURGICAL, ENT
	79		PACK, SURGICAL DRAPE
	79		SHEET, DRAPE
	79		SHEET, DRAPE, DISPOSABLE
	79	B	DRAPE, PURE LATEX SHEET, WITH SELF RETAINING FINGER COT
DRESSING	79	A	DRESSING
	80		DRESSING, AEROSOL
	80		DRESSING, NONADHERENT
	76		DRESSING, PERIODONTAL
	80		KIT, DRESSING
	80		PAD, DRESSING
	80	B	DRESSING, BURN
	80		DRESSING, GEL
	80		DRESSING, PERMEABLE, MOISTURE
	77		DRESSING, TRACHEOSTOMY TUBE
	79		DRESSING, WOUND AND BURN, HYDROGEL
	79		DRESSING, WOUND AND BURN, OCCLUSIVE
	76	C	MATERIAL, DRESSING, SURGICAL, POLYLACTIC ACID
DRILL	87	B	BIT, DRILL
	76		BUR, DENTAL
	79		BUR, SURGICAL, GENERAL & PLASTIC SURGERY
	87		BURR, ORTHOPEDIC
	87		DRILL, BONE
	87		DRILL, BONE CEMENT
	87		DRILL, CANNULATED
	79		DRILL, CHUCK

	76		DRILL, DENTAL, INTRAORAL
	79		DRILL, FINGERNAIL
	77		DRILL, MIDDLE EAR SURGERY
	76		DRILL, ORAL SURGERY
	77		DRILL, SURGICAL, ENT (ELECTRIC OR PNEUMATIC) INCLUDING HANDPIECE
	84		PERFORATOR, DRILL
	84		POWERED COMPOUND DRILLS, BURRS, TREPHINES & ACCESSORIES
	84		POWERED SIMPLE DRILLS, BURRS, TREPHINES & ACCESSORIES
	84	C	DRILL, CRANIAL
DRIVER	76	A	DRIVER, BAND, ORTHODONTIC
	87		DRIVER, PROSTHESIS
	79		DRIVER, SURGICAL, PIN
	87		DRIVER, WIRE
	76		DRIVER, WIRE, AND BONE DRILL, MANUAL
	87	B	DRIVER/EXTRACTOR, BONE NAIL/PIN
	87		DRIVER/EXTRACTOR, BONE PLATE

Keyword	Therapeutic Code	Class	Description
DROPPER	77	A	DROPPER, EAR
	73		DROPPER, ETHER
	86		DROPPER, EYE
	80		DROPPER, MEDICINE
	77		ENT DRUG APPLICATOR
DRUM	86	A	DRUM, EYE KNIFE TEST
	86		DRUM, OPTICOKINETIC
	77		TYMPANOSCOPE
DRYER	90	A	DRYER, FILM, RADIOGRAPHIC
DUODENOSCOPE	78	B	ESOPHAGO GASTRO DUODENOSCOPE
DURA	84	D	DURA SUBSTITUTE
	84		LYOPHILIZED HUMAN DURA MATER
	84		STIMULATOR, SPINAL CORD, IMPLANTED, FOR BLADDER EVACUATION
DYNAMOMETER	87	B	DYNAMOMETER
	87		DYNAMOMETER, PHYSICAL MEDICINE
DYSFUNCTION	78	A	ERECTILE DYSFUNCTION DEVICE
	85	B	VIBRATOR FOR THERAPEUTIC USE, GENITAL
EAR	77	A	TYMPANOSCOPE

	79 77 77 77	C	PROSTHESIS, EAR, INTERNAL PROSTHESIS, PARTIAL OSSICULAR REPLACEMENT REPLACEMENT, OSSICULAR PROSTHESIS, TOTAL REPLACEMENT, TYMPANIC MEMBRANE
ECHOCARDIOGRAPHY	74	B	ECHOCARDIOGRAPH
ECHOENCEPHALOGRAPH	84	B	ECHOENCEPHALOGRAPH
ECHOOPHTHALMOGRAPH	86	B	ECHOOPHTHALMOGRAPH (ULTRASONIC SCANNER)
EJECTOR	76	A	MOUTHPIECE, SALIVA EJECTOR
ELBOW	89 89	A	ASSEMBLY, SHOULDER/ELBOW/FOREARM/WRIST/HAND, MECHANICAL JOINT, ELBOW, EXTERNAL LIMB COMPONENT, MECHANICAL
	87 87 87 87 87 87	C	PROSTHESIS, ELBOW, CONSTRAINED, CEMENTED PROSTHESIS, ELBOW, HUMERAL COMPONENT PROSTHESIS, ELBOW, NON -CONSTRAINED, UNIPOLAR PROSTHESIS, ELBOW, RADIAL COMPONENT PROSTHESIS, ELBOW, TOTAL PROSTHESIS, ELBOW, ULNAR COMPONENT
ELECTROCARDIOGRAPH	74 74 74 90	B	ELECTROCARDIOGRAPH MONITOR, ECG, AMBULATORY, REAL -TIME RECORDER, LONG TERM, ECG, PORTABLE (HOLTER MONITOR) SYNCHRONIZER,ECG/RESPIRATOR, RADIOGRAPHIC
	74 74 74	C	MONITOR, HEART RATE, R-WAVE (ECG) SYSTEM, ECG ANALYSIS TELEMETRY UNIT, PHYSIOLOGICAL, ECG
ELECTROCAUTERY	86 79 79 85	C	CAUTERY, OPTHALMIC ELECTROCAUTERY UNIT, BATTERY POWERED ELECTROCAUTERY UNIT, LINE POWERED ELECTROCAUTERY, GYNECOLOGIC (AND ACCESSORIES)
ELECTROCONVULSIVE	84	C	DEVICE, ELECTROCONVULSIVE THERAPY
ELECTRODE	84 84 73 85 86 84 74	B	CUTANEOUS ELECTRODE ELECTRODE, BIOPOTENTIAL, SURFACE, METALLIC ELECTRODE, BLOOD GAS, CARBON -DIOXIDE ELECTRODE, CLIP, FETAL SCALP (AND APPLICATOR) ELECTRODE, CORNEAL ELECTRODE, CORTICAL ELECTRODE, ELECTROCARDIOGRAPH

Keyword	Therapeutic Code	Class	Description

	84		ELECTRODE, ELECTROENCEPHALOGRAPHIC
	84		ELECTRODE, ELECTROMYOGRAPHIC
	86		ELECTRODE, ELECTRONYSTAGMOGRAPHIC
	79		ELECTRODE, ELECTROSURGICAL
	78		ELECTRODE, ELECTROSURGICAL, ACTIVE, UROLOGICAL
	78		ELECTRODE, ESOPHAGEAL
	78		ELECTRODE, FLEXIBLE SUCTION COAGULATOR
	74		ELECTRODE, GEL
	79		ELECTRODE, GEL, ELECTROSURGICAL
	84		ELECTRODE, METALLIC WITH SOFT PAD COVERING
	84		ELECTRODE, NASOPHARYNGEAL
	84		ELECTRODE, NEEDLE
	89		ELECTRODE, NEEDLE, DIAGNOSTIC ELECTROMYOGRAPH
	84		ELECTRODE, NEUROLOGICAL
	84		ELECTRODE, NEUROMUSCULAR STIMULATOR
	74		ELECTRODE, PACEMAKER, EXTERNAL
	78		ELECTRODE, PH, STOMACH
	84		ELECTRODE, SKIN SURFACE, OPHTHALMIC
	84		ELECTRODE, TENS
	73		ELECTRODE, TRANSCUTANEOUS, OXYGEN
	84		GEL, ELECTRODE
	74	D	ELECTRODE, DEFIBRILLATOR (INTERNAL, NON-IMPLANTED)
	84		ELECTRODE, DEPTH
	74		ELECTRODE, PACEMAKER, TEMPORARY
	74		ELECTRODE, PACEMAKER, TRANSTHORACIC
	74		ELECTRODE, PERCUTANEOUS CONDUCTION TISSUE ABLATION
	74		LEAD, ELECTRODE, CARDIOVERTER, DEFIBRILLATOR, PERMANENT
	74		LEAD, ELECTRODE, PACEMAKER, PERMANENT
	84		STABILIZED EPIDURAL SPINAL ELECTRODE
ELECTROENCEPHALOGRAPH	84	B	ELECTROENCEPHALOGRAPH
ELECTROGALVANIC	89	B	STIMULATOR, MUSCLE, POWERED
ELECTROLYSIS	86	B	UNIT, ELECTROLYSIS, AC -POWERED, OPHTHALMIC
ELECTROMYOGRAPH	89	B	ELECTROMYOGRAPH
ELECTRONYSTAGMOGRAPH	86	B	ELECTRONYSTAGMOGRAPH (ENG)
ELECTROSHOCK	84	C	DEVICE, ELECTROCONVULSIVE THERAPY
ELECTROSURGICAL	85	B	COAGULATOR, LAPAROSCOPIC, UNIPOLAR (AND ACCESSORIES)
	85		COAGULATOR-CUTTER, ENDOSCOPIC, BIPOLAR (AND ACCESSORIES)
	85		COAGULATOR-CUTTER, ENDOSCOPIC, UNIPOLAR (AND ACCESSORIES)
	79	C	EQUIPMENT, ELECTROSURGICAL, SPECIAL PURPOSE
	76		UNIT, ELECTROSURGICAL, AND ACCESSORIES
ELECTROTHERAPEUTIC	80	B	UNIT, ELECTROTHERAPEUTIC

ELEVATOR	86 77 84 76 79 85	A	ELEVATOR, CORNEAL ELEVATOR, ENT ELEVATOR, NEUROSURGICAL ELEVATOR, SURGICAL, DENTAL ELEVATOR, SURGICAL, GENERAL & PLASTIC SURGERY ELEVATOR, UTERINE
EMBOLIC	74	D	EMBOLIC PROTECTION DEVICE
EMBOLISM	73	C	KIT, DIAGNOSTIC, PULMONARY, RADIO AEROSOL
EMBOLIZATION	84 74	D	ARTIFICIAL EMBOLIZATION DEVICE DEVICE, EMBOLIZATION, ARTERIAL
EMERGENCY	85	C	UNIT, EMERGENCY CARE, NEONATAL
ENCEPHALOGRAPH	84	B	ECHOENCEPHALOGRAPH

Keyword	Therapeutic Code	Class	Description
	84		ELECTROENCEPHALOGRAPH
ENDODONTIC	76	B	INSTRUMENT, ENDODONTIC
ENDOILLUMINATOR	86	B	ENDOILLUMINATOR
ENDOSCOPE	77	A	PHARYNGOSCOPE
	78	B	ANOSCOPE, NON-POWERED
	78		CANNULA AND TROCAR, SUPRAPUBLIC, NON-DISPOSABLE
	78		CHOLEDOCHOSCOPE, FLEXIBLE OR RIGID
	78		CYSTOURETHROSCOPE
	78		ENDOSCOPE AND/OR ACCESSORIES
	78		ENDOSCOPE, FIBER OPTIC
	78		ENDOSCOPE, FLEXIBLE
	84		ENDOSCOPE, NEUROLOGICAL
	78		ENDOSCOPE, RIGID
	85		ENDOSCOPE, TRANSCERVICAL (AMNIOSCOPE), AND ACCESSORIES
	78		ESOPHAGO GASTRO DUODENOSCOPE
	78		ESOPHAGOSCOPE, GENERAL & PLASTIC SURGERY
	78		GASTROSCOPE, GASTRO-UROLOGY
	85		HYSTEROSCOPE (AND ACCESSORIES)
	79		INSTRUMENT, SURGICAL, ENDOSCOPIC/L APAROSCOPIC (NON-POWERED)
	78		LAPAROSCOPE, GENERAL & PLASTIC SURGERY
	78		MEDIASTINOSCOPE
	78		PANENDOSCOPE (GASTRODUODENOSCOPE)
	78		PERITONEOSCOPE
	78		PROCTOSCOPE
	78		RESECTOSCOPE

	73 78 78 78 78		SCOPE, FIBEROPTIC INTUBATION SET, NEPHROSCOPE SIGMOIDOSCOPE, FLEXIBLE SPHYNCTEROSCOPE TELESCOPE, RIGID, ENDOSCOPE
	85	D	ENDOSCOPE, FETAL BLOOD SAMPLING (AND ACCESSORIES)
ENDOSSEOUS	76 76	C	IMPLANT, ENDOSSEOUS IMPLANT, ENDOSSEOUS FOR BONE FILLING AND/OR AUGMENTATION
ENEMA ENTEROSCOPE	90 78 78	B B	KIT, BARIUM ENEMA, DISPOSABLE KIT, ENEMA, (FOR CLEANING PURPOSE) ENTEROSCOPE
ENUCLEATOR	86 79	A	ENUCLEATOR ENUCLEATOR, GENERAL/PLASTIC SURGERY
ERGOMETER	89	B	ERGOMETER, TREADMILL
ERISOPHAKE	86	A	ERISOPHAKE
ESOPHAGOSCOPE	78	B	ESOPHAGOSCOPE, GENERAL & PLASTIC SURGERY
ESOPHAGUS	79	C	PROSTHESIS, ESOPHAGEAL
ESTHESIOMETER	84	A	ESTHESIOMETER
	86	B	OCULAR ESTHESIOMETER
ETCHING	76	C	AGENT, TOOTH BONDING, RESIN
EUGENOL	76	C	ZINC OXIDE EUGENOL
EUTHYSCOPE	86	A	OPHTHALMOSCOPE, AC -POWERED
EVACUATOR	76	A	EVACUATOR, ORAL CAVITY
	78 78	B	EVACUATOR, BLADDER, MANUALLY OPERATED TUBE, STOMACH EVACUATOR (GASTRIC LAVAGE)
EXCAVATOR	76 77	A	EXCAVATOR, DENTAL, OPERATIVE EXCAVATOR, EAR
EXCHANGE	74	B	EXCHANGE DEVICE, PERCUTANEOUS TRANSLUMINAL CATHETER

Keyword	Therapeutic Code	Class	Description
	74		FILTER, BLOOD, CARDIOPULMONARY BYPASS, ARTERIAL LINE

	74		FILTER, BLOOD, CARDIOTOMY SUCTION LINE, CARDIOPULMONARY BYPASS
EXCHANGER	74 74	B	DEVICE, HYPOTHERMIA (BLANKET, PLUMBING & HEAT EXCHANGER) HEAT-EXCHANGER, CARDIOPULMONARY BYPASS
EXCISER	74	D	DEVICE, LASER, ANGIOPLASTY, CORONARY
EXERCISER	74 89 89 89I 73	A	BOTTLE, BLOW EXERCISER, HAND EXERCISER, MEASURING EXERCISER, NON-MEASURING EXERCISER, RESPIRATORY
	89 90 89	B	EXERCISER, FINGER, POWERED EXERCISER, NUCLEAR DIAGNOSTIC (CARDIAC STRESS TABLE) EXERCISER, PASSIVE, NON-MEASURING
EXHAUST	79	A	APPARATUS, EXHAUST, SURGICAL
EXOPHTHALMOMETER	86	B	EXOPHTHALMOMETER
EXPANDER	79 79	A C	EXPANDER, SURGICAL, SKIN GRAFT SKIN EXPANDER, INFLATABLE
EXPLORER	76	A	EXPLORER, OPERATIVE
EXPRESSOR	86 86	A	EXPRESSOR EXPRESSOR, LENS LOOP
EXTRACTOR	86 80 79 87	A	EXTRACTOR, CATARACT EXTRACTOR, COMEDONE EXTRACTOR, METAL, MAGNETIC PROTRACTOR
	87 87 87 85	B	DRIVER/EXTRACTOR, BONE NAIL/PIN DRIVER/EXTRACTOR, BONE PLATE EXTRACTOR EXTRACTOR, VACUUM, FETAL
EYE	86 86 86 86	C	IMPLANT, EYE SPHERE IMPLANT, EYE VALVE PROSTHESIS, EYE, INTERNAL PROSTHESIS, EYELID
FABRIC	80	A	FABRIC, PAIN RELIEF
FACELIFT FACIAL	89 89 84 77	B C	DEVICE, THERAPY, DIRECT CURRENT, LOW INTENSITY UNIT, MAGNETIC, THERAPEUTIC PROSTHESIS, CRANIOFACIAL PROSTHESIS, FACIAL, MANDIBULAR IMPLANT
FALLOPIAN	85	B	CANNULA, INSUFFLATION, UTERINE (AND ACCESSORIES)
	85 85	C	DEVICE, OCCLUSION, TUBAL (TOD), CONTRACEPTIVE PROSTHESIS, FALLOPIAN TUBE

FALLOPOSCOPE	85	B	FALLOPOSCOPE
FASTENER	84 87 87 87	C	FASTENER, CRANIOPLASTY PLATE FASTENER, FIXATION, BIODEGRADABLE, HARD TISSUE FASTENER, FIXATION, BIODEGRADABLE, SOFT TISSUE FASTENER, FIXATION, NONDEGRADABLE, SOFT TISSUE
FEEDING	80 80 78	B	KIT, FEEDING, ADULT (ENTERAL) PUMP, INFUSION, ENTERAL SET, GAVAGE, INFANT, STERILE
FEELER	87	A	CARTILAGE FEELER
FEMUR	87 87 87	C	PROSTHESIS, FEMORAL HEAD PROSTHESIS, FEMOROTIBIAL, CONSTRAINED (METAL -ON-POLYMER) PROSTHESIS, UPPER FEMORAL
FERTILITY	85	B	FERTILITY DIAGNOSTIC DEVICE

Keyword	Therapeutic Code	Class	Description
FETOSCOPE	85	D	AMNIOSCOPE, TRANSABDOMINAL (FETOSCOPE) (AND ACCESSORIES)
FIBER	80	A	FIBER, MEDICAL, ABSORBENT
FILE	87 76 79 76 76 79	A	FILE FILE, BONE, SURGICAL FILE, CALLOUS FILE, MARGIN FINISHING, OPERATIVE FILE, ORTHODONTIC, PERIODONTIC FILE, SURGICAL, GENERAL & PLASTIC SURGERY
	76	B	FILE, PULP CANAL, ENDODONTIC
FILIFORM	77	A	SET, FILLIFORM, ESTACHIAN
	78	B	FILLIFORM AND FILIFORM FOLLOWER
FILLER	89 87	C	FILLER, BONE VOID, OSTEOINDUCTION FILLER, CALCIUM SULPHATE PREFORMED PELLETS
FILLING	76	A	INSTRUMENT, FILLING, PLASTIC, DENTAL
	76	B	FILLING, TEMPORARY, OTC
	76 76E 76Q 76	C	COATING, FILLING MATERIAL, RESIN LINER, CAVITY, CALCIUM HYDROXIDE MATERIAL, DENTAL FILLING RESIN, ROOT CANAL FILLING
FILM	90 90 90	A	DEVICE, SPOT FILM FILM, X-RAY FILM, X-RAY CASSETTE

	90		FILM, X-RAY, DENTAL, INTRAORAL
FILTER	79 78	A	FILTER, ASPIRATOR FILTER, KIDNEY STONE
	73 74 74 78 73 73 80 74 90 80 73 80	B	FILTER, BACTERIAL, BREATHING CIRCUIT FILTER, BLOOD, CARDIOPULMONARY BYPASS, ARTERIAL LINE FILTER, BLOOD, CARDIOTOMY SUCTION LINE, CARDIOPULMONARY FILTER, BLOOD, DIALYSIS FILTER, CONDUCTION, ANESTHETIC FILTER, GAS FILTER, INFUSION LINE FILTER, PREBYPASS, CARDIOPULMONARY BYPASS FILTER, RADIOGRAPHIC FILTER, SYRINGE FILTER, VENTILATOR NEEDLE, FILTER
	74	D	FILTER, INTRAVASCULAR, CARDIOVASCULAR
FINGER	87 87 87	C	PROSTHESIS, FINGER, CONSTRAINED, METAL, CEMENTED PROSTHESIS, FINGER, CONSTRAINED, POLYMER PROSTHESIS, FINGER, TOTAL
FIRST- AID	79	A	KIT, FIRST AID
FITTING	80	B	FITTING, LUER
FIXATION	86 73 87 86	A	DEVICE, FIXATION, OPHTHALMIC DEVICE, FIXATION, TRACHEAL TUBE FIXATION DEVICE COMPONENT, EXTERNAL INSTRUMENT, SCLERAL FIXATION
	87 87 87 87 87 87	C	CERCLAGE FIXATION DEVICE, FIXATION, PROXIMAL FEMORAL, IMPLANT FIXATION DEVICE, JAW FRUCTURE FIXATION DEVICE, SPINAL, EXTERNAL IMPLANT, FIXATION DEVICE, CONDYLAR PLATE IMPLANT, FIXATION DEVICE, SPINAL

Keyword	Therapeutic Code	Class	Description
	87		NAIL, FIXATION, BONE
FIXATOR	79	B	LOCALIZER & FIXATOR, LESION, BREAST
	76	C	EXTERNAL MANDIBULAR FIXATOR AND/OR DISTRACTOR
FLASHER	86	B	FLASHER, AFTER -IMAGE

FLOSS	76	A	FLOSS, DENTAL
FLOWMETER	78	A	DEVICE, URINE FLOW RATE MEASURING, NON-ELECTRICAL, DISPOSABLE
	73	B	FLOWMETER, ANESTHESIA
	74		FLOWMETER, BLOOD, CARDIOVASCULAR
	73		FLOWMETER, CALIBRATION, GAS
	73		FLOWMETER, NONBACK-PRESSURE COMPENSATED, BOURDON GAUGE
	73		FLOWMETER, TUBE, THORPE, BACK -PRESSURE COMPENSATED
	74	C	FLOWMETER, BLOOD, LASER
	74		FLOWMETER, BLOOD, NON-INVASIVE ELECTROMAGNETIC OR DOPPLER
	78		FLOWMETER, BLOOD, ULTRASONIC
FLUID	80	B	CONTAINER, I.V.
	80		INFUSION FLUID THERMAL WARMER
	86	C	FLUID, INTRAOCULAR
	87		FLUID, JOINT LUBRICATING
FLUOROSCOPIC	90	C	RADIOGRAPHIC/FLUOROSCOPIC UNIT FIXED
	90		RADIOGRAPHIC/FLUOROSCOPIC UNIT, MOBILE C -ARM
	90		RADIOGRAPHIC/FLUROSCOPIC UNIT, ANGIOGRAPHIC, DIGITAL
	90		SYSTEM, X-RAY, ANGIOGRAPHIC
FLUSHING	74	B	DEVICE, FLUSHING, AUTOMATIC
FOAM	79	C	ABSORBABLE HEMOSTATIC AGENTS NON-COLLAGEN BASED
FOGARTY	74	D	CATHETER, EMBOLECTOMY
FOIL	76	B	FOIL, DENTAL
FOLEY	79	B	CATHETER, BALLOON TYPE
	78		TRAY, CATHETERIZATION, STERILE URETHRAL, WITH OR WITHOUT CATHETER
FOLLOWER	78	B	FILLIFORM AND FILIFORM FOLLOWER
FOOT	89	A	ASSEMBLY, THIGH/KNEE/SHANK/ANKLE/FOOT, EXTERNAL
	89		COMPONENT, EXTERNAL, LIMB, ANKLE/FOOT
	87		PROSTHESIS, FOOT
	87	C	PROSTHESIS, FOOT ARCH
FORCEPS	79	A	FORCEPS, APPROXIMATION
	76		FORCEPS, ARTICULATION PAPER
	78		FORCEPS, DISCONNECT
	79		FORCEPS, DRESSING
	76		FORCEPS, DRESSING, DENTAL
	77		FORCEPS, ENT
	79		FORCEPS, FIXATION
	78		FORCEPS, GALLBLADDER (BILIARY DUCT)

	79		FORCEPS, GENERAL & PLASTIC SURGERY
	79		FORCEPS, HEMOSTATIC
	78		FORCEPS, INTESTINAL (CLAMPS)
	79		FORCEPS, LUNG
	85		FORCEPS, OBSTETRICAL
	87		FORCEPS, ORTHOPEDIC
	76		FORCEPS, RONGEUR, SURGICAL
	79		FORCEPS, SPLINTER
	79		FORCEPS, SPONGE
	80		FORCEPS, STERILIZER TRANSFER
	85		FORCEPS, SURGICAL, GYNECOLOGICAL
	79		FORCEPS, SUTURE

Keyword	Therapeutic Code	Class	Description
	79		FORCEPS, TISSUE
	77		FORCEPS, TONGUE SEIZING
	77		FORCEPS, TONSIL
	76		FORCEPS, TOOTH EXTRACTOR, SURGICAL
	79		FORCEPS, UTILITY
	77		FORCEPS, WIRE CLOSURE, ENT
	79		FORCEPS, WIRE HOLDING
	87		GOUGE FORCEPS
	79		TENACULUM, OTHER (FORCEPS)
	79	B	FORCEPS, BIOPSY
	77		FORCEPS, BIOPSY, BRONCHOSCOPE (RIGID) (DISPOSABLE)
	78		FORCEPS, BIOPSY, ELECTRIC
	78		FORCEPS, BIOPSY, NON-ELECTRIC
	79		FORCEPS, ELECTROSURGICAL
	78		FORCEPS, GRASPING, FLEXIBLE ENDOSCOPIC
	86		FORCEPS, OPHTHALMIC (DISPOSABLE)
	78		FORCEPS, STONE MANIPULATION
	73		FORCEPS, TUBE INTRODUCTION
	79		INSTRUMENT GUARD
	79		INSTRUMENT, SURGICAL, ENDOSCOPIC/LAPAROSCOPIC (NON-POWERED)
FOREARM	89	A	ASSEMBLY, SHOULDER/ELBOW/FOREARM/WRIST/HAND, MECHANICAL
FORK	87	A	FORK
	84		FORK, TUNING

FORMING	84 84	A	INSTRUMENT, CLIP FORMING/CUTTING INSTRUMENT, CRANIOPLASTY MATERIAL FORMING
FORNIXSCOPE	86	A	FORNIXSCOPE
FRACTURE	79	A	FACIAL FRACTURE APPLIANCE, EXTERNAL
FRAGMENTATION	84	D	DEVICE, NEUROSURGICAL, FRAGMENTATION AND ASPIRATION
FRAME	76 86 87 86 87	A	FRAME, RUBBER DAM FRAME, SPECTACLE FRAME, TRACTION FRAME, TRIAL, OPHTHALMIC FRAME, TURNING
FREEZING	79	C	CRYOSURGICAL UNIT & ACCESSORIES
FRESNEL	86	A	LEN S, CONDENSING, DIAGNOSTIC
FUNDUS	86	A	LENS, CONDENSING, DIAGNOSTIC
	86	B	CAMERA, OPHTHALMIC, AC -POWERED
FUSING	76	B	SOLDER, PROSTHODONTIC APPLIANCES
GAG	77	A	GAG, MOUTH
GALVANIC	89	B	STIMULATOR, MUSCLE, POWERED
GASTRODUODENOSCOPE	78	B	PANENDOSCOPE (GASTRODUODENOSCOPE)
GASTROSCOPE	78	B	GASTROSCOPE, GASTRO-UROLOGY
GASTROSTOMY	78	B	CATHETER, MALECOT
GAUGE	87 76 86 77 77	A	GAUGE, DEPTH GAUGE, DEPTH, INSTRUMENT, DENTAL GAUGE, LENS, OPHTHALMIC GAUGE, MASTOID GAUGE, MEASURING
	73 80	B	GAUGE, GAS PRESSURE, CYLINDER/PIPELINE GAUGE, PRESSURE
	74	C	GAUGE, PRESSURE, CORONARY, CARDIOPULMONARY BYPASS
GAUZE	80 80	A	BANDAGE, GAUZE COMPRESS, GAUZE

Keyword	Therapeutic Code	Class	Description

	79		GAUZE ROLL
	80		PACKER, GAUZE
	79		SPONGE, GAUZE
	79	B	GAUZE, NONABSORBABLE, MEDICATED (INTERNAL SPONGE)
	79		GAUZE, NONABSORBABLE, NON-MEDICATED, (INTERNAL SPONGE)
	79		GAUZE, NONABSORBABLE, X-RAY DETECTABLE (INTERNAL SPONGE)
GAVAGE	78	B	SET, GAVAGE, INFANT, STERILE
GEL	89	A	GEL, ULTRASONIC COUPLING
	80		GEL, ULTRASONIC TRANSMISSION
	78	B	JELLY, LUBRICATING, FOR TRANSURETHRAL SURGICAL INSTRUMENT
	79	C	ABSORBABLE HEMOSTATIC AGENTS NON-COLLAGEN BASED
GENERATOR	77	B	GENERATOR, AEROSOL
	73		GENERATOR, OXYGEN, PORTABLE
	87		GENERATOR, SHOCK-WAVE (FOR PAIN RELIEF)
	77		MASKER, TINNITIS
	77		VALVE, SPEAKING, TRACHEAL
	79	C	GENERATOR, ELECTROSURGICAL, COAGULATION, CANCER
	90		GENERATOR, HIGH VOLTAGE X-RAY THERAPEUTIC
	90		GENERATOR, HIGH-VOLTAGE, X-RAY, DIAGNOSTIC
	84		GENERATOR, LESION, RADIOFREQUENCY
	90		GENERATOR, LOW VOLTAGE, THERAPEUTIC X-RAY
	90		GENERATOR, ORTHOVOLTAGE, THERAPEUTIC X-RAY
	74		GENERATOR, PULSALITE FLOW, CARDIOPULMONARY BYPASS
	90		GENERATOR, RADIOGRAPHIC, CAPACITOR DISCHARGE
	74	D	MATERIALS, REPAIR OR REPLACEMENT, PACEMAKER
	74		PROGRAMMER, PACEMAKER
	74		PULSE-GENERATOR, PACEMAKER, EXTERNAL
	74		PULSE-GENERATOR, PACEMAKER, EXTERN AL, PROGRAMMABLE
	74		PULSE-GENERATOR, PACEMAKER, IMPLANTABLE
	74		PULSE-GENERATOR, PROGRAM MODULE
GLASSES	86	A	EYEGLASSES
GLOVE	80	B	GLOVE, PATIENT EXAMINATION
	79		GLOVE, SURGICAL
GLUCOMETER	78	C	MONITOR, BLOOD GLUCOSE (TEST)
GLUE	79	C	GLUE, SURGICAL TISSUE
GONIOMETER	87	A	GONIOMETER, MECHANICAL
	87		GONIOMETER, ORTHOPEDIC
GOUGE	77	A	GOUGE, NASAL (ENT)
	79		GOUGE, SURGICAL, GENERAL & PLASTIC SURGERY

	77	B	CURETTE, NASAL (DISPOSABLE)
GOWN	79 79	A	GOWN, ISOLATION, SURGICAL GOWN, SURGICAL
GRAFT	89 78	C	BONE GRAFT, SUBSTITUTE GRAFT, VASCULAR ACCESS
	87 79 74 74 74 74	D	GRAFT, BONE GRAFT, SKIN GRAFT, VASCULAR, BIOLOGICAL PROSTHESIS, ARTERIAL GRAFT, BOVINE CAROTID ARTERY PROSTHESIS, VASCULAR GRAFT, OF 6MM AND GREATER DIAMETER PROSTHESIS, VASCULAR GRAFT, OF LESS THAN 6MM DIAMETER SYSTEM, ENDOVASCULAR GRAFT, AORTIC ANEURYSM TREATMENT
GRANULES	76	C	GRANULES, TRICALCIUM PHOSPHATE FOR DENTAL BONE REPAIR
GRID	86	A	GRID, AMSLER

Keyword	Therapeutic Code	Class	Description
	90	B	GRID, RADIOGRAPHIC
GROWTH	87	C	STIMULATOR, OSTEOGENESIS, ELECTRIC, BATTERY-OPERATED, INVASIVE
GUARD	76 78	A	GUARD, DISK GUARD, SHUNT
	79	B	INSTRUMENT GUARD
GUIDE	79 78 87 87 79 79 79 86	B	GUIDE GUIDE, CATHETER GUIDE, DRILL GUIDE, GIGLI SAW GUIDE, NEEDLE GUIDE, SURGICAL, INSTRUMENT GUIDE, SURGICAL, NEEDLE INTRAOCULAR LENS GUIDE
	76	C	MATERIAL, PERIODONTAL TISSUE AUGMENTATION/REGENERATION
GUILLOTINE	77	A	GUILLOTINE, TONSIL
GUN GURNEY	78 80	A A	TIE GUN, DIALYSIS STRETCHER, HAND -CARRIED

GUTTA PERCHA	76	C	GUTTA PERCHA
HAIR	80	B	DEVICE, HAIR REGROWTH
	79	C	INSTRUMENT, SURGICAL, POWERED , LASER
HALTER	89	A	HEAD HALTER, TRACTION
HAMMER	79 79 84	A	HAMMER, SURGICAL HEAD, SURGICAL, HAMMER PERCUSSOR
HAND	89 89 89 87	A	ASSEMBLY, SHOULDER/ELBOW/FOREARM/WRIST/HAND, MECHANICAL HAND, EXTERNAL LIMB COMPONENT, MECHANIC AL HAND, EXTERNAL LIMB COMPONENT, POWERED PROSTHESIS, HAND
HANDLE	76 79 79 85	A	HANDLE, INSTRUMENT, DENTAL HANDLE, SCALPEL HANDLE, SURGICAL, PLASTIC & GENERAL HANDLE, TRACTION
	87 79	B	INSTRUMENT HANDLE, ORTHOPEDIC INSTRUMENT, SURGICAL, ENDOSCOPIC/LAPAROSCOPIC (NON-POWERED)
HANDPIECE	84 76	A	HANDPIECE (BRACE), DRILL HANDPIECE, FIBEROPTIC
	86 76 76 76 76	B	ACCESSORIES, PHACOFRAGMENTATION/EMULSIFICATION UNIT HANDPIECE, AIR -POWERED, DENTAL HANDPIECE, BELT AND/OR GEAR DRIVEN, DENTAL HANDPIECE, CONTRA-AND RIGHT-ANGLE ATTACHMENT, DENTAL HANDPIECE, DIRECT DRIVE, AC -POWERED
HAPLOSCOPE	86	A	HAPLOSCOPE
HEADER	74	C	TERMINAL HEADER OR PLUG FOR PULSE GENERAT OR
HEADGEAR	76	B	HEADGEAR, EXTRAORAL, ORTHODONTIC
HEADLAMP	86 86	A	HEADLAMP, OPERATING, AC -POWERED HEADLAMP, OPERATING, BATTERY-OPERATED
HEADLIGHT	86 86	A	HEADLIGHT, ENT HEADLIGHT, FIBEROPTIC FOCUSING
HEARING- AID	77 77	B	HEARING AID, GROUP AND AUDITORY TRAINER HEARING-AID, AIR-CONDUCTION
	77	C	HEARING AID, IMPLANTED BONE CONDUCTION
HEART	74	A	HEAT-EXCHANGER, CARDIOPULMONARY BYPASS
	74	D	HEART, ARTIFICAL

Keyword	Therapeutic Code	Class	Description
HEAT	89	A	PACK, HEAT, MOIST
	76	B	HEAT SOURCE FOR BLEACHING TEETH
	80	C	WARMER, INFANT RADIANT
HEATER	73	B	HEATER, BREATHING SYSTEM W/WO CONTROLLER (NOT HUMIDIFIER OR NEBULIZER)
	85		HEATER, PERINEAL, RADIANT, NON CONTACT
HELMET	80	A	HELMET, HEAD PROTECTION
	79		HELMET, SURGICAL
HEMOCONCENTRATOR	74	B	HEMOCONCENTRATOR
HEMODIALYSIS	78	A	TIE GUN, DIALYSIS
	78	B	FILTER, BLOOD, DIALYSIS
	78		PROTECTOR, TRANSDUCER, DIALYSIS
	78		SINGLE NEEDLE DIALYSIS SET (CO-AXIAL FLOW)
	78		SOLUTION-TEST STANDARD CONDUCTIVITY, DIALYSIS
	78		TEST EQUIPMENT, DIALYSIS UNIT
	78		TRAY, START/STOP (INCLUDING CONTENTS), DIALYSIS
	78		TUBING, DIALYSATE (AND CONNECTOR)
	78	C	APPARATUS, HEMOPERFUSION, SORBENT
	78		GRAFT, VASCULAR ACCESS
	78		HEMOFILTRATION UNIT
	78		MONITOR, TEMPERATURE, DIALYSIS
	78		SUBSYSTEM, PROPORTIONING
	78		UNIT, HEMODIALYSIS (KIDNEY MACHINE)
HEMOFILTRATION	78	B	ACCESSORY, BLOOD CIRCUIT, HEMODIALYSIS
	78	C	HEMOFILTRATION UNIT
HEMOPERFUSION	78	B	ACCESSORY, BLOOD CIRCUIT, HEMODIALYSIS
	78	C	APPARATUS, HEMOPERFUSION, SORBENT
HEMOSTAT	79	A	HEMOSTAT
	76		HEMOSTAT, SURGICAL
HEMOSTATIC	79	C	ABSORBABLE HEMOSTATIC AGENTS NON-COLLAGEN BASED
	79	D	ABSORBABLE HEMOSTATIC AGENTS, COLLAGEN BASED
HERNIA	79	C	MESH, SURGICAL, POLYMERIC
HIP	87	C	PROSTHESIS, HIP CUP INSERT
	87		PROSTHESIS, HIP, ACETABULAR COMPONENT, METAL, NON -

			CEMENTED
	87		PROSTHESIS, HIP, ACETABULAR COMPONENT, POLYETHYLENE
	79		PROSTHESIS, HIP, ACETABULAR MESH
	79		PROSTHESIS, HIP, CEMENT RESTRICTOR
	87		PROSTHESIS, HIP, CONSTRAINED, CEMENTED OR UNCEMENTED, METAL/ POLYMER
	87		PROSTHESIS, HIP, FEMORAL COMPONENT, CEMENTED, METAL
	87		PROSTHESIS, HIP, HEMI-, ACETABULAR, CEMENTED, METAL
	87		PROSTHESIS, HIP, HEMI-, FEMORAL, METAL, NON-CEMENTED
	87		PROSTHESIS, HIP, HEMI-, FEMORAL, METAL/POLYMER, CEMENTED OR UNCEMENTED
	87		PROSTHESIS, HIP, METAL STEM/CERAMIC SELF-LOCKING BALL
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED (METAL CEMENTED ACETABULAR COMPONENT)
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED METAL/CERAMIC/POLYMER
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED OR HEMI-, METAL/PTFE
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/CERAMIC/CERAMIC
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/CERAMIC/CERAMIC, CEMENTED
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, CEMENTED
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, NON-POROUS, CALCIUM-PHOSPHATE
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, POROUS UNCEMENTED
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, UNCEMENTED
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED, POROUS COATED
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED, UNCEMENTED, POROUS, METAL/POLYMER

Keyword	Therapeutic Code	Class	Description
HOE	76	A	HOE, PERIODONTIC
HOLDER	73	A	DEVICE, FIXATION, TRACHEAL TUBE
	80		DEVICE, INTRAVASCULAR CATHETER, SECUREMENT
	84		HOLDER, HEAD, NEUROSURGICAL (SKULL CLAMP)
	90		HOLDER, HEAD, RADIOGRAPHIC
	80		HOLDER, INFANT POSITION
	87		HOLDER, LEG, ARTHROSCOPY
	74	B	HOLDER, HEART VALVE, PROSTHESIS

HOLTER	74	B	RECORDER, LONG TERM, ECG, PORTABLE (HOLTER MONITOR)
HOOD	79	A	HOOD, SURGICAL
	73	B	HOOD, OXYGEN, INFANT
HOOK	73 89 89 85 78 77 86 79 86 79 84 77 77 85	A	HOOK, ETHER HOOK, EXTERNAL LIMB COMPONENT, MECHANICAL HOOK, EXTERNAL LIMB COMPONENT, POWERED HOOK, FIBROID, GYNECOLOGICAL HOOK, GASTRO-UROLOGY HOOK, MICROSURGICAL EAR HOOK, SCLERAL FIXATION HOOK, SKIN HOOK, STRABISMUS (SEE 86HNQ) HOOK, SURGICAL, GENERAL & PLASTIC SURGERY HOOK, SYMPATHECTOMY HOOK, TONSIL SUTURING HOOK, TRACHEAL, ENT INSTRUMENT, DESTRUCTIVE, FETAL, OBSTETRIC
	86	B	HOOK, OPHTHALMIC
HOT	89 89 89	A	PACK, HOT OR COLD, DISPOSABLE PACK, HOT OR COLD, REUSABLE PACK, HOT, CHEMICAL
HUMIDIFIER	73 73 73 73	B	HUMIDIFIER, HEAT/MOISTURE EXCHANGE HUMIDIFIER, HEATED HUMIDIFIER, NON-HEATED HUMIDIFIER, RESPIRATORY GAS, (D IRECT PATIENT INTERFACE)
HYALURONIC	86	C	FLUID, INTRAOCULAR
HYDROCEPHALIC	84 84	B D	INSTRUMENT, SHUNT SYSTEM IMPLANTATION SHUNT, CENTRAL NERVOUS SYSTEM AND COMPONENTS
HYPERTHERMIA	78	C	SYSTEM, HYPERTHERMIA, RF/MICROWAVE (BENIGN PROSTATIC HYPERPLASIA)
HYPODERMIC	79 79	B	NEEDLE, ASPIRATION AND INJECTION, DISPOSABLE NEEDLE, ASPIRATION AND INJECTION, REUSABLE
HYPOTHERMIA	74 80 78 74	B	DEVICE, HYPOTHERMIA (BLANKET, PLUMBING & HEAT EXCHANGER) DEVICE, HYPOTHERMIA THERAPY - INHALATION REWARMING DEVICE, TESTICULAR HYPOTHERMIA HEART INSULATION/PROTECTION POUCH
HYSTEROSCOPE	85	B	HYSTEROSCOPE (AND ACCESSORIES)
ILEOSTOMY	78	A	OSTOMY APPLIANCE (ILEOSTOMY, COLOSTOMY)
ILLUMINATOR	86 78	A	ILLUMINATOR, COLOR VISION PLATE ILLUMINATOR, FIBEROPTIC, FOR ENDOSCOPE

	79	B	ILLUMINATOR, FIBEROPTIC, SURGICAL FIELD
IMAGE	86 86 90	A	AID, VISION IMAGE INTENSIFICATION BRUSH, HAIDINGER, (INCLUDING MACULAR INTEGRITY) DEVICE, SPOT FILM
	90	B	SYSTEM, IMAGE INTENSIFICATION
IMAGING	78	B	IMAGING, GASTROINTESTINAL, WIRELESS, CAPSULE CAMERA

Keyword	Therapeutic Code	Class	Description
	90 76 90 90		SCANNER, WHOLE BODY, NUCLEAR SYSTEM, IMAGING, DENTAL, DIGITIAL - FILMLESS SYSTEM, NUCLEAR MAGNETIC RESONANCE IMAGIN G UNIT, IMAGING, THERMAL
	90 90 90 90 90	C	RADIOGRAPHIC/FLUROSCOPIC UNIT, ANGIOGRAPHIC, DIGITAL SYSTEM IMAGING, PULSED DOPPLER, ULTRASONIC SYSTEM, IMAGING, PULSED ECHO, ULTRASONIC SYSTEM, IMAGING, ULTRASONIC, OPHTHALMIC SYSTEM, IMAGING, X-RAY, ELECTROSTATIC
IMMOBILIZER	80 87 87 87 87 87 87 89	A	DEVICE, INTRAVASCULAR CATHETER, SECUREMENT IMMOBILIZER, ARM IMMOBILIZER, ELBOW IMMOBILIZER, HIP, POST-OP, ABDUCTION IMMOBILIZER, KNEE IMMOBILIZER, SHOULDER IMMOBILIZER, WRIST SPLINT, DENIS BROWN
IMPACTOR	87	A	IMPACTOR
IMPLANT	87	B	STIMULATOR, FUNCTIONAL NEUROMUSCULAR, SCOLIOSIS
	87 77 87 85 86 87 79 76 76	C	CARBON-FIBER IMPLANT FOR ARTHROPLASTY COCHLEAR IMPLANT FASTENER, FIXATION, BIODEGRADABLE, SOFT TISSUE IMPLANT (FOR FEMALE INCONTINENCE) IMPLANT, ABSORBABLE (SCLERAL BUCKLING METHOD) IMPLANT, CARTILAGE, FOR ARTICULAR CARTILAGE REPAIR IMPLANT, DERMAL, OTHER, FOR AESTHETIC USE IMPLANT, ENDOSSEOUS IMPLANT, ENDOSSEOUS FOR BONE FILLING AND/OR AUGMENTATION

	86		IMPLANT, EYE SPHERE
	86		IMPLANT, EYE VALVE
	79		IMPLANT, MUSCLE, PECTORALIS
	86		IMPLANT, ORBITAL, EXTRA-OCULAR
	78		IMPLANT, REFLUX, ANTI-GASTROESOPHAGEAL
	86		IMPLANT, RETINAL
	76		IMPLANT, SUBPERIOSTEAL
	80		IMPLANTED SUBCUTANEOUS PERITONEAL ACCESS DEVICE
	78		INJECTABLE BULKING AGENT FOR GASTROENTEROLOGY
	78		INTRAGASTRIC IMPLANT FOR MORBID OBESITY
	76		JOINT, TEMPOROMANDIBULAR, IMPLANT
	79		MALAR IMPLANT
	79		MESH, SURGICAL, POLYMERIC
	79		POLYMER, ENT COMPOSITE SYNTHETIC PTFE WITH CARBON -FIBRE ENT
	77		POLYMER, ENT SYNTHETIC-PIFE, SILICONE ELASTOMER, POLYETHYLENE, POLYURETHANE
	77		POLYMER, ENT, SYNTHETIC, POROUS POLYETHYLENE
	80		PORT & CATHETER, SUBCUTANEOUS, INTRASPINAL
	77		REPLACEMENT, TYMPANIC MEMBRANE
	79	D	DERMAL IMPLANTS OF COLLAGEN FOR AESTHETIC USE
	89		IMPLANT, RESORBABLE BOVINE COLLAGEN, MENISCAL REPAIR
	74		PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE
IMPLANTATION	85	A	PROSTHESIS IMPLANTATION INSTRUMENT, FALLOPIAN TUBE
	87		PROSTHESIS IMPLANTATION INSTRUMENT, ORTHOPEDIC
	87	B	DRIVER/EXTRACTOR, BONE PLATE
	84		INSTRUMENT, SHUNT SYSTEM IMPLANTATION

Keyword	Therapeutic Code	Class	Description
IMPOTENCE	78	C	DEVICE, IMPOTENCE, MECHANICAL/HYDRAULIC
IMPRESSION	76	A	MATERIAL, ALL, IMPRESSION
	76		MATERIAL, IMPRESSION TRAY, RESIN
	76		TUBE IMPRESSION AND MATRIX
INCISION	78	B	DRAIN, PENROSE
	79		KIT, INCISION AND DRAINAGE
INCONTINENCE	78	A	BAG, URINE COLLECTION, LEG, FOR EXTERNAL USE
	78		DEVICE, INCONTINENCE, UROSHEATH TYPE
	78	B	DEVICE, INCONTINENCE, INFLATABLE, FEMALE
	78	C	DEVICE, FECAL INCONTINENCE, IMPLANTED
	78		DEVICE, INCONTINENCE, MECHANICAL/HYDRAULIC
	85		IMPLANT (FOR FEMALE INCONTINENCE)

	78		INJECTABLE BULKING AGENT FOR GASTROENTEROLOGY
INCUBATOR	80 80	C	INCUBATOR, NEONATAL INCUBATOR, NEONATAL, TRANSPORT
INFLATOR INFUSER	74 80	A A	PUMP, AIR, MANUAL CUFF INFLATING PRESSURE INFUSOR FOR I.V. BAGS
INFUSION	80 80 90	B	APPARATUS, INFUSION, MANUAL BONE MARROW COLLECTION/TRANSFUSION KIT CATHETER, RADIOGRAPHIC (NON-VASCULAR)
	80 90	C	INFUSION SYSTEM, IMPLANTABLE, DRUG ADMINISTRATION SYSTEM, RADIONUCLIDE INFUSION
	80	D	CLOSED -LOOP BLOOD GLUCOSE CONTROLLER
INHALER	77	A	INHALER, NASAL
	77	B	NEBULIZER, MEDICINAL
INHIBITOR	89	C	INHIBITOR, POSTOPERATIVE FIBROSIS, TENOLYSIS
INJECTION	80 77 80	B	KIT, DRUG INJECTION, HOME USE SET, LARYNGEAL INJECTION SITE, SAMPLING/INJECTION, ASEPTIC
	79	C	IMPLANT, DERMAL, OTHER, FOR AESTHETIC USE
INJECTOR	90	A	INJECTOR, HAND HELD
	85 74 78 76 80 80	B	INJECTOR & ACCESSORIES, UTERINE MANIPULATOR INJECTOR AND SYRINGE, ANGIOGRAPHIC INJECTOR, INSULIN INJECTOR, JET, MECHANICAL -POWERED INJECTOR, MEDICATION (INOCULATOR) INJECTOR, SYRINGE
	74 74	C	INJECTOR, CONTRAST MEDIUM, AUTOMATIC INJECTOR, THERMAL DILUTION
	74	D	CATHETER, OXIMETER, FIBEROPTIC
INOCULATOR	80	B	INJECTOR, MEDICATION (INOCULATOR)
INSEMINATION	85	B	EQUIPMENT, IN -VITRO FERTILIZATION/EMBRYO TRANSFER
INSERT	78 77	A	INSERT, BLOOD PUMP PROTECTOR, HEARING (INSERT)
	86	B	INSERT, DRY EYE
INSERTER	77 77	A	INSERTER, MYRINGOTOMY TUBE INSERTER, SACCULOTOMY TACK
	86	B	INTRAOCULAR LENS GUIDE
INSOLE	80	A	MEDICAL INSOLES
INSTRUMENT	87	A	INSTRUMENT SET FOR ORTHOPEDIC SURGERY

	76		INSTRUMENT, DENTAL, MANUAL
	85		INSTRUMENT, MANUAL, SPECIALIZED OBSTETRIC-GYNECOLOGIC
	84		INSTRUMENT, MICROSURGICAL

Keyword	Therapeutic Code	Class	Description
	76		INSTRUMENT, ORTHODONTIC
	76		INSTRUMENT, PERIODONTAL
	84		INSTRUMENT, SURGICAL, NON-POWER ED
	79		KIT, INSTRUMENTS AND ACCESSORIES, SURGICAL
	79		MICROSURGICAL INSTRUMENT
	87		ORTHOPEDIC MANUAL SURGICAL INSTRUMENT
	76		SET, INSTRUMENT FOR DENTAL SURGERY
	77		SET, INSTRUMENT FOR MIDDLE EAR SURGERY
	79		SET, INSTRUMENT, PODIATRY
	78		SURGICAL INSTRUMENTS, G-U, MANUAL (AND ACCESSORIES)
	76	B	INSTRUMENT, DIAMOND, DENTAL
	74		INSTRUMENT, SURGICAL, CARDIOVASCULAR
	87		INSTRUMENT, SURGICAL, ORTHOPEDIC, AC -POWERED MOTOR AND ACCESSORY/ATTACHMENT
	87		INSTRUMENT, SURGICAL, ORTHOPEDIC, PNEUMATIC POWERED & ACCESSORY/ATTACHMENT
	87		INSTRUMENT, SURGICAL, SONIC AND ACCESSORY/ATTACHMENT
	79		SURGICAL INSTRUMENT KIT, DISPOSABLE
	79		SURGICAL INSTRUMENT, DISPOSABLE
INSUFFLATOR	78	B	INSUFFLAT OR, AUTOMATIC CARBON-DIOXIDE FOR ENDOSCOPE
	85		INSUFFLATOR, CARBON-DIOXIDE, UTEROTUBAL (AND ACCESSORIES)
	85		INSUFFLATOR, HYSTEROSCOPIC
	85		INSUFFLATOR, LAPAROSCOPIC
INSULIN	80	D	CLOSED -LOOP BLOOD GLUCOSE CONTROLLER
INTRAGASTRIC	78	C	INTRAGASTRIC IMPLANT FOR MORBID OBESITY
INTRAVENOUS	80	B	CONTAINER, I.V.
	74		FLOWMETER, BLOOD, CARDIOVASCULAR
	79		I.V. START KIT
	80		INTRAVASCULAR (I.V.) ADMINISTRATION SET
	80		SET, I.V. FLUID TRANSFER
	80		STOPCOCK, I.V. SET

	90	C	SYSTEM, RADIONUCLIDE INFUSION
INTRODUCER	86 87	A	INTRODUCER, SPHERE NAIL/PLATE, INTRODUCER
	78 74 85 79 73 74	B	GUIDE, CATHETER INTRODUCER, CATHETER INTRODUCER, CONTRACEPTIVE DIAPHRAGM INTRODUCER, NEEDLE INTRODUCER, SPINAL NEEDLE KIT, INTRODUCER, PACEMAKER, LEAD
	85	C	INTRAUTERINE, DEVICE, CONTRACEPTIVE (IUD) AND INTRODUCER
INTUBATION	73 86	B	SET, INTUBATION SYSTEM, INTUBATION, LACRIMAL
INVERSION UNIT	87	A	INVERSION UNIT
IONTOPHORESIS	89 89 78	B	DEVICE, IONTOPHORESIS DEVICE, IONTOPHORESIS, OTHER USES SYSTEM, DIAGNOSTIC, CYSTIC FIBROSIS
IRIDIUM	90	C	SOURCE, WIRE, IRIDIUM, RADIOACTIVE
IRRADIATOR	78	C	IRRADIATOR, BLOOD, EXTRACORPOREAL
IRRIGATION	77 78 87	A	KIT, IRRIGATION, ORAL PERINEAL, IRRIGATION KIT TUBE, INTRAMEDULLARY, FLUSHING
	86 79 86	B	DEVICE, IRRIGATION, OCULAR SURGERY EQUIPMENT, SUCTION/IRRIGATION, ENDOSCOPIC KIT, IRRIGATION, EYE

Keyword	Therapeutic Code	Class	Description
	80 77 78		KIT, IRRIGATION, WOUND STIMULATOR, CALORIC -WATER TRAY, IRRIGATION, STERILE
	86	C	INSTRUMENT, VITREOUS ASPIRATION AND CUTTING, AC - POWERED
IRRIGATOR	77	A	IRRIGATOR, SINUS

	86 76 78 80 78	B	IRRIGATOR, OCULAR, EMERGENCY IRRIGATOR, ORAL IRRIGATOR, OSTOMY IRRIGATOR, SUCTION SYSTEM, IRRIGATOR, COLONIC
ISOMETER	87	B	ISOMETER
ISOTOPE	90	C	SOURCE, ISOTOPE, SEALED, GOLD, TITANIUM, PLATINUM
JELLY	78	B	JELLY, LUBRICATING, FOR TRANSURETHRAL SURG ICAL INSTRUMENT
JOCK	80	A	THERAPEUTIC SCROTAL SUPPORT
KERATOME	86	A	INSTRUMENT, SURICAL, RADIAL KERATOTOMY
	86 86 86	B	KERATOME, AC -POWERED KERATOME, BATTERY-POWERED KNIFE, KERATOME (DISPOSABLE)
KERATOMETER	86	B	KERATOMETER
KERATOPROSTHESIS	86	C	KERATOPROSTHESIS, NON-CUSTOM
KERATOSCOPE	86 86 86	A	KERATOSCOPE KERATOSCOPE, AC -POWERED KERATOSCOPE, BATTERY-POWERED
KNEE	89 89	A	ASSEMBLY, THIGH/KNEE/SHANK/ANKLE/FOOT, EXTERNAL JOINT, KNEE, EXTERNAL LIMB COMPONENT
	87 87 87 87 87 87 87 8 87 87 87 87 87	C	PROSTHESIS, KNEE PATELLOFEMOROTIBIAL CONSTRAINED, CEMENTED, POLYMER/METAL PROSTHESIS, KNEE, FEMOROTIBIAL, CONSTRAINED, CEMENTED, METAL PROSTHESIS, KNEE, FEMOROTIBIAL, NON-CONSTRAINED, CEMENTED, METAL/POLYMER PROSTHESIS, KNEE, FEMOROTIBIAL, SEMI-CONSTRAINED, CEMENTED, METAL/POLYMER PROSTHESIS, KNEE, HEMI-, FEMORAL PROSTHESIS, KNEE, HEMI-, PATELLAR RESURFACING, UNCEMENTED PROSTHESIS, KNEE, HEMI-, TIBIAL RESURFACING, U NCEMENTED PROSTHESIS, KNEE, HINGED (METAL -METAL) PROSTHESIS, KNEE, PATELLAR PROSTHESIS, KNEE, PATELLOFEMORAL, SEMI-CONSTRAINED, CEMENTED, METAL/POLYMER PROSTHESIS, KNEE, PATELLOFEMOROTIBIAL, SEMI-CONSTRAINED, CEMENTED , POLYMER PROSTHESIS, KNEE, TIBIAL PROSTHESIS, KNEE, TOTAL PROSTHESIS, KNEE, UNICOMPARTMENTAL, CEMENTED
KNIFE	79	A	KNIFE, AMPUTATION
	86 85 84 77	B	KNIFE, CATARACT KNIFE, CERVICAL CONE KNIFE, DURA HOOK KNIFE, EAR

	86		KNIFE, KERATOME (DISPOSABLE)
	77		KNIFE, LARYNGEAL
	76		KNIFE, MARGIN FINISHING, OPERATIVE
	79		KNIFE, MENISCUS
	77		KNIFE, MYRINGOTOMY (DISPOSABLE)
	77		KNIFE, NASAL
	86		KNIFE, OPHTHALMIC
	87		KNIFE, ORTHOPEDIC
	76		KNIFE, PERIODONTIC

Keyword	Therapeutic Code	Class	Description
	79		KNIFE, SCALPEL (DISPOSABLE)
	79		KNIFE, SKIN GRAFTING
	79		KNIFE, SURGICAL
	77		KNIFE, TONSIL
	79		SCALPEL, ONE-PIECE (DISPOSABLE)
KRYPTON	86	C	OPHTHALMIC LASER
LACRIMAL	86	C	PROSTHESIS, LACRIMAL DUCT
LAMP	76	A	ACTIVATOR, ULTRAVIOLET, FOR POLYMERIZATION
	78		LAMP, ENDOSCOPE, INCANDESCENT
	80		LAMP, EXAMINATION (LIGHT)
	79		LAMP, OPERATING ROOM
	79		LAMP, SURGICAL
	79		LAMP, SURGICAL, INCANDESCENT
	89	B	LAMP, HEAT
	89		LAMP, INFRARED
	79		LAMP, ULTRAVIOLET, PHYSICAL MEDICINE
	79		LIGHT, ULTRAVIOLET, DERMATOLOGICAL
LANCET	79	B	LANCET, BLOOD
LAPAROSCOPE	79	B	INSTRUMENT, SURGICAL, ENDOSCOPIC/LAPAROSCOPIC (NON-POWERED)
	78		LAPAROSCOPE, GENERAL & PLASTIC SURGERY
	85		LAPAROSCOPE, GYNECOLOGIC (AND ACCESSORIES)
LAPAROSCOPY	78	B	SET, LAPAROSCOPY
LARYNGOSCOPE	77	B	LARYNGOSCOPE
	73		LARYNGOSCOPE, NON-RIGID
	73		LARYNGOSCOPE, RIGID
LARYNX	77	B	LARYNX, ARTIFICIAL, BATTERY POWERED
	77	C	PROSTHESIS, LARYNX

LASER	86 79 76 79	B	INSTRUMENT, VISUAL FIELD, LASER LASER FOR WOUND HEALING (CLASS A-CA) LASER, FLUORESCENCE CARIES DETECTION SYSTEM, SMOKE EVACUATION, LASER
	79 80 76 78 86 86 90 80 79 79 85 79 79 86 90 86 79	C	INSTRUMENT, SURGICAL, POWERED, LASER LASER, COPPER VAPOR LASER, DENTAL LASER, LITHOTRIPTOR LASER, NEODYMIUM:YAG, OPHTHALMIC FOR POSTERIOR CAPSULOTOMY LASER, OPHTHALIMC, PHOTOCOAGULATOR LASER, PHOTODYNAMIC THERAPY (PDT) LASER, Q-SWITCHED LASER, SURGICAL, CARBON -DIOXIDE LASER, SURGICAL, DYE LASER, SURGICAL, GYNECOLOGIC LASER, SURGICAL, HOLMIUM LASER, SURGICAL, NEODYMIUM, YAG LASER, SYSTEM, EXCIMER LASER, THERAPEUTIC OPHTHALMIC LASER SYSTEM, LASER, PHOTODYNAMIC THERAPY
	74	D	DEVICE, LASER, ANGIOPLASTY, CORONARY
LATEX	78	A	SHEATH, CORRUGATED RUBBER, FOR NONINDWELLING CATHETER
LAVAGE	80 78	B	LAVAGE, JET TUBE, STOMACH EVACUATOR (GASTRIC LAVAGE)
LEAD	90	A	APRON, PROTECTIVE

Keyword	Therapeutic Code	Class	Description
	90 90		SHIELD, X-RAY SHIELD, X-RAY, PORTABLE
	74	B	ELECTRODE, ELECTROCARDIOGRAPH
	74	C	LEAD, ANCHORING SLEEVE, IMPLANTABLE
	74 74 74 74 74	D	ELECTRODE, PACEMAKER, TEMPORARY LEAD, ELECTRODE, CARDIOVERTER, DEFIBRILLATOR, PERMANENT LEAD, ELECTRODE, PACEMAKER, PERMANENT LEAD, EXTENDER, PACEMAKER, IMPLANTABLE LEAD, PACEMAKER (CATHETER)

	74		LEAD, PACEMAKER , IMPLANTABLE, INDIFFERENT
LEG	87	A	PROSTHESIS, LEG
LEGGING	80	A	NON-INFLATABLE COMPRESSION LEGGING
LENS	86 86 78 86 86 86 86 86 86 86	A	BINOCULAR LOUPE, LOW POWER DISTOMETER INSTRUMENT, SPECIAL LENS, FOR ENDOSCOPE LENS, BAGOLINI LENS, CONDENSING, DIAGNOSTIC LENS, FRESNEL, FLEXIBLE, DIAGNOSTIC LENS, FUNDUS, HRUBY, DIAGNOSTIC LENS, MADDOX LENS, SPECTACLE, CUSTOM LENS, SPECTACLE, NON-CUSTOM (PRESCRIPTION) SET, LENS, TRIAL, OPHTHALMIC
	86 86 86 86 86 86 86 86 86	B	LENS, CONTACT (OTHER MATERIAL) - DAILY LENS, CONTACT (POLYMETHYLMETHACRYLATE) LENS, CONTACT, BIFOCAL LENS, CONTACT, DISPOSABLE LENS, CONTACT, GAS-PERMEABLE LENS, CONTACT, POLYMETHYLMETH ACRYLATE, DIAGNOSTIC LENS, CONTACT, TINTED LENS, SURGICAL, LASER LENSES, SOFT CONTACT, DAILY WEAR LENSES, SOFT CONTACT, EXTENDED WEAR (LESS THAN C0 DAYS)
	86 86	C	LENS, INTRAOCULAR LENS, MULTIFOCAL INTRAOCULAR
LENSOMETER	86	A	LENSOMETER
LEVER	85	A	VECTIS, OBSTETRICAL
LIFTER	79	A	LIFTER, SKIN
LIGAMENT	87	C	PROSTHESIS, LIGAMENT
LIGATOR	85	A	LIGATOR, UMBILICAL
	78	B	LIGATOR, HEMORRHOIDAL
LIGATURE	76	C	LOCK, WIRE, AND LIGATURE, INTRAORAL
LIGHT	76 78 78 78 78 78 76 76 86 76 76	A	ACTIVATOR, ULTRAVIOLET, FOR POLYMERIZATION LIGHT SOURCE, ENDOSCOPE, XENON ARC LIGHT SOURCE, FIBEROPTIC, ROUTINE LIGHT SOURCE, HALOGEN LIGHT SOURCE, INCONDESCENT, DIAGNOSTIC LIGHT SOURCE, PHOTOGRAPHIC, FIBEROPTIC LIGHT, DENTAL, INTRAORAL LIGHT, FIBER OPTIC, DENTAL LIGHT, HEADBAND, SURGICAL LIGHT, SURGICAL HEADLIGHT, DENTAL LIGHT, SURGICAL OPERATING, DENTAL

Keyword	Therapeutic Code	Class	Description
	79		LIGHT, SURGICAL, CEILING MOUNTED
	79		LIGHT, SURGICAL, ENDOSCOPE
	79		LIGHT, SURGICAL, FIBEROPTIC
	79		LIGHT, SURGICAL, FLOOR STANDING
	79		LIGHT, SURGICAL, INSTRUMENT
	86		PENLIGHT, BATTERY-POWERED
	80	B	LIGHT, THERAPY, SEASONAL AFFECTIVE DISORDER (SAD)
	79		LIGHT, ULTRAVIOLET, DERMATOLOGICAL
	86		MAXWELL SPOT, AC -POWERED
	80	C	LIGHT, BILIRUBIN (PHOTOTHERAPY)
LINEAR ACCELERATOR	90	C	ACCELERATOR, LINEAR, MEDICAL
LINER	76	C	LINER, CAVITY, CALCIUM HYDROXIDE
	76		LIN ER, CAVITY, OTHER
	87		PROSTHESIS, HIP CUP INSERT
LIPOSUCTION	79	C	DEVICE, LIPECTOMY, SUCTION
LITHOTRIPTOR	78	A	BILIARY MECHANICAL LITHOTRIPTOR
	78	C	LITHOTRIPTOR
	78		LITHOTRIPTOR, ELECTRO-HYDRAULIC
	78		LITHOTRIPTOR, EXTRAC ORPOREAL, SHOCKWAVE
	78		LITHOTRIPTOR, ULTRASONIC
LOCALIZER	79	B	LOCALIZER & FIXATOR, LESION, BREAST
LOCATOR	80	A	LIQUID CRYSTAL VEIN LOCATION DEVICE
	86		LOCATOR, MAGNETIC
	73	B	LOCATOR, ACUPUNCTURE POINT
	73		LOCATOR, EPIDURAL SPACE
	86		LOCATOR, METAL, ELECTRONIC
	76		LOCATOR, ROOT APEX
	79		LOOP, IDENTIFICATION, SURGICAL
LOCK	80	B	SITE, SAMPLING/INJECTION, ASEPTIC
	76	C	LOCK, WIRE, AND LIGATURE, INTRAORAL
LOOP	86	A	LOOP, LENS
	77		LOOP, W IRE
	74	B	LOOP, ENDARTERECTOMY
	79		LOOP, IDENTIFICATION, SURGICAL
	74		LOOP, VASCULAR
LOUPE	86	A	BINOCULAR LOUPE, LOW POWER

	79		LOUPE, DIAGNOSTIC/SURGICAL
LUBRICANT	78 80	B	JELLY, LUBRICATING, FOR TRANSURETHRAL SURGICAL INSTRUMENT PATIENT LUBRICANT
	87	C	FLUID, JOINT LUBRICATING
LUNG	74	B	HEAT-EXCHANGER, CARDIOPULMONARY BYPASS
	73 73 73	C	KIT, DIAGNOSTIC, PULMONARY, RADIO AEROSOL MEMBRANE, LUNG (FOR LONG-TERM RESPIRATORY SUPPORT) VENTILATOR, EXTERNAL BODY, NEGATIVE PRESSURE, ADULT (CUIRASS)
MAGNET	86	A	MAGNET, PERMANENT
	86 74	B	MAGNET, AC -POWERED MAGNET, TEST, PACEMAKER
MAGNETIC	90 89	B	SCANNER, WHOLE BODY, NUCLEAR UNIT, MAGNETIC, THERAPEUTIC
MAGNIFIER	77 86 79	A	MAGNIFIER, AURAL (PNEUMATIC OTOSCOPE) MAGNIFIER, HAND HELD, LOW VISION MAGNIFIER, OPERATING
MAINTAINER	76	B	MAINTAINER, SPACE PREFORMED, ORTHODONTIC

Keyword	Therapeutic Code	Class	Description
MALAR	79	C	MALAR IMPLANT
MALLET	79 76 79	A	MALLET, BONE MALLET, DENTAL MALLET, SURGICAL, GENERAL & PLASTIC SURGERY
MAMMOGRAPHIC	90	C	SYSTEM, X-RAY, MAMMOGRAPHIC
MANAGEMENT	90	C	SYSTEM, MANAGEMENT, RADIOTHERAPY
MANDREL	76	A	MANDREL
MANIPULATOR	86	A	INSTRUMENT, LENS MANIPULATION
	85	B	INJECTOR & ACCESSORIES, UTERINE MANIPULATOR
MANOMETER	74 74 78	A	MANOMETER, BLOOD PRESSURE, ANEROID MANOMETER, BLOOD PRESSURE, MERCURY MANOMETER, WATER

	74 80 80	B	MANOMETER, BLOOD PRESSURE, VENOUS MANOMETER, SPINAL FLUID SPHYGMOMANOMETER, ELECTRONIC (ARTERIAL PRESSURE)
MARKER	76 79	A	MARKER, PERIODONTIC MARKER, SKIN
	79 86 86 86	B	LOOP, IDENTIFICATION, SURGICAL MARKER, OCULAR MARKER, SCLERA PEN, MARKING, SURGICAL
	79	C	MARKER, RADIOGRAPHIC, IMPLANTABLE
MASK	86 79	A	MASK, EYE MASK, SURGICAL
	73 73 73 73 73 77	B	MASK, AEROSOL ADMINISTRATION MASK, GAS, ANESTHESIA MASK, OXYGEN MASK, OXYGEN, LOW CONCENTRATION, VENTURI MASK, OXYGEN, NON-REBREATHING MASK, TRACHEOSTOMY
MASKER	77	B	MASKER, TINNITIS
MASSAGER	89	A	MASSAGER, THERAPEUTIC, MANUAL
	89 89 89 89	B	MASSAGER, BATTERY-POWERED MASSAGER, POWERED INFLATABLE TUBE MASSAGER, THERAPEUTIC, ELECTRIC TAB LE, PHYSICAL THERAPY, MULTI FUNCTION
MATERNITY	85	A	KIT, MATERNITY
MATRIX	76 76	A	MATRIX, DENTAL TUBE IMPRESSION AND MATRIX
MATTRESS	80 80 80	A	MATTRESS, OPERATING TABLE NON-POWERED FLOTATION THERAPY MATTRESS PAD, MATTRESS, THERAPEUTIC
	80 80 80	B	MATTRESS, AIR FLOTATION, ALTERNATING PRESSURE MATTRESS, ALTERNATING PRESSURE TEMPERATURE REGULATED WATER MATTRESS
MAXWELL SPOT	86	B	MAXWELL SPOT, AC -POWERED
MEASUREMENT	86	A	DISTANCE MEASUREMENT, PUPILLARY/NASAL -PUPILLARY
	84 74 78	B	DEVICE, SKIN POTENTIAL MEASUREMENT SYSTEM, MEASUREMENT, BLOOD PRESSURE, NON-INVASIVE SYSTEM, MEASUREMENT, URODYNAMIC
MEASURING	86 78	A	DEVICE, MEASURING, LENS RADIUS, OPHTHALMIC DEVICE, URINE FLOW RATE MEASURING, NON-ELECTRICAL, DISPOSABLE

	86		INSTRUMENT, MEASURING, CORNEAL RADIUS

Keyword	Therapeutic Code	Class	Description
	86		INSTRUMENT, MEASURING, LENS, AC -POWERED
	86		INSTRUMENT, MEASURING, STEREOPSIS
	76		MEASURER, GINGIVAL FLUID
MEDIA	85	B	MEDIA, REPRODUCTIVE
MEDIASTINOSCOPE	78	B	MEDIASTINOSCOPE
MEMBRANE	73	C	MEMBRANE, LUNG (FOR LONG-TERM RESPIRATORY SUPPORT)
	77		REPLACEMENT, TYMPANIC MEMBRANE
MENISCOTOME	87	A	MENISCOTOME
MENISCUS	87	A	INSTRUMENT SET FOR ORTHOPEDIC SURGERY
	87		MENISCOTOME
	87	C	FASTENER, FIXATION, NONDEGRADABLE, SOFT TISSUE
MESH	79	C	MESH, METAL
	79		MESH, SURGICAL
	79		MESH, SURGICAL, POLYMERIC
METAL	76	C	METAL, BASE
METER	85	A	EXTERNAL PELVIMETER
	80	B	BILIRUBINOMETER, CUTANEOUS (JAUNDICE METER)
	73		METER, AIRWAY PRESSURE (INSPIRATORY FORCE)
	78		METER, DIALYSATE CONDUCTIVITY
	73		METER, PEAK FLOW, SPIROMETRY
	84		METER, SKIN RESISTANCE, BATTERY POWERED
	78	C	METER, CONDUCTIVITY, NON-REMOTE
METHYL -METACRYLATE	84	C	METHYL METACRYLATE FOR CRANIOPLASTY
MICROFILTER	80	B	MICROFILTER, BLOOD TRANSFUSION
MICROSCOPE	86	A	BIOMICROSCOPE, SLIT-LAMP, AC -POWERED
	79		MICROSCOPE, OPERATING & ACCESSORIES, AC -POWERED, OPHTHALMIC
	79		MICROSCOPE, OPERATING, NON-ELECTRIC, OPHTHALMIC
	79		MICROSCOPE, SURGICAL
	79		MICROSCOPE, SURGICAL, GENERAL & PLASTIC SURGERY
	86		SPECTACLE MICROSCOPE, LOW -VISION
	79		SYSTEM, MICROSCOPE, SURGICAL

MICROWAVE	89	B	DIATHERMY, MICROWAVE, FOR USE IN APPLYING THERAPEUTIC DEEP HEAT
	89		DIATHERMY, MICROWAVE, FOR USE OTHER THAN APPLYING THERAPEUTIC DEEP HEAT
	78	C	SYSTEM, HYPERTHERMIA, RF/MICROWAVE (BENIGN PROSTATIC HYPERPLASIA)
	78		SYSTEM, THERMOTHERAPY, RF/MICROWAVE (BENIGN PROSTATIC HYPERPLASIA)
MILL	87	A	BONE MILL
	87		SET, HOLLOW MILL
MIRROR	78	A	ENDOSCOPE, MIRROR
	77		MIRROR, ENT
	79		MIRROR, GENERAL & PLASTIC SURGERY
	86		MIRROR, HEADBAND, OPHTHALMIC
	76		MIRROR, MOUTH
MIXER	87	A	MIXER, CEMENT, FOR CLINICAL USE
	73	B	MIXER, BREATHING GASES, ANESTHESIA INHALATION
MOBILIZER	77	A	MOBILIZER, ENT
MODULE	74	C	SYSTEM, PATIENT MONITORING - MULTI-FUNCTION COMPONENTS
MOLD	85	B	MOLD, VAGINAL
	77	C	MOLD, MIDDLE EAR
MONITOR	90	A	SCREEN, INTENSIFYING, RADIOGRAPHIC
	80		TELEVISION MONITOR, ENDOSCOPE
	80		TELEVISION MONITOR, MICROSCOPE
	74	B	MANOMETER, BLOOD PRESSURE, VENOUS
	73		METER, AIRWAY PRESSURE (INSPIRATORY FORCE)

Keyword	Therapeutic Code	Class	Description
	73		METER, PEAK FLOW, SPIROMETRY
	73		MONITOR (APNEA DETECTOR), VENTILATORY EFFORT
	74		MONITOR, BLOOD PRESSURE, NON-INDWELLING
	74		MONITOR, BLOOD PRESSURE, TRANSDUCER, NON-INDWELLING
	73		MONITOR, BREATHING FREQUENCY
	74		MONITOR, ECG, AMBULATORY, REAL -TIME
	89		MONITOR, ELECTROMYOGRAPHIC
	78		MONITOR, ESOPHAGEAL MOTILITY, AND TUBE
	78		MONITOR, ESOPHAGEAL PRESSURE
	86		MONITOR, EYE MOVEMENT
	86		MONITOR, EYE MOVEMENT, DIAGNOSTIC

	73		MONITOR, IMPEDANCE PNEUMOGRAPH
	90		MONITOR, PATIENT POSITION, LIGHT BEAM
	76		MONITOR, PERIODONTAL TISSUE
	80		MONITOR, TEMPERATURE, GENERAL & PLASTIC SURGERY
	78		PENILE TUMESCENCE MONITOR
	73		PLETHYSMOGRAPH, VOLUME
	74		RECORDER, LONG TERM, ECG, PORTABLE (HOLTER MONITOR)
	74		SYSTEM, THERMAL REGULATING
	74	C	BLOOD PRESSURE/OXYGEN SATURATION IN THE BLOOD MONITOR
	74		BLOOD PRESSURE/TEMPERATURE MONITOR
	74		DEFIBRILLATOR/MONITOR, BATTERY POWERED
	74		DEFIBRILLATOR/MONITOR, LINE POWERED
	74		MONITOR AND/OR CONTROL, LEVEL SENSING, CARDIOPULMONARY
	73		MONITOR, AIRWAY PRESSURE (INCLUDES GAUGE AND/OR ALARM)
	85		MONITOR, BLOOD FLOW, ULTRASONIC
	74		MONITOR, BLOOD GAS, ON-LINE, CARDIOPULMONARY BYPASS
	73		MONITOR, BLOOD GAS, TRANSCUTANEOUS OXYGEN
	78		MONITOR, BLOOD GLUCOSE (TEST)
	74		MONITOR, BLOOD PRESSURE, INDWELLING
	74		MONITOR, BLOOD PRESSURE, TRANSDUCER, INDWELLING
	74		MONITOR, BLOOD-PRESSURE, NEONATAL, ULTRASONIC/DOPPLER
	74		MONITOR, CARDIAC (INCL. CARDIOTACHOMETER & RATE ALARM)
	74		MONITOR, CARDIAC OUTPUT, THERMAL (BALLOON TYPE CATHETER)
	74		MONITOR, CARDIAC OUTPUT, TREND (ARTERIAL PRESSURE PULSE
	84		MONITOR, CEREBRAL FUNCTION
	74		MONITOR, ELECTROCARDIOGRAPH
	85		MONITOR, ELECTROENCEPHALOGRAPHIC, FETAL (AND ACCESSORIES)
	84		MONITOR, ELECTROENCEPHALOGRAPHIC, GENERAL & PLASTIC SURGERY
	85		MONITOR, HEART RATE, FETAL, ULTRASONIC
	74		MONITOR, HEART RATE, NEONATAL
	74		MONITOR, HEART RATE, R-WAVE (ECG)
	73		MONITOR, HEMODYNAMIC
	78		MONITOR, HEMOFILTRATION
	84		MONITOR, LESION TEMPERATURE
	73		MONITOR, LUNG WATER MEASUREMENT
	85		MONITOR, NEONATAL, PHYSIOLOGICAL
	73		MONITOR, OXYGEN (VENTILATORY) W/WO ALARM
	84		MONITOR, OXYGEN, BRAIN
	74		MONITOR, PHYSIOLOGICAL, PATIENT
	73		MONITOR, POB, CONTINUOUS
	78		MONITOR, PRESSURE, HEMODIALYSIS, EXTRACORPOREAL
	74		MONITOR, PULSE RATE
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Keyword	c Code	Class	Description
	73		MONITOR, RESPIRATORY
	80		MONITOR, SPINAL-FLUID PRESSURE
	80		MONITOR, TEMPERATURE (WITH PROBE)
	78		MONITOR, TEMPERATURE, DIALYSIS
	78		MONITOR, ULTRAFILTRATION
	85		MONITOR, ULTRASONIC, FETAL
	90		MONITOR, ULTRASONIC, NON-FETAL
	85		MONITOR, UTERINE CONTRACTION, EXTERNAL
	73		MONITOR, VENTILATION
	80	D	CLOSED -LOOP BLOOD GLUCOSE CONTROLLER
	85		FETAL PH MONITOR
	84		IMPLANTED INTRACRANIAL PRESSURE MONITOR
	84		MONITOR, CEREBRAL BLOOD FLOW, THERMAL DIFFUSION
	74		MONITOR, PRESSURE, CARDIAC, ARTERIAL
MONITORING	80	B	DEVICE, MONITORING, BALLOON/CUFF PRESSURE
	80		KIT, PRESSURE MONITORING (AIR/GAS)
	74	C	PATIENT MONITORING SYSTEM, MAINFRAME
	74		SYSTEM, PATIENT MONITORING - CENTRAL STATION
	74		SYSTEM, PATIENT MONITORING - MULTI-FUNCTION COMPONENTS
	84	D	DEVICE, INTRACRANIAL PRESSURE MONITORING
MORCELLATOR	79	B	CUTTER, SURGICAL
MORSELIZER	79	A	CRUSHER, CARTILAGE
MOTILITY	78	B	SYSTEM, GASTROINTESTINAL MOTILITY (ELECTRICAL)
MOTOR	84	B	MOTOR, DRILL, PNEUMATIC
	79		MOTOR, SURGICAL INSTRUMENT, AC -POWERED
	79		MOTOR, SURGICAL INSTRUMENT, PNEUMATIC POWERED
MOUTHPIECE	76	A	MOUTHPIECE, SALIVA EJECTOR
	73	B	MOUTHPIECE, BREATHING
MOVEMENT	86	A	OCULO-MOTOR MOVEMENT TRAINING, OPHTHALMIC
MRI	90	B	SCANNER, WHOLE BODY, NUCLEAR
MUSCLE	89	B	DEVICE, THERAPY, DIRECT CURRENT, LOW INTENSITY
	87		DYNAMOMETER
	87		DYNAMOMETER, PHYSICAL MEDICINE
	79	C	IMPLANT, MUSCLE, PECTORALIS
MYELOGRAM	84	B	KIT, MYELOGRAM
MYOMETER	89	B	MYOMETER, MUSCLE FORCE MEASUREMENT

NASAL	79	C	PROSTHESIS, RHINOPLASTY/NASAL DORSAL IMPLANT
NASOPHARYNGOSCOPE	77	B	NASOPHARYNGOSCOPE (FLEXIBLE OR RIGID)
NEBULIZER	73 73 73 77 73 73	B	NEBULIZER (DIRECT PATIENT INTERFACE) NEBULIZER NON-HEATED NEBULIZER, HEATED NEBULIZER, MEDICINAL NEBULIZER, MEDICINAL, NON-VENTILATORY (ATOMIZER) NEBULIZER, ULTRASONIC
NEEDLE	80 79	A	DEVICE, INTRAVASCULAR CATHETER SECUREMENT NEEDLE, KNIFE
	80 78 73 73 73 74 79	B	DEVICE, MEDIC ATION RECONSTITUTION/TRANSER KIT, BIOPSY NEEDLE KIT, CRICOTHYROTOMY LOCATOR, ACUPUNCTURE POINT NEEDLE, ACUPUNCTURE NEEDLE, ANGIOGRAPHIC NEEDLE, ASPIRATION AND INJECTION, DISPOSABLE

Keyword	Therapeutic Code	Class	Description
	79 85 80 79 74 79 85 74 73 76 73 78 80 78 79 80 74		NEEDLE, ASPIRATION AND INJECTION, REUSABLE NEEDLE, BIOPSY, MAMMARY NEEDLE, BLOOD COLLECTING NEEDLE, BONE MARROW NEEDLE, CARDIAC NEEDLE, CATHETER NEEDLE, CERCLAGE, GYNECOLOGICAL NEEDLE, CHOLANGIOGRAPHY NEEDLE, CONDUCTION, ANESTHETIC (W/WO INTRODUCER) NEEDLE, DENTAL NEEDLE, EMERGENCY AIRWAY NEEDLE, ENDOSCOPIC (DISPOSABLE) NEEDLE, FILTER NEEDLE, FISTULA NEEDLE, GASTRO-UROLOGY NEEDLE, HYPODERMIC, SINGLE LUMEN NEEDLE, INTRA- ARTERIAL

	80 84 85 86 86 78 78 90 80 79 79 80 77 79		NEEDLE, INTRAVENOUS NEEDLE, NEUROSURGICAL SUTURE NEEDLE, OOCYTE ASPIRATION NEEDLE, OPHTHALMIC (DISPOSABLE) NEEDLE, OPHTHALMIC SUTURIN G NEEDLE, PNEUMOPERITONEUM, SIMPLE NEEDLE, PNEUMOPERITONEUM, SPRING LOADED NEEDLE, RADIOGRAPHIC NEEDLE, SPINAL, SHORT TERM NEEDLE, SUTURING, DISPOSABLE NEEDLE, SUTURING, REUSABLE NEEDLE, SYRINGE, PUNCTURE PROTECTIVE NEEDLE, TONSIL SUTURING SCLEROTHERAPY NEEDLE/CATHETER
	90 79	C	NEEDLE, ISOTOPE, GOLD, TITANIUM, PLATINUM SUTURE/NEEDLE COMBINATION
NEPHROSCOPE	78	B	SET, NEPHROSCOPE
NIPPER NITRIC OXIDE	77 73	A C	NIPPER, MALLEUS APPARATUS, NITRIC OXIDE DELIVERY
NMR	90	B	SCANNER, WHOLE BODY, NUCLEAR
NOSE	79	C	PROSTHESIS, NOSE, INTERNAL
NOZZLE	85	B	NOZZLE, DOUCHE
NUT	87	C	WASHER, BOLT, NUT
NYSTAGMOGRAPH	84	B	NYSTAGMOGRAPH
OBTURATOR	73 78	B	AIRWAY, ESOPHAGEAL (OBTURATOR) OBTURATOR, FOR ENDOSCOPE
OCCLUDER	86	A	OCCLUDER, OPHTHALMIC
	74 74	B	OCCLUDER, CATHETER TIP OCCLUDER, VASCULAR
	74	D	OCCLUDER, PATENT DUCTUS, ARTERIOSUS
OCCLUSION	85	C	DEVICE, OCCLUSION, TUBAL (TOD), CONTRACEPTIVE
ONCOLOGIC	90	C	LASER, THERAPEUTIC
OPHTHALMODYNAMOMETER	84	B	OPHTHALMODYNAMOMETER
OPHTHALMOMETER	86	A	OPHTHALMOMETER
OPHTHALMOSCOPE	86 86	A	OPHTHALMOSCOPE, AC -POWERED OPHTHALMOSCOPE, BATTERY-POWERED

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Keyword	Code	Class	Description
	86 86		OPHTHALMOSCOPE, DIRECT OPHTHALMOSCOPE, IN -DIRECT
	86	B	OPHTHALMOSCOPE, LASER
ORBITAL	86	C	IMPLANT, ORBITAL, EXTRA-OCULAR
ORTHODONTIC	76	B	ADHESIVE, BRACKET AND TOOTH CONDITIONER, RESIN
	76	C	PLATE, BONE
ORTHOSIS	89 89 89 89 89 89 89 89 89	A	ORTHOSIS, CERVICAL ORTHOSIS, CERVICAL -THORACIC, RIGID ORTHOSIS, CORRECTIVE SHOE ORTHOSIS, LIMB BRACE ORTHOSIS, LUMBAR ORTHOSIS, LUMBO-SACRAL ORTHOSIS, RIB FRACTURE, SOFT ORTHOSIS, SACROILIAC, SOFT ORTHOSIS, THORACIC
	89 87	B C	STIMULATOR, SCOLIOSIS (ORTHOSIS) ORTHOSIS, SPINAL PEDICLE FIXATION
OSCILLOMETER	74	B	OSCILLOMETER
OSCILLOSCOPE	80	B	OSCILLOSCOPE
OSSICULAR	77 77 77	C	PROSTHESIS, PARTIAL OSSICULAR REPLACEMENT REPLACEMENT, OCCICULAR, POROUS POLYETHYLENE REPLACEMENT, OSSICULAR PROSTHESIS, TOTAL
OSTEOGENESIS	87	B	STIMULATOR, BONE GROWTH, NON -INVASIVE
OSTEOTOME	79 76 79 79	A	CHISEL (OSTEOTOME) CHISEL, BONE, SURGICAL OSTEOTOME, MANUAL OSTEOTOME, ORTHOPEDIC
	79	B	BLADE, OSTEOTOME AND OTHER CUTTING INSTRUMENTS (DISPOSABLE)
OSTOMY	78	A	OSTOMY APPLIANCE (ILEOSTOMY, COLOSTOMY)
OTOSCOPE	77 77	A	MAGNIFIER, AURAL (PNEUMATIC OTOSCOPE) OTOSCOPE
OXIMETER	74 74 80 80	C	BLOOD PRESSURE/OXYGEN SATURATION IN THE BLOOD MONITOR OXIMETER, EAR OXIMETER, FINGER OXIMETER, PULSE

	74 74	D	CATHETER, OXIMETER, FIBEROPTIC OXIMETER, INTRACARDIAC
OXYGEN	73 73 73 73	B	KIT, ADMINISTRATION, OXYGEN UNIT, EMERGENCY OXYGEN AND RESUSCITATION UNIT, LIQUID OXYGEN, PORTABLE UNIT, OXYGEN THERAPY, PORTABLE
OXYGENATOR	74	C	OXYGENATOR, CARDIOPULMONARY BYPASS
PACEMAKER	74 74 74	C	CAP, LEAD, PACEMAKER LEAD, ANCHORING SLEEVE, IMPLANTABLE PACEMAKER, CARDIAC, EXTERNAL TRANSCUTANEOUS (NON-INVASIVE)
	74 74 74 74 74 74	D	MATERIALS, REPAIR OR REPLACEMENT, PACEMAKER PACEMAKER, HEART, IMPLANTABLE, ANTI -TACHYCARDIA PACEMAKER, HEART, IMPLANTABLE, DUAL CHAMBER PACEMAKER, HEART, IMPLANTABLE, NON-PROGRAMMABLE PACEMAKER, HEART, IMPLANTABLE, RATE RESPONSIVE PULSE-GENERATOR, PROGRAM MODULE
PACHYMETER	86	B	PACHYMETER
PACING	74	D	TEMPORARY PACIN G SYSTEM, ACUTE, INTERNAL, ATRIAL

Keyword	Therapeutic Code	Class	Description
PACKER	80 85	A	PACKER, GAUZE PACKER, UTERINE
PACKING	79	B	PACKING, SURGICAL (NASAL, VAGINAL)
PACS	90	B	RADIOGRAPHIC PICTURE ARCHIVING/COMMUNICATION SYSTEM (PACS)
PAD	80 86 79 80 80 80 80 80 80 80	A	PAD, DRESSING PAD, EYE PAD, KELLY PAD, MATTRESS, THERAPEUTIC PAD, PRESSURE, AIR PAD, PRESSURE, FOAM (ELBOW, HEEL) PAD, PRESSURE, FOAM CONVOLUTED PAD, PRESSURE, GEL PAD, PRESSURE, GEL, OPERATING TABLE PROTECTOR, SKIN PRESSURE
	74	B	PAD, DEFIBRILLATOR PADDLE
PADDIE PADDLE	84 74	B B	PADDIE, COTTONOID PADDLE, PAD, ELECTRODE, DEFIBRILLATOR (EXTERNAL)

PANCREATOSCOPE	78	B	PANCREATOSCOPE, BILIARY
PANENDOSCOPE	78 78	B	PANENDOSCOPE (GASTRODUODENOSCOPE) URETHROSCOPE
PANTOGRAPH	76	A	PANTOGRAPH
PAP	85	B	KIT, PAP SMEAR
PAPER	76	A	PAPER, ARTICULATION
PARALLELOMETER	76	A	PARALLELOMETER
PARENTERAL	78	B	KIT, ADMINISTRATION, PARENTERAL
PASSER	87	A	PASSER
	87	B	PASSER, WIRE, ORTHOPEDIC
PASSING	79	B	INSTRUMENT, LIGATURE PASSING AND KNOT TYING
PASTE	76	C	PASTE, INJECTABLE FOR VOCAL CORD AUGMENTATION
PATCH	79	C	MESH, SURGICAL, POLYMERIC
	74 74 74	D	LEAD, ELECTRODE, CARDIOVERTER, DEFIBRILLATOR, PERMANENT PATCH, PERICARDIAL PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE
PELVIMETER	85	A	EXTERNAL PELVIMETER
	85	B	INTERNAL PELVIMETER
PEN	78 86	B	INJECTOR, INSULIN PEN, MARKING, SURGICAL
PENETROMETER	90	B	PENETROMETER
PENIS	78 78 78	C	PROSTHESIS, PENILE PROSTHESIS, PENIS, INFLATABLE PROSTHESIS, PENIS, RIGID ROD
PERCEPTION	86	A	OCULO-MOTOR MOVEMENT TRAINING, OPHTHALMIC
PERCUSSOR	84	A	PERCUSSOR
	73	B	PERCUSSOR, POWERED -ELECTRIC
PERFORATOR	77	A	PERFORATOR, ANTRUM
	84	B	PERFORATOR, DRILL
PERFUSION	78 78 80	B	SET, PERFUSION, KIDNEY, DISPOSABLE SYSTEM, PERFUSION, KIDNEY TUBING, FLUID DELIVERY
	80	C	PUMP, INFUSION

PERIAURAL	77	A	PROTECTOR, HEARING (CIRCUMAURAL)
PERIMETER	86 86	A	PERIMETER, AC -POWERED PERIMETER, MANUAL

Keyword	Therapeutic Code	Class	Description
PERINEOMETER	85	B	PERINEOMETER
PERITONEAL	78	B	SCREW, DECLOTTING
	78 78	C	SYSTEM, DIALYSATE DELIVERY, SINGLE PATIENT SYSTEM, PERITONEAL, AUTOMATIC DELIVERY
PERITONEOSCOPE	78	B	PERITONEOSCOPE
PERIURETHRAL	78	C	INJECTABLE BULKING AGENT FOR GASTROENTEROLOGY
PESSARY	85	B	PESSARY, VAGINAL
PHACOEMULSIFICATION	86	B	ACCESSORIES, PHACOFRAGMENTATION/EMULSIFICATION UNIT
	86	C	SYSTEM, PHACOEMULSIFICATION & ACCESSORIES
PHACOFRAGMENTATION	86	B	ACCESSORIES, PHACOFRAGMENTATION/EMULSIFICATION UNIT
	86	C	UNIT, PHACOFRAGMENTATION AND ACCESSORIES
PHANEROSCOPE	80	B	PHANEROSCOPE
PHANTOM	90 90 90 90 90 90	B	PHANTOM, ANTHROPOMORPHIC, NUCLEAR PHANTOM, ANTHROPOMORPHIC, RADIOGRAPHIC PHANTOM, DIGITAL SUBTRACTION ANGIOGRAPHY (DSA) PHANTOM, FLOOD SOURCE, NUCLEAR PHANTOM, TEST-PATTERN, RADIONUCLIDE TEST PATTERN, RADIOGRAPHIC
PHARYNGOSCOPE	77	A	PHARYNGOSCOPE
PHLEBOGRAPH	74	B	PHLEBOGRAPH, IMPEDANCE
PHONOCARDIOGRAPH	74	B	PHONOCARDIOGRAPH
PHOTOACTIVATION	79	C	SYSTEM, LASER, PHOTODYNAMIC THERAPY
PHOTOCOAGULATOR	86	C	PHOTOCOAGULATOR AND ACCESSORIES
PHOTOGRAPHIC	78	A	ACCESSORIES, PHOTOGRAPHIC, FOR ENDOSCOPE (EXCLUDE LIGHT SOURCES)

PHOTOKERATOSCOPE	86	A	PHOTOKERATOSCOPE
PHOTOPHERESIS	78	C	EXTRACORPOREAL PHOTOPHERSIS SYSTEM
PHOTOSTIMULATOR	80	B	PHOTOSTIMULATOR
PHOTOTHERAPY	80	C	PHOTOTHERAPY UNIT, NEONATAL
PICK	76 77	A	PICK, MASSAGING PICK, MICROSURGICAL, EAR
PILLOW	87	A	PILLOW, CERVICAL
PIN	80	B	DEVICE, MEDICATION RECONSTITUTION/TRANSER
	87 87 76	C	PIN, FIXATION, SMOOTH PIN, FIXATION, THREADED PIN, RETENTIVE AND SPLINTING, AND ACCESSORY INSTRUMENTS
PINWHEEL	84	A	PINWHEEL
PIPETTE	85	B	PIPETTE, VAGINAL POOL SMEAR
PISTOL	74	B	DEVICE, INFLATION CONTROL FOR DILATION BALLOONS
PLACIDO	86	A	KERATOSCOPE
PLANNING	84 90	C	STEREOTAXIC PLANNING SOFTWARE SYSTEM, PLANNING, RADIATION THERAPY TREATMENT
PLAQUE	76	A	KIT, PLAQUE DISCLOSING
PLASTER	80	A	FABRIC, PAIN RELIEF
PLATE	87 76 8D 87 79	C	COMPRESSION PLATE AND INSTRUMENT SET PLATE, BONE PLATE, BONE, SKULL (CRANIOPLASTY) PLATE, FIXATION, BONE SET, BONE PLATE & SCREW
PLEDGET	74 74	D	PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE PLEDGET, DACRON, TEFLON, POLYPROPYLENE
PLETHYSMOGRAPH	74 74 73	B	PLETHYSMOGRAPH, IMPEDANCE PLETHYSMOGRAPH, PHOTOELECTRIC, PNEUMATIC OR HYDRAULIC PLETHYSMOGRAPH, PRESSURE

Keyword	Therapeutic Code	Class	Description

	73		PLETHYSMOGRAPH, VOLUME
PLIERS	78 76 78 76 79	A	PLIER, CRIMP PLIER, ORTHODONTIC PLIER, TUBE PLIERS, OPERATIVE PLIERS, SURGICAL
PLOTTER	90	B	PLOTTER, PATIENT CONTOUR
PLUG	78	A	PLUG, CATHETER
	73 86	B	BUTTON, TRACHEOSTOMY TUBE PLUG, SCLERAL
	86 74	C	PLUG, PUNCTUM TERMINAL HEADER OR PLUG FOR PULSE GENERATOR
PNEUMOPERITONEUM	78	B	APPARATUS, PNEUMOPERITONEUM, AUTOMATIC
PNEUMOTACHOMETER	73	B	PNEUMOTACHOMETER
PNEUMOTHORAX	73	B	APPARATUS, PNEUMOTHORAX
POINT	76 76	A B	POINT, ABRASIVE POINT, PAPER, ENDODONTIC
	76	C	POINT, SILVER, ENDODONTIC
POLISHER	86	B	POLISHER, EXTRACAPSULAR EXTRACTION PROCEDURE
POLISHING	76	A	AGENT, POLISHING, ABRASIVE, ORAL CAVITY
POLYGRAPH	80	B	POLYGRAPH
POLYMER	79 77 77	C	POLYMER, ENT COMPOSITE SYNTHETIC PTFE WITH CARBON -FIBRE POLYMER, ENT SYNTHETIC-PIFE, SILICONE ELASTOMER, POLYMER, ENT, SYNTHETIC, POROUS POLYETHYLENE
POLYP	78	B	SNARE, FLEXIBLE (DISPOSABLE)
PORT	80	B	SITE, SAMPLING/INJECTION, ASEPTIC
	80 80 80 78	C	PORT & CATHETER, IMPLANTED, SUBCUTANEOUS, INTRAVASCULAR PORT & CATHETER, SUBCUTANEOUS, INTRASPINAL PORT AND CATHETER, INFUSION, IMPLANTED, SUBCUTANEOUS PORT, GASTROSTOMY FEED
POSITIONER	84 84	B	INSTRUMENT, STEREOTAXIC POSITIONER, ELECTRODE, ELECTROENCEPHALOGRAPH
POST	76	C	POST, ROOT CANAL
POSTURE	89	A	AID, POSTURE

POUCH	74 85	B C	HEART INSULATION/PROTECTION POUCH POUCH, INTRAVAGINAL (FEMALE CONDOM)
POWDER	76	C	POWDER, PORCELAIN
PRECISION	76	B	ATTACHMENT, PRECISION, ALL
PREP	80 80	A	KIT, PREP KIT, SKIN SCRUB
PREPARER	76	A	PREPARER, ROOT CANAL, ENDODONTIC
PRESS	77	A	PRESS, VEIN
PRESSURE	89	A	DEVICE, PRESSURE APPLYING
	74 89 73	B	CUFF, INFLATION DEVICE, CRYOTHERAPY/COMPRESSION UNIT, CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP, CPPB)
	74	D	KIT, BLOOD PRESSURE, CENTRAL VENOUS
PRIMER	76 76	C	PRIMER, CAVITY, RESIN VARNISH, CAVITY
PRISM	78 86 86 86	A	ENDOSCOPIC, PRISM PRISM, BAR, OPHTHALMIC PRISM, FRESNEL, OPHTHALMIC PRISM, ROTARY, OPHTHALMIC

Keyword	Therapeutic Code	Class	Description
	86	B	PRISM, GONIOSCOPIC
PROBE	87 78 78 77 86 86 76 78 86	A	PROBE PROBE AND DIRECTOR, GASTRO-UROLOGY PROBE, COMMON DUCT PROBE, ENT PROBE, LACHRYMAL PROBE, OPHTHALMIC PROBE, PERIODONTIC PROBE, RECTAL, NON-POWERED PROBE, TRABECULOTOMY
	86 86 78 79 73	B	ACCESSORIES, PHACOFRAGMENTATION/EMULSIFICATION UNIT PROBE AND COUNTER, ISOTOPE, FOR PHOSPHORUS CB PROBE, HEATING, TISSUE, LAPAROSCOPE PROBE, LASER PROBE, PH CATHETER

	84 80 90 85		PROBE, RADIOFREQUENCY LESION PROBE, TEMPERATURE PROBE, UPTAKE, NUCLEAR SOUND, UTERINE (DISPOSABLE)
	74 90	C	PROBE, BLOOD FLOW, EXTRAVASCULAR PROBE, ULTRASONIC
	74 74	D	CATHETER, ELECTRODE RECORDING, OR PROBE, ELECTRODE RECORDING PROBE, THERMODILUTION
PROCTOSCOPE	78	B	PROCTOSCOPE
PROGRAMMER	74	D	PROGRAMMER, PACEMAKER
PROJECTOR	86 90	A	PROJECTOR, OPHTHALMIC PROJECTOR, X-RAY FILM
PROPHYLAXIS	76	A	KIT, DENTAL PROPHYLAXIS
	76	B	ULTRASONIC PROPHYLAXIS UNIT,DENTAL
PROPORTIONING	78	C	SUBSYSTEM, PROPORTIONING
PROSTHESIS	79 87 87 87 87 87	A	PROSTHESIS, ADHESIVE, EXTERNAL PROSTHESIS, ARM PROSTHESIS, FOOT PROSTHESIS, HAND PROSTHESIS, LEG PROSTHESIS, TRIAL
	87 87 87 87 79 84 79 87 87 87 87 87 87 79 86 86 77	C	PROSTHESIS, ANKLE, SEMI-CONSTRAINED, CEMENTED, METAL/POLYMER PROSTHESIS, ANKLE, TALAR COMPONENT PROSTHESIS, ANKLE, TIBIAL COMPONENT PROSTHESIS, CARPAL PROSTHESIS, CHIN, INTERNAL PROSTHESIS, CRANIOFACIAL PROSTHESIS, EAR, INTERNAL PROSTHESIS, ELBOW, CONSTRAINED, CEMENTED PROSTHESIS, ELBOW, HUMERAL COMPONENT PROSTHESIS, ELBOW, NON -CONSTRAINED, UNIPOL AR PROSTHESIS, ELBOW, RADIAL COMPONENT PROSTHESIS, ELBOW, TOTAL PROSTHESIS, ELBOW, ULNAR COMPONENT PROSTHESIS, ESOPHAGEAL PROSTHESIS, EYE, INTERNAL PROSTHESIS, EYELID PROSTHESIS, FACIAL, MANDIBULAR IMPLANT

Keyword	Therapeutic Code	Class	Description

	85		PROSTHESIS, FALLOPIAN TUBE
	87		PROSTHESIS, FEMORAL HEAD
	87		PROSTHESIS, FEMOROTIBIAL, CONSTRAINED (METAL -ON-POLYMER)
	87		PROSTHESIS, FINGER, CONSTRAINED, METAL, CEMENTED
	87		PROSTHESIS, FINGER, CONSTRAINED, POLYMER
	87		PROSTHESIS, FINGER, TOTAL
	87		PROSTHESIS, FOOT ARCH
	87		PROSTHESIS, HIP CUP INSERT
	87		PROSTHESIS, HIP, ACETABULAR COMPONENT, METAL, NON - CEMENTED
	87		PROSTHESIS, HIP, ACETABULAR COMPONENT, POLYETHYLENE
	79		PROSTHESIS, HIP, ACETABULAR MESH
	79		PROSTHESIS, HIP, CEMENT RESTRICTOR
	87		PROSTHESIS, HIP, CONSTRAINED, CEMENTED OR UNCEMENTED, METAL/ POLYMER
	87		PROSTHESIS, HIP, FEMORAL COMPONENT, CEMENTED, METAL
	87		PROSTHESIS, HIP, HEMI-, ACETABULAR, CEMENTED, METAL
	87		PROSTHESIS, HIP, HEMI-, FEMORAL, METAL, NON-CEMENTED
	87		PROSTHESIS, HIP, HEMI-, FEMORAL, METAL/POLYMER, CEMENTED OR UNCEMENTED
	87		PROSTHESIS, HIP, METAL STEM/CERAMIC SELF-LOCKING BALL
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED (METAL CEMENTED ACETABULAR COMPONENT)
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED METAL/CERAMIC/POLYMER
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED OR HEMI-, METAL/PTFE
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/CERAMIC/CERAMIC
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/CERAMIC/CERAMIC, CEMENTED
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, CEMENTED
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, NON-POROUS, CALCIUM-PHOSPHATE
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, POROUS UNCEMENTED
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, UNCEMENTED
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED, POROUS COATED
	87		PROSTHESIS, HIP, SEMI-CONSTRAINED, UNCEMENTED, POROUS, METAL/POLYMER
	87		PROSTHESIS, JOINT, OTHER
	87		PROSTHESIS, KNEE PATELLOFEMOROTIBIAL CONSTRAINED, CEMENTED, POLYMER/METAL
	87		PROSTHESIS, KNEE, FEMOROTIBIAL, CONSTRAINED, CEMENTED, METAL
	87		PROSTHESIS, KNEE, FEMOROTIBIAL, NON-CONSTRAINED, C EMENTED, METAL/POLYMER
	87		PROSTHESIS, KNEE, FEMOROTIBIAL, SEMI-CONSTRAINED, CEMENTED, METAL/POLYMER
	87		PROSTHESIS, KNEE, HEMI-, FEMORAL
	87		PROSTHESIS, KNEE, HEMI-, PATELLAR RESURFACING,

			UNCEMENTED
	87		PROSTHESIS, KNEE, HEMI-, TIBIAL RESURFACING, UNCEMENTED
	87		PROSTHESIS, KNEE, HINGED (METAL -METAL)
	87		PROSTHESIS, KNEE, PATELLAR
	87		PROSTHESIS, KNEE, PATELLOFEMORAL, SEMI-CONSTRAINED, CEMENTED, METAL/POLYMER
	87		PROSTHESIS, KNEE, PATELLOFEMOROTIBIAL, SEMI-CONSTRAINED, CEMENTED, POLYMER
	87		PROSTHESIS, KNEE, TIBIAL
	87		PROSTHESIS, KNEE, TOTAL
	87		PROSTHESIS, KNEE, UNICOMPARTMENTAL, CEMENTED
	86		PROSTHESIS, LACRIMAL DUCT
	77		PROSTHESIS, LARYNX
	87		PROSTHESIS, LIGAMENT
	79		PROSTHESIS, NOSE, INTERNAL
	77		PROSTHESIS, PARTIAL OSSICULAR REPLACEMENT
	78		PROSTHESIS, PENILE
	78		PROSTHESIS, PENIS, INFLATABLE
	78		PROSTHESIS, PENIS, RIGID ROD
	79		PROSTHESIS, RHINOPLASTY/NASAL DORSAL IMPLANT

Keyword	Therapeutic Code	Class	Description
	87		PROSTHESIS, SHOULDER
	87		PROSTHESIS, SHOULDER, HEMI-, GLENOID, METALLIC CEMENTED
	87		PROSTHESIS, SHOULDER, HEMI-, HUMERAL, METALLIC UNCEMENTED
	87		PROSTHESIS, SHOULDER, HUMERAL (BIPOLAR HEMI-SHOULDER) METAL/POLYMER
	87		PROSTHESIS, TENDON
	87		PROSTHESIS, TENDON, PASSIVE
	78		PROSTHESIS, TESTICULAR
	87		PROSTHESIS, TOE
	79		PROSTHESIS, TRACHEAL
	87		PROSTHESIS, UPPER FEMORAL
	78		PROSTHESIS, URETHRAL SPHINCTER
	87		PROSTHESIS, WRIST, B PART METAL -PLASTIC ARTICULATION, SEMI -CONSTRAINED
	87		PROSTHESIS, WRIST, C PART METAL -PLASTIC -METAL ARTICULATION, SEMI-CONSTRAINED
	87		PROSTHESIS, WRIST, CARPAL SCAPHOID
	87		PROSTHESIS, WRIST, CARPAL TRAPEZIUM
	87		PROSTHESIS, WRIST, CARPAL, LUNATE
	87		PROSTHESIS, WRIST, HEMI-, ULNAR
	74	D	HEART, ARTIFICAL
	74		PROSTHESIS, ARTERIAL GRAFT, BOVINE CAROTID ARTERY
	79		PROSTHESIS, BREAST, INFLATABLE, INTERNAL, SALINE
	79		PROSTHESIS, BREAST, NONINFLATABLE, INTERNAL, SALINE

	79 74 74		PROSTHESIS, BREAST, NONINFLATABLE, INTERNAL, SILICONE GEL-FILLED PROSTHESIS, VASCULAR GRAFT, OF 6MM AND GREATER DIAMETER PROSTHESIS, VASCULAR GRAFT, OF LESS THAN 6MM DIAMETER
PROSTHODONTIC	76	B	MATERIALS, FABRICATING PROSTHODONTIC APPLIANCES, DENTAL LAB.
PROTECTION	74	D	EMBOLIC PROTECTION DEVICE
PROTECTOR	73 87 77 77 78 76 80 79	A	PROTECTOR, DENTAL PROTECTOR, FINGER PROTECTOR, HEARING (CIRCUMAURAL) PROTECTOR, HEARING (INSERT) PROTECTOR, OSTOMY PROTECTOR, SILICATE PROTECTOR, SKIN PRESSURE PROTECTOR, WOUND, PLASTIC
	79 79 78	B	INSTRUMENT GUARD PROTECTOR, TISSUE, HYDROPHILIC POLYMER PROTECTOR, TRANSDUCER, DIALYSIS
PROTRACTOR	87	A	PROTRACTOR
PTFE	78 76	C	INJECTABLE BULKING AGENT FOR GASTROENTEROLOGY PASTE, INJECTABLE FOR VOCAL CORD AUGMENTATION
PULMONARY	73 73 73 73	B	ANALYZER, PULMONARY FUNCTION CALCULATOR, PULMONARY FUNCTION DATA CALCULATOR, PULMONARY FUNCTION INTERPRETATOR (DIAGNOSTIC) COMPUTER, PULMONARY FUNCTION LABORATORY
	73	C	KIT, DIAGNOSTIC, PULMONARY, RADIO AEROSOL
	74	D	BAND, PULMONARY ARTERY
PUMP	74 85 80	A	PUMP, AIR, MANUAL CUFF INFLATING PUMP, BREAST, NON-POWERED PUMP, URINARY COLLECTION BAG
	74 74 77 78	B	COMPRESSION UNIT, INTERMITTENT (ANTI-EMBOLISM PUMP) COUNTER-PULSATING DEVICE, EXTERNAL NEBULIZER PUMP, ELECTRICALLY POWERED PUMP, AIR, NON-MANUAL, FOR ENDOSCOPE

Keyword	Therapeutic Code	Class	Description

	80		PUMP, ALTERNATING PRESSURE PAD
	74		PUMP, BLOOD, CARDIOPULMONARY BYPASS, ROLLER TYPE
	78		PUMP, BLOOD, EXTRA LUMINAL
	85		PUMP, BREAST, POWERED
	74		PUMP, EXTRACORPOREAL PERFUSION
	80		PUMP, INFUSION, ELASTOMERIC
	80		PUMP, INFUSION, ENTERAL
	77		PUMP, NEBULIZER, MANUAL
	79		PUMP, PORTABLE, ASPIRATION (MANUAL OR POWERED)
	85		SYSTEM, ABORTION, VACUUM
	76		UNIT, SUCTION OPERATORY
	74	C	PUMP, BLOOD, CARDIOPULMONARY BYPASS, NON-ROLLER TYPE
	80		PUMP, INFUSION
	80		PUMP, INFUSION, AMBULATORY
	80		PUMP, INFUSION, IMPLANTED
	80		PUMP, INFUSION, INSULIN
	73		PUMP, INFUSION, PATIENT CONTROLLED ANALGESIA
	74		PUMP, WITHDRAWAL/INFUSION
PUNCH	78	A	INSTRUMENT, CATHETER, PUNCH
	77		PUNCH, ADENOID
	77		PUNCH, ANTRUM
	77		PUNCH, ATTIC
	87		PUNCH, BONE
	86		PUNCH, CORNEO-SCLERAL
	79		PUNCH, DERMAL
	77		PUNCH, EAR
	77		PUNCH, ETHMOID
	87		PUNCH, FEMORAL NECK
	79		PUNCH, HAIR TRANSPLANT
	77		PUNCH, NASAL
	76		PUNCH, RUBBER DAM, DENTAL
	84		PUNCH, SKULL
	77		PUNCH, TONSIL
	79	B	INSTRUMENT, SURGICAL, ENDOSCOPIC/LAPAROSCOPIC (NON-POWERED)
	74		PUNCH, AORTIC (DISPOSABLE)
	78		PUNCH, BIOPSY
PUNCTOMETER	86	A	RULER, NEARPOINT (PUNCTOMETER)
PUNCTURE	84	B	KIT, LUMBAR PUNCTURE
PUPILLOMETER	86	A	PUPILLOMETER, AC -POWERED
	86		PUPILLOMETER, MANUAL
PURIFIER	78	C	SUBSYSTEM, WATER PURIFICATION
PUSHER	76	A	PUSHER, BAND, ORTHODONTIC
	87		PUSHER, SOCKET
RACK	86	A	RACK, SKIASCOPIC
RADIATION	90	C	SYSTEM, PLANNING, RADIATION THERAPY TREATMENT
	90		SYSTEM, SIMULATION, RADIATION THERAPY

	86		UNIT, BETA, RADIATION, OPHTHALMIC
RADIOGRAPHIC	90 76	B	SYSTEM, X-RAY, TOMOGRAPHIC UNIT, RADIOGRAPHIC, DIAGNOSTIC, DENTAL (X-RAY)
	90 90 90 90	C	RADIOGRAPHIC UNIT, DIGITAL RADIOGRAPHIC UNIT, DIGITAL SUBTRACTION, ANGIOGRAPHIC (DSA) SYSTEM, X-RAY, ANGIOGRAPHIC SYSTEM, X-RAY, FLUOROSCOPIC, IMAGE-INTENSIFIED

Keyword	Therapeutic Code	Class	Description
	90 90 90 90		SYSTEM, X-RAY, FLUOROSCOPIC, NON-IMAGE-INTENSIFIED SYSTEM, X-RAY, MAMMOGRAPHIC SYSTEM, X-RAY, MOBILE, FLUOROSCOPIC UNIT, X-RAY, MOBILE, EXPLOSION-SAFE
RADIOMETER	80	B	RADIOMETER, PHOTOTHERAPY
RADIONUCLIDE	90 90 90	C	SOURCE, BRACHYTHERAPY, RADIONUCLIDE SOURCE, TELETHERAPY, RADIONUCLIDE SYSTEM, RADIATION THERAPY, RADIONUCLIDE
RAIL	80	A	BEDRAIL
RASP	77 77 77 79	A	RASP, EAR RASP, FRONTAL -SINUS RASP, NASAL RASP, SURGICAL, GENERAL & PLASTIC SURGERY
	79	B	RASP, BONE
RAZOR	80	A	KIT, PREP
READER	86 86	A	READER, BAR, OPHTHALMIC READER, PRISM, OPHTHALMIC
REAMER	87	B	REAMER
REBREATHING	73 90	B	DEVICE, REBREATHING SYSTEM, REBREATHING, RADIONUCLIDE
RECEIVER	74 74 80	B	TRANSMITTER AND RECEIVER, ELECTROCARDIOGRAPH, TELEPHONE TRANSMITTER AND RECEIVER, PHYSIOLOGICAL SIGNAL, RADIOFREQUENCY TRANSMITTER/RECEIVER SYSTEM, FETAL MONITOR, TELEPHONE
RECORDER	74 90	A	RECORDER, MAGNETIC TAPE, MEDICAL RECORDER, RADIOGRAPHIC VIDEO TAPE

	74 73 74 85 73	B	RECORDER, LONG TERM, ECG, PORTABLE (HOLTER MONITOR) RECORDER, LONG TERM, RESPIRATION RECORDER, PAPER CHART RECORDER, PRESSURE, INTRAUTERINE VENTILATORY EFFORT RECORDER
REFLEX	84	A	PERCUSSOR
REFRACTOMETER	86	B	REFRACTOMETER, OPHTHALMIC
REGENERATION	76	C	MATERIAL, PERIODONTAL TISSUE AUGMENTATION/REGENERATION
REGULATOR	73 73 80 78 79 80 74	B	REGULATOR, OXYGEN, MECHANICAL REGULATOR, PRESSURE, GAS CYLINDER REGULATOR, SUCTION (W GAUGE) REGULATOR, SUCTION, LOW VOLUME (GASTRIC) REGULATOR, SUCTION, SURGICAL REGULATOR, VACUUM SYSTEM, THERMAL REGULATING
REINFORCEMENT	79	C	MESH, SURGICAL, POLYMERIC
RELINER	76	B	RELINER, DENTURE, OTC
REMOVAL	80 87 84 79 87	A	AIRWAY, OBSTRUCTION REMOVAL (CHOKE SAVER) INSTRUMENT, CAST APPLICATION/REMOVAL, MANUAL INSTRUMENT, CLIP REMOVAL KIT, SUTURE REMOVAL SET, INSTRUMENT, CEMENT REMOVAL, ORTHOPEDIC SURGERY
REMOVER	76 85 79	A	REMOVER, CROWN/INLAY REMOVER, INTRAUTERINE DEVICE, CONTRACEPTIVE, HOOK-TYPE REMOVER, STAPLE, SURGICAL
REPAIR	74 76 76	B	KIT, CATHETER REPAIR, NON-BALLOON KIT, DENTURE REPAIR KIT, DENTURE REPAIR, OTC

Keyword	Therapeutic Code	Class	Description
	74	D	KIT, BALLOON REPAIR, CATHETER
REPOSITOR	86	A	REPOSITOR, IRIS
REPROCESSING	78	B	REPROCESSING UNIT, DIALYZER

RESECTOSCOPE	78 78	B	RESECTOSCOPE WORKING ELEMENT OF RESECTOSCOPE
RESERVOIR	80 74	B	DEVICE, MEDICATION RECONSTITUTION/TRANSER RESERVOIR, BLOOD, CARDIOPULMONARY BYPASS
RESIN	76 76 76	B	ADHESIVE, BRACKET AND CONDITIONER, RESIN RESIN, DENTURE, RELINING, REPAIRING, REBASING RESIN, ORTHODONTIC
	76 76 76	C	MATERIAL, TOOTH SHADE, RESIN RESIN, ROOT CANAL FILLING VARNISH, CAVITY
RESINOUS	76	C	RESINOUS COMPOUND
RESPONSE	84	B	UNIT, EVOKED RESPONSE
RESTORATION	79 76	A C	EXTERNAL AESTHETIC RESTORATION MATERIAL AGENT, TOOTH BONDING,RESIN
RESTORATIVE	76 76	C	DENTAL RESTORATIVE SYSTEM (ETCHANT, PRIMER, ADHESIVE) MATERIAL, TOOTH SHADE, RESIN
RESUSCITATOR	74 74 73	A	AID, CARDIOPULMONARY RESUSCITATION RESUSCITATOR, CARDIAC, MECHANICAL RESUSCITATOR, EMERGENCY, PROTECTIVE, INFECTION
	73 73	B	UNIT, EMERGENCY OXYGEN AND RESUSCITATION VENTILATOR, EMERGENCY, MANUAL (RESUSCITATOR)
	73	C	VENTILATOR, EMERGENCY, POWERED (RESUSCITATOR)
RETAINER	76 79	A	RETAINER, MATRIX RETAINER, SURGICAL
	76 76 79	B	RETAINER, DENTAL RETAINER, SCREW EXPANSION, ORTHODONTIC RETAINER, VISCERAL
RETENTION	79	A	RETENTION DEVICE, SUTURE
RETINAL	86	C	IMPLANT, RETINAL
RETINOSCOPE	86 86	A	RETINOSCOPE, AC-POWERED RETINOSCOPE, BATTERY-POWERED
RETRACTION RETRACTOR	76 78 84 74 77 79 84 85 84	A A	KIT, GINGIVAL, RETRACTION RETRACTOR, BLADDER RETRACTOR, BRAIN RETRACTOR, CARDIAC RETRACTOR, ENT RETRACTOR, ORBITAL RETRACTOR, SELF-RETAINING, FOR NEUROSURGERY RETRACTOR, VAGINAL SPOON, PITUITARY

	86 79 74	B	RETRACTOR, OPHTHALMIC (DISPOSABLE) RETRACTOR, SURGICAL, GENERAL & PLASTIC SURGERY (DISPOSABLE) RETRACTOR, VESSEL
RETRIEVAL	74	B	DEVICE, PERCUTANEOUS RETRIEVAL
RETRIEVER	87 79	A	RETRIEVER, DRILL OR SCREW TENDON RETRIEVER
	78 78	B	RETRIEVER, ENDOMAGNETIC SNARE, FLEXIBLE (DISPOSABLE)
RHINOANEMOMETER	73	B	RHINOANEMOMETER (MEASUREMENT OF NASAL DECONGESTION)
RIBDAM	78	A	RIBDAM

Keyword	Therapeutic Code	Class	Description
RING	78 76 78 86 79	A	RING, CRIM P RING, DENTAL (CASTING) RING, LAPAROTOMY RING, OPHTHALMIC (FLIERINGA) RING, SUTURE
	85 87 86	C	DEVICE, OCCLUSION, TUBAL (TOD), CONTRACEPTIVE RING/SHELL, PROTRUSIO RING, CAPSULAR TENSION, IRIS DIAPHRAGM
	74	D	RING, ANNULOPLASTY
ROD	78 77	A	ROD, COLOSTOMY ROD, MEASURING EAR
	87	C	ROD, FIXATION, INTRAMEDULLARY AND ACCESSORIES
RONGEUR	87 78 87 86 84 77 77	A	RONGEUR RONGEUR, CYSTOSCOPIC RONGEUR, INTERVERTEBRAL DISK RONGEUR, LACHRYMAL SAC RONGEUR, MANUAL RONGEUR, MASTOID RONGEUR, NASAL
	84	B	RONGEUR, POWERED

RULER	86 79	A	RULER, NEARPOINT (PUNCTOMETER) TAPE, MEASURING, RULERS AND CALIPERS
SAMPLER	85 85	B	SAMPLER, AMNIOTIC FLUID (AMNIOCENTESIS TRAY) SAMPLER, BLOOD, FETAL
SAMPLING	73 80 85 80	B	KIT, SAMPLING, ARTERIAL BLOOD KIT, SAMPLING, BLOOD KIT, SAMPLING, ENDOMETRIAL SITE, SAMPLING/INJECTION, ASEPTIC
SAW	77 79 77 87	A	SAW, LARYNGEAL SAW, MANUAL AND ACCESSORIES SAW, NASAL SAW, WIRE
	79 79 87 87 79 77	B	BLADE, SURGICAL, SAW, GENERAL & PLASTIC SURGERY SAW SAW, BONE, PNEUMATIC SAW, HANDPIECE SAW, POWERED, AND ACCESSORIES SAW, SURGICAL, ENT (ELECTRIC OR PNEUMATIC)
SCALE	80 80	A	SCALE, INFANT SCALE, SURGICAL SPONGE
SCALER	76	A	SCALER, PERIODONTIC
	76 76	B	SCALER, ROTARY SCALER, ULTRASONIC
SCALPEL	79 79 79	B	BLADE, SCALPEL (DISPOSABLE) KNIFE, SCALPEL (DISPOSABLE) SCALPEL, ONE-PIECE (DISPOSABLE)
SCANNER	90 74 84 90 90 90 90	B	CAMERA, SCINTILLATION (GAMMA) ECHOCARDIOGRAPH ECHOENCEPHALOGRAPH SCANNER, FLUORESCENT SCANNER, RECTILINEAR, NUCLEAR SCANNER, WHOLE BODY, NUCLEAR SYSTEM, TOMOGRAPHIC, NUCLEAR

Keyword	Therapeutic Code	Class	Description
	90	C	SCANNER, COMPUTED TOMOGRAPHY, X-RAY

	90		SCANNER, ULTRASONIC, GENERAL PURPOSE
	90		SYSTEM, IMAGING, PULSED ECHO, ULTRASONIC
	90		SYSTEM, IMAGING, ULTRASONIC, OPHTHALMIC
SCAV ENGING	73	B	APPARATUS, GAS-SCAVENGING
SCISSORS	79	A	GENERAL USE SURGICAL SCISSORS
	80		MEDICAL DISPOSABLE SCISSORS
	78		SCISSORS FOR CYTOSCOPE
	80		SCISSORS, BANDAGE/GAUZE/PLASTER
	74		SCISSORS, CARDIOVASCULAR
	76		SCISSORS, COLLAR AND CROWN
	86		SCISSORS, CORNEAL
	77		SCISSORS, EAR
	86		SCISSORS, ENUCLEATION
	85		SCISSORS, EPISIOTOMY
	80		SCISSORS, GENERAL DISSECTING
	85		SCISSORS, GYNECOLOGICAL
	86		SCISSORS, IRIS
	77		SCISSORS, NASAL
	84		SCISSORS, NEUROSURGICAL (DURA)
	86		SCISSORS, OPHTHALMIC, TENOTOMY
	87		SCISSORS, ORTHOPEDIC
	78		SCISSORS, RECTAL
	76		SCISSORS, SURGICAL TISSUE, DENTAL
	79		SCISSORS, SUTURE
	86		SCISSORS, SUTURE, OPHTHALMIC
	74		SCISSORS, THORACIC
	77		SCISSORS, TONSIL
	85		SCISSORS, UMBILICAL
	77		SCISSORS, WIRE CUTTING, ENT
	79	B	INSTRUMENT, SURGICAL, ENDOSCOPIC/LAPAROSCOPIC (NON-POWERED)
	86		SCISSORS, OPHTHALMIC (DISPOSABLE)
SCOOP	87	A	ORTHOPEDIC SCOOP
	78		SCOOP, COMMON DUCT
	78		SCOOP, GALLSTONE
SCOOTER	89	A	VEHICLE, MOTORIZED C-WHEELED
SCOPE	73	B	SCOPE, FIBEROPTIC INTUBATION
SCRAPER	76	A	SCRAPER, TONGUE
	85	B	SCRAPER, CYTOLOGY (CERVICAL)
SCREEN	86	A	SCREEN TANGENT, PROJECTION AC -POWERED
	90		SCREEN, INTENSIFYING, RADIOGRAPHIC
	86		SCREEN, TANGENT, AC -POWERED (CAMPIMETER)
	86		SCREEN, TANGENT, FELT (CAMPIMETER)
	86		SCREEN, TANGENT, TARGET
SCREENING	87	A	EQUIPMENT, SCREENING SCOLIOSIS
	77	B	UNIT, SCREENING, AUDITORY FUNCTION
SCREW	77	A	SCREW, ORAL

	77		SCREW, TONSIL
	78 85	B	SCREW, DECLOTTING SCREW, FIBROID, GYNECOLOGICAL
	87 87 87	C	FASTENER, FIXATION, BIODEGRADABLE, SOFT TISSUE FASTENER, FIXATION, NONDEGRADABLE, SOFT TISSUE IMPLANT, FIXATION DEVICE, CONDYLAR PLATE

Keyword	Therapeutic Code	Class	Description
	87 87 84 87 76 79		IMPLANT, FIXATION DEVICE, SPINAL ORTHOSIS, SPINAL PEDICLE FIXATION SCREW, CRANIOPLASTY PLATE SCREW, FIXATION, BONE SCREW, FIXATION, INTRAOSSEOUS SET, BONE PLATE & SCREW
SCREWDRIVER	84	A	SCREWDRIVER, SKULLPLATE
	87	B	SCREWDRIVER (BATTERY-POWERED)
SCRUB	80	A	KIT, SKIN SCRUB
SEALANT	76	B	MATERIALS, FABRICATING PROSTHODONTIC APPLIANCES, DENTAL LAB.
	76	C	SEALANT, PIT AND FISSURE, AND CONDITIONER, RESIN
SEARCHER	77	A	SEARCHER, MASTOID
SECUREMENT	80	A	DEVICE, INTRAVASCULAR CATHETER SECUREMENT
SEED	90 90	C	SEED, ISOTOPE IAB5 SEED, ISOTOPE, GOLD, TITANTIUM, PLATINUM
SELECTOR SENSITIVITY	78 73 84	A A	SELECTOR, SIZE, OSTOMY ALGESIMETER, MANUAL ESTHESIOMETER
SENSOR	74 73	B	SENSOR, BLOOD GAS, IN -LINE, CARDIOPULMONARY BYPASS SENSOR, OXYGEN
SEPARATOR	84 87 78	A	SEPARATOR, DURAL SEPARATOR, NERVE, NON-ELECTRICAL SEPARATOR, PYLORUS
	78	C	SEPARATOR, AUTOMATED, BLOOD CELL AND PLASMA, THERAPEUTIC USE
SETTER	76	A	SETTER, BAND, ORTHODONTIC
SHANK	89	A	ASSEMBLY, THIGH/KNEE/SHANK/ANKLE/FOOT, EXTERNAL

SHAVE	80	A	KIT, PREP
SHEATH	78 78	A	DEVICE, INCONTINENCE, UROSHEATH TYPE SHEATH, CORRUGATED RUBBER, FOR NONINDWELLING CATHETER
	78 80	B	SHEATH, FOR ENDOSCOPE SHEATH, SEMINAL COLLECTION
SHEET	79 79 79 79 79	A B	SHEET, BURN SHEET, DRAPE SHEET, DRAPE, DISPOS ABLE SHEET, OPERATING ROOM DRAPE, PURE LATEX SHEET, WITH SELF RETAINING FINGER COT
SHEETING	79	C	RECONSTRUCTIVE SHEETING, PLASTIC SURGERY
SHELL	87	C	RING/SHELL, PROTRUSIO
SHELLAC	76	A	PLATE, BASE, SHELLAC
SHIELD	85 85 86 90 90 90 90 90	A	SHIELD, BREAST SHIELD, CIRCUMCISION SHIELD, EYE, OPHTHALMIC SHIELD, GONADAL SHIELD, MAGNETIC FIELD SHIELD, X-RAY SHIELD, X-RAY, PORTABLE SHIELD, X-RAY, THROAT
	79 86	B	INSTRUMENT GUARD SHIELD, CORNEAL
	86	D	COLLAGEN CORNEAL SHIELD
SHOE	79 89 87	A	SHOE AND SHOE COVER, CONDUCTIVE SHOE, CAST SHOE, ORTHOPEDIC

Keyword	Therapeutic Code	Class	Description
SHOULDER	89 89	A	ASSEMBLY, SHOULDER/ELBOW/FOREARM/WRIST/HAND, MECHANICAL JOINT, SHOULDER, EXTERNAL LIMB COMPONENT
	87	C	PROSTHESIS, SHOULDER

	87		PROSTHESIS, SHOULDER, HEMI-, GLENOID, METALLIC CEMENTED
	87		PROSTHESIS, SHOULDER, HEMI-, HUMERAL, METALLIC UNCEMENTED
	87		PROSTHESIS, SHOULDER, HUMERAL (BIPOLAR HEMI-SHOULDER) METAL/POLYMER
SHUNT	74	B	LOOP, ENDARTERECTOMY
	86	C	SHUNT, INTRAOCULAR
	78		SHUNT, PERITONEAL (PERITONEO-VENOUS)
	78		SHUNT, PLEURO-PERITONEAL
	84	D	SHUNT, CENTRAL NERVOUS SYSTEM AND COMPONENTS
SIALOGRAPHY	90	B	CATHETER, RADIOGRAPHIC (NON-VASCULAR)
SIGMOIDOSCOPE	78	B	SIGMOIDOSCOPE, FLEXIBLE
SIMULATION	90	C	SYSTEM, SIMULATION, RADIATION THERAPY
SIMULATOR	74	A	SIMULATOR, HEART SOUND
	73	B	SIMULATOR, LUNG
SIMULTAN	86	A	SIMULATAN (INCLUDING CROSSED CYLINDER)
SIPHON	80	A	SYSTEM, DRAINAGE, THORACIC, WATER SEAL
	73	B	DRAIN, TEE (WATER TRAP)
SIZER	74	B	SIZER, HEART VALVE PROSTHESIS
	79		SIZER, MAMMARY
	78		TUBE, CALIBRATION, GRASTROPLASTY
SKID	87	A	SKID, BONE
SLEEVE	79	A	SLEEVE, GOWN, SURGICAL (OPERATING ROOM)
	79	B	INSTRUMENT GUARD
	74		SLEEVE, COMPRESSIBLE LIMB
SLING	89	A	SLING, ARM
	89		SLING, ARM, OVERHEAD SUPPORTED
	87		SLING, KNEE
	87		SLING, LEG
	89		SLING, OVERHEAD SUSPENSION, WHEELCHAIR
SMOKE	79	B	SYSTEM, SMOKE EVACUATION, LASER
SNARE	77	A	SNARE, EAR
	86		SNARE, ENUCLEATING
	77		SNARE, NASAL
	78		SNARE, NON-ELECTRICAL
	78		SNARE, RIGID SELF -OPENING
	79		SNARE, SURGICAL
	77		SNARE, TONSIL
	79	B	SNARE, ENDOSCOPIC
	78		SNARE, FLEXIBLE (DISPOSABLE)
	79		SNARE, POLYP

SOCK	87	A	SOCKS, FRACTURE
SOFTWARE	74 80 90	B	COMPUTER, DIAGNOSTIC, PROGRAMMABLE COMPUTER, PATIENT DATA MANAGEMENT RADIOGRAPHIC PICTURE ARCHIVING/COMMUNICATION SYSTEM (PACS)
	84	C	STEREOTAXIC PLANNING SOFTWARE
	74	D	PULSE-GENERATOR, PROGRAM MODULE
SOLDER	76	B	SOLDER, PROSTHODONTIC APPLIANCES
SOLUTION	86 74 76 80	B	ACCESSORIES TO CONTACT LENSES - CLEANING AND WETTING AGENTS KIT, ADMINISTRATION, CARDIOPLEGIA SOLUTION SOLUTION, CARIES REMOVAL SOLUTION, INSTRUMENT, LAPROSCOPIC, ANTI-FOG

Keyword	Therapeutic Code	Class	Description
	80		SOLUTIONS, STERILE, PATIENT CARE
SONOMETER	90	C	SONOMETER, BONE
SOUND	74 78	A	SOUND, BRONCHOCELE SOUND, METAL, INTERCONNECTED
	78 85	B	SOUND, URETHRAL, METAL OR PLASTIC (DISPOSABLE) SOUND, UTERINE (DISPOSABLE)
SPACER	87	C	SPACER, CEMENT
SPATULA	84 85 79 77 86 79 79	A	SPATULA, BRAIN SPATULA, CERVICAL, CYTOLOGICAL SPATULA, LUNG SPATULA, MIDDLE EAR SPATULA, OPHTHALMIC SPATULA, ORTHOPEDIC SPATULA, SURGICAL, GENERAL & PLASTIC SURGERY
SPECTACLE	86 86 86 86 86	A	EYEGLASSES HAPLOSCOPE SPECTACLE, MAGNIFYING SPECTACLE, OPERATING (LOUPE), OPHTHALMIC SYSTEM, SPECTACLE, FITTING
SPECULUM	79 79 77 79 78	A	SPECULUM, ENT SPECULUM, ILLUMINATED SPECULUM, NASAL SPECULUM, NON-ILLUMINATED SPECULUM, RECTAL

	85 85		SPECULUM, VAGINAL, METAL SPECULUM, VAGINAL, METAL, FIBEROPTIC
	86 85 85	B	SPECULUM, OPHTHALMIC (DISPOSABLE) SPECULUM, VAGINAL, NONMETAL (DISPOSABLE) SPECULUM, VAGINAL, NONMETAL, FIBEROPTIC
SPERMICIDE	85 85	B	CONDOM WITH NONOXYNOL-9 CONTRACEPTIVE, VAGINAL (FOAM, GEL, SUPPOSITORY)
SPHINCTER	78	C	PROSTHESIS, URETHRAL SPHINCTER
SPHINCTEROSCOPE	78	B	SPHYNCTEROSCOPE
SPHINCTEROTOME	79	B	PAPILLOTOME/SPHINCTEROTOME
SPHYGMOMANOMETER SPIROMETER	80 73 73 73	B B	SPHYGMOMANOMETER, ELECTRONIC (ARTERIAL PRESSURE) SPIROMETER, DIAGNOSTIC SPIROMETER, MONITORING (W/WO ALARM) SPIROMETER, THERAPEUTIC (INCENTIVE)
SPLINT	77 89 87 89 89 79 79 89 87 87 77 89 87	A	INTRANASAL SEPTAL SPLINT SPLINT, ABDUCTION, CONGENITAL HIP DISLOCATION SPLINT, ABDUCTION, SHOULDER SPLINT, CLAVICAL SPLINT, DENIS BROWN SPLINT, EXTREMITY, INFLATABLE, EXTERNAL SPLINT, EXTREMITY, NONINFLATABLE, EXTERNAL SPLINT, HAND, AND COMPONENTS SPLINT, MOLDED ALUMINIUM SPLINT, MOLDED PLASTIC SPLINT, NASAL SPLINT, TEMPORARY TRAINING SPLINT, TRACTION
	76 78	C	SPLINT, ENDODONTIC STABILIZER SPLINT, URETERAL

Keyword	Therapeutic Code	Class	Description
SPONGE	80 79 79	A	FIBER, MEDICAL, ABSORBENT SPONGE, EXTERNAL SPONGE, GAUZE
	85 79 86	B	CONTRACEPTIVE SPONGE SPONGE FOR INTERNAL USE SPONGE, OPHTHALMIC
SPOON	77 86 80 86	A	SPOON, EAR SPOON, LENS SPOON, MEDICINE SPOON, OPHTHALMIC

	84		SPOON, PITUITARY
SPRAY	80	A	SPRAY, PRE-TAPE
SPREADER	78 73 87	A	SPREADER, BLADDER NECK SPREADER, CUFF SPREADER, RIB
SPRING SPUD	76 86	B A	SPRING, ORTHODONTIC SPUD, OPHTHALMIC
STABILIZER	80 78	A	DEVICE, INTRAVASCULAR CATHETER SECUREMENT STABILIZER, SHUNT
	74 79	B	DEVICE, STABILIZER, HEART SUPPORT, INTERNAL ORGAN, SURGICAL
STAIN	76	C	POWDER/LIQUID/STAIN, PORCELAIN
STAPLE	79	B	STAPLE, REMOVABLE (SKIN)
	87 87 79	C	STAPLE, ABSORBABLE STAPLE, FIXATION, BONE STAPLE, IMPLANTABLE
STAPLER	79	B	STAPLER, SURGICAL
	79	C	SUTURE UNIT, AUTOMATIC (STAPLER)
STAPLING	87	C	STAPLING SET
STARTER	87	A	STARTER, BONE SCREW
STEEL	77	C	MATERIAL, METALLIC -STAINLESS STEEL, TANTALUM, PLATINUM, VITALLIUM
STENT	77 85	B	STENT, LARYNGEAL STENT, VAGINAL
	78 78 78 73 78 78 78 78	C	STENT, BILIARY STENT, COLONIC, METALLIC, EXPANDABLE STENT, ESOPHAGEAL STENT, METALLIC, EXPANDABLE STENT, PANCREATIC STENT, URETERAL STENT, URETHRAL, BULBOUS, PERMANENT OR SEMI-PERMANENT STENT, URETHRAL, PROSTATIC, PERMANENT OR SEMI-PERMANENT
	74	D	STENT, CARDIOVASCULAR
STEREOSCOPE	86 86	A	STEREOSCOPE, AC -POWERED STEREOSCOPE, BATTERY-POWERED
STEREOTAXIC	84	B	INSTRUMENT, STEREOTAXIC
STERILIZER	76	B	STERILIZER, BOILING WATER

	80		STERILIZER, CHEMICAL
	80		STERILIZER, DRY HEAT
	80		STERILIZER, ETHYLENE OXIDE GAS
	85		STERILIZER, FORMALDEHYDE
	76		STERILIZER, GLASS BEAD
	80		STERILIZER, OTHER
	86		STERILIZER, SOFT LENS, THERMAL AC POWERED

Keyword	Therapeutic Code	Class	Description
	80		STERILIZER, STEAM (AUTOCLAVE)
	86		STERILIZER, TONOMETER
	80		STERILIZER, ULTRAVIOLET
	80		STERILIZER/WASHER, ENDOSCOPE
STETHOSCOPE	85	A	STETHOSCOPE, FETAL
	74		STETHOSCOPE, MECHANICAL
	74	B	STETHOSCOPE, DIRECT (ACOUSTIC)
	74		STETHOSCOPE, ELECTRONIC
	74		STETHOSCOPE, ELECTRONIC -AMPLIFIED
	73		STETHOSCOPE, ESOPHAGEAL
	85	C	DETECTOR, FETAL HEART, ULTRASONIC (DOPPLER)
STIMULATOR	80	B	DEVICE, COLIC TREATMENT
	89		DEVICE, THERAPY, DIRECT CURRENT, LOW INTENSITY
	80		PHOTOSTIMULATOR
	84		STIMULATOR, AUDITORY, EVOKED RESPONSE
	87		STIMULATOR, BONE GROWTH, NON -INVASIVE
	77		STIMULATOR, CALORIC -WATER
	84		STIMULATOR, ELECTRICAL, EVOKED RESPONSE
	78		STIMULATOR, ELECTRICAL, INCONTINENCE (NON-IMPLANTABLE)
	73		STIMULATOR, ELECTRO- ACUPUNCTURE
	84		STIMULATOR, ELECTRO- ANALGESIC
	87		STIMULATOR, FUNCTIONAL NEUROMUSCULAR, SCOLIOSIS
	89		STIMULATOR, MUSCLE, DIAGNOSTIC
	89		STIMULATOR, MUSCLE, POWERED
	77		STIMULATOR, NERVE
	84		STIMULATOR, NERVE LOCATING, FACIAL
	73		STIMULATOR, NERVE, AC -POWERED
	73		STIMULATOR, NERVE, BATTERY POWERED
	73		STIMULATOR, NERVE, PERIPHERAL, ELECTRIC
	84		STIMULATOR, NERVE, TRANSCUTANEOUS, FOR PAIN RELIEF
	84		STIMULATOR, NEUROMUSCULAR, EXTERNAL FUNCTIONAL
	84		STIMULATOR, PHOTIC, EVOKED RESPONSE
	89		STIMULATOR, SCOLIOSIS (ORTHOSIS)
	89		STIMULATOR, ULTRASOUND AND MUSCLE, FOR USE IN APPLYING THERAPEUTIC DEEP HEAT
	89		STIMULATOR, WOUND HEALING
	76		STIMULATOR, SALIVARY SYSTEM

	78 84 78 78 87 84	C	INTESTINAL STIMULATOR STIMULATOR, CRANIAL ELECTROTHERAPY STIMULATOR, ELECTRICAL FOR INCONTINENCE (IMPLANTABLE) STIMULATOR, ELECTRICAL, IMPLANTED FOR GASTROPARESIS STIMULATOR, OSTEOGENESIS, ELECTRIC, BATTERY-OPERATED, STIMULATOR, PERIPHERAL NERVE, IMPLANTED (PAIN RELIEF)
	84 84 84 84 84 84 84 84 84 84	D	IMPLANTED AUTONOMIC NERVE STIMULATOR FOR EPILEPSY STABILIZED EPIDURAL SPINAL ELECTRODE STIMULATOR, CEREBELLAR, IMPLANTED STIMULATOR, DIAPHRAGMATIC/PHRENIC NERVE, IMPLANTED STIMULATOR, INTRACEREBRAL/SUBCORTICAL, IMPLANTED STIMULATOR, NEUROMUSCULAR, IMPLANTED STIMULATOR, SPINAL CORD, IMPLANTED (PAIN RELIEF) STIMULATOR, SPINAL CORD, IMPLANTED, FOR BLADDER EVACUATION STIMULATOR, VEGUS NERVE, IMPLANTED, EPILEPSY TOTALLY IMPLANTED SPINAL CORD STIMULATOR FOR PAIN RELIEF
STIRRUP	78	A	STIRRUP

Keyword	Therapeutic Code	Class	Description
	89		STIRRUP, EXTERNAL BRACE COMPONENT
STOCKINETTE	87	A	STOCKINETTE
STOCKING	80 80 80	A	NON-INFLATABLE COMPRESSION LEGGING STOCKING, ELASTIC STOCKING, MEDICAL SUPPORT
STOPCOCK	80	B	STOPCOCK, I.V. SET
STOPPER	80	B	SITE, SAMPLING/INJECTION, ASEPTIC

STRAP	87	A	STRAP, CLAVICLE
	80		THERAPEUTIC SCROTAL SUPPORT
	80		TOURNIQUET
STRETCHER	80	A	STRETCHER, BASKET, PORTABLE
	80		STRETCHER, HAND -CARRIED
	80		STRETCHER, HYDRAULIC
	90		STRETCHER, RADIOGRAPHIC
	80		STRETCHER, WHEELED, MECHANICAL
	89		STRETCHER, WHEELED, POWERED
STRIP	80	A	ADHESIVE STRIP
	79		CLOSURE, SKIN, ADHESIVE STRIP
	76		STRIP, POLISHING AGENT
	80		STRIP, TEMPERATURE, FOREHEAD, LIQUID CRYSTAL
	86	B	STRIP, SCHIRMER
	84	C	STRIP, CRANIOSYNOSTOSIS, PREFORMED
STRIPPER	74	A	STRIPPER, ARTERY, INTRALUMINAL
	87		STRIPPER, SURGICAL
	79		STRIPPER, TENDON
	74		STRIPPER, VEIN, EXTERNAL
	79		STRIPPER, VEIN, REUSABLE
	79	B	STRIPPER, VEIN, DISPOSABLE
STROLLER	89	A	STROLLER, ADAPTIVE
STYLET	77	A	STYLET, BRONCHIAL
	79		STYLET, SURGICAL, GENERAL & PLASTIC SURGERY
	78		STYLET, URETERAL
	78	B	STYLET FOR CATHETER, GASTRO-UROLOGY
	74		STYLET, CATHETER
	80		STYLET, NEEDLE
	73		STYLET, TRACHEAL TUBE
SUBPERIOSTEAL	76	C	IMPLANT, SUBPERIOSTEAL
SUCKER	74	B	SUCKER, CARDIOTOMY RETURN, CARDIOPULMONARY BYPASS
SUCTION	76	A	MOUTHPIECE, SALIVA EJECTOR
	80	B	APPARATUS, SUCTION, OPERATING ROOM, WALL VACUUM POWERED
	74		APPARATUS, SUCTION, PATIENT CARE
	79		APPARATUS, SUCTION, SINGLE PATIENT USE, PORTABLE, NONPOWERED
	79		APPARATUS, SUCTION, WARD USE, PORTABLE, AC-POWERED
	79		EQUIPMENT, SUCTION/IRRIGATION, ENDOSCOPIC
	90		FISTULOGRAPHY INSTRUMENT, VACUUM SUCTION
	78		INSTRUMENT, BIOPSY, SUCTION
	73		KIT, SUCTION, AIRWAY
	79		PUMP, PORTABLE, ASPIRATION (MANUAL OR POWERED)
	80		SUCTION SNAKE BITE KIT

	76		UNIT, SUCTION OPERATORY
	77 79	C	DEVICE, ANTICHOKE, SUCTION DEVICE, LIPECTOMY, SUCTION
SUIT	79	A	SUIT, SURGICAL

Keyword	Therapeutic Code	Class	Description
SUPPORT	87 89 89 87 87 87 87 79 78 89 89 73 90 89 89 80 89	A	SUPPORT, ANKLE (ANKLET) SUPPORT, ARCH SUPPORT, ARM SUPPORT, BACK SUPPORT, ELBOW SUPPORT, FOOT SUPPORT, HAND SUPPORT, HEAD, SURGICAL, ENT SUPPORT, HERNIA SUPPORT, KNEE SUPPORT, LEG SUPPORT, PATIENT POSITION SUPPORT, PATIENT POSITION, RADIOGRAPHIC SUPPORT, THIGH SUPPORT, WRIST THERAPEUTIC SCROTAL SUPPORT UNIT, SUPPORT, AMBULATION
	79	B	SUPPORT, INTERNAL ORGAN, SURGICAL
SUTURE	79	A	APPARATUS, SUTURING, STOMACH AND INTESTINAL
	79	B	KIT, SUTURE
	79 79 79 79 79 79 79 79 79 79 79	C	SUTURE UNIT, AUTOMATIC (STAPLER) SUTURE, ABSORBABLE SUTURE, ABSORBABLE, SYNTHETIC, POLYGLYCOLIC ACID SUTURE, DENTAL SUTURE, NONABSORBABLE SUTURE, NONABSORBABLE, STEEL, MONOFILAMENT AND MULTIFILAMENT SUTURE, NONABSORBABLE, SYNTHETIC, POLYAMIDE SUTURE, NONABSORBABLE, SYNTHETIC, POLYESTER SUTURE, NONABSORBABLE, SYNTHETIC, POLYETHYLENE SUTURE, NONABSORBABLE, SYNTHETIC, POLYPROPYLENE SUTURE, SURGICAL, NONABSORBABLE, POLYBUTESTER SUTURE/NEEDLE COMBINATION
	79 79 79	D	SUTURE, ABSORBABLE, NATURAL SUTURE, CARDIOVASCULAR SUTURE, NON ABSORBABLE SILK

SWAB	80 80	A	SWAB, ORAL CARE SWABS, COTTON
	80	B	SWAB, SPECIMEN COLLECTION
SYNCHRONIZER	90	B	SYNCHRONIZER, ECG/RESPIRATOR, RADIOGRAPHIC
SYNOPTOPHORE	86	A	SYNOPTOPHORE
SYNOVIAL	87	C	FLUID, JOINT LUBRICATING
SYRINGE	80	A	SYRINGE, ORAL (MEDICATION DISPENSER)
	74 80 80 80 73 84 74 80 76 76 76	B	INJECTOR AND SYRINGE, ANGIOGRAPHIC INJECTOR, SYRINGE IRRIGATING SYRINGE STERILE IRRIGATING SYRINGE SYRINGE, ANESTHESIA SYRINGE, ANGIOGRAPHIC SYRINGE, BALLOON INFLATION SYRINGE, BULB SYRINGE, BULB, AIR OR WATER SYRINGE, CARTRIDGE SYRINGE, DENTAL

Keyword	Therapeutic Code	Class	Description
	80 80 77 80 80 76 80 76 80 76 80 76		SYRINGE, DISPOSABLE, WITH/WITHOUT NEEDLE SYRINGE, DRUG, LUER -LOCK SYRINGE, ENT SYRINGE, HYPODERMIC SYRINGE, INSULIN SYRINGE, IRRIGATING SYRINGE, OPTHALMIC SYRINGE, PERIODONTIC, ENDODONTIC, IRRIGATING SYRINGE, PISTON SYRINGE, RESTORATIVE AND IMPRESSION MATERIAL SYRINGE, TUBERCULIN UNIT, SYRINGE, AIR AND/OR WATER
TABLE	80 89 90 85 85 89 90 90 90 87	A	TABLE, EXAMINATION/TREATMENT TABLE, MECHANICAL TABLE, NUCLEAR MEDICINE TABLE, OBSTETRICAL, AC POWERED (AND ACCESSORIES) TABLE, OBSTETRICAL, MANUAL (AND ACCESSORIES) TABLE, POWERED TABLE, RADIOGRAPHIC, NON-TILTING, POWERED TABLE, RADIOGRAPHIC, STATIONARY TOP TABLE, RADIOGRAPHIC, TILTING TABLE, SURGICAL WITH ORTHOPEDIC ACCESSORIES, AC - POWERED

	87		TABLE, SURGICAL WITH ORTHOPEDIC ACCESSORIES, MANUAL
	80		TABLE, ULTRASOUND
	78		TABLE, UROLOGICAL (CYSTOLOGICAL)
	89		UNIT, SUPPORT, AMBULATION
	90	B	EXERCISER, NUCLEAR DIAGNOSTIC (CARDIAC STRESS TABLE)
	89		TABLE, PHYSICAL THERAPY, MULTI FUNCTION
TACK	77	C	TACK, SACCULOTOMY (CODY TACK)
TACTILE	84	A	ESTHESIOMETER
TAMP	87	A	TAMP
TAMPON	85	B	TAMPON, MENSTRUAL, SCENTED, DEODORIZED
	85		TAMPON, MENSTRUAL, UNSCENTED
TANK	78	B	TANK, HOLDING, DIALYSIS
TAP	87	B	TAP, BONE
TAPE	79	A	ADHESIVE TAPE AND ADHESIVE BANDAGE
	80		TAPE, ADHESIVE
	80		TAPE, ADHESIVE, HYPOALLERGENIC
	80		TAPE, ADHESIVE, WATERPROOF
	80		TAPE, COTTON
	79		TAPE, MEASURING, RULERS AND CALIPERS
	86		TAPE, NYSTAGMUS
	79		TAPE, ORTHOPEDIC
	78		TAPE, TELEVISION & VIDEO, CLOSED-CIRCUIT, USED DURING ENDOSCOPIC PROCEDURE
	80		TAPE, UMBILICAL
TEAR	86	B	STRIP, SCHIRMER
	86		SYSTEM, INTUBATION, LACRIMAL
TEFLON	78	C	INJECTABLE BULKING AGENT FOR GASTROENTEROLOGY
	76		PASTE, INJECTABLE FOR VOCAL CORD AUGMENTATION
	74	D	PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE
TELEMETRY	80	B	TELEMETRY UNIT, PHYSIOLOGICAL, MULTIPLE CHANNEL
	80		TELEMETRY UNIT, PHYSIOLOGICAL, TEMPERATURE
	74	C	TELEMETRY UNIT, PHYSIOLOGICAL, ECG

Keyword	Therapeutic Code	Class	Description
TELESCOPE	86	A	TELESCOPE, SPECTACLE, LOW -VISION
	77	B	TELESCOPE, LARYNGEAL-BRONCHIAL
	78		TELESCOPE, RIGID, ENDOSCOPE

TELETHERAPY	90	C	SYSTEM, RADIATION THERAPY, RADIONUCLIDE
TELEVISION	90	A	SYSTEM, TELEVISION, SLOW SCAN
TENACULUM	79 85	A	TEN ACULUM, OTHER (FORCEPS) TENACULUM, UTERINE
TENDON	87 87	C	PROSTHESIS, TENDON PROSTHESIS, TENDON, PASSIVE
TENT	73 80 73 73 73	B	HOOD, OXYGEN, INFANT TENT, MIST TENT, OXYGEN TENT, OXYGEN, ELECTRICALLY POWERED TENT, PEDIATRIC AEROSOL
TEST	76 74 90 78 90	B	KIT, TEST, PERIODONTAL MAGNET, TEST, PACEMAKER PHANTOM, TEST-PATTERN, RADIONUCLIDE SOLUTION-TEST STANDARD CONDUCTIVITY, DIALYSIS TEST PATTERN, RADIOGRAPHIC
TESTER	86	A	TESTER, COLOR VISION
	78 78 77 86 74 74 84 74 76 90	B	METER, DIALYSATE CONDUCTIVITY TEST EQUIPMENT, DIALYSIS UNIT TESTER, AUDITORY IMPEDANCE TESTER, BRIGHTNESS ACUITY TESTER, DEFIBRILLATOR TESTER, ELECTROCARDIOGRAPH CABLE TESTER, ELECTRODE/LEAD, ELECTROENCEPHALOGRAPH TESTER, PACEMAKER ELECTRODE FUNCTION TESTER, PULP TESTER, RADIOLOGY QUALITY ASSURANCE
TESTICULAR	78	C	PROSTHESIS, TESTICULAR
TESTING	89	B	SYSTEM, ISOKINETIC TESTING AND EVALUATION
THERMAL	89	A	THERMAL WEAR, THERAPEUTIC
	80 74 78	B	INFUSION FLUID THERMAL WARMER SYSTEM, THERMAL REGULATING THERMAL DEVICE FOR HEMORRHOIDS
THERMOGRAPHIC	85 85	C	SYSTEM, THERMOGRAPHIC, LIQUID CRYSTAL THERMOGRAPHIC DEVICE, INFRARED
THERMOMETER	80 80 80 80 80 80	A	KIT, THERMOMETER STRIP, TEMPERATURE, FOREHEAD, LIQUID CRYSTAL THERMOMETER, CLINICAL MERCURY THERMOMETER, FLUID COLUMN THERMOMETER, LIQUID CRYSTALS THERMOMETER , PACIFIER
	80 80 80	B	THERMOMETER, CHEMICAL COLOR CHANGE THERMOMETER, ELECTRONIC THERMOMETER, ELECTRONIC, CLINICAL

	80		THERMOMETER, INFRARED
THERMOTHERAPY	78	C	SYSTEM, THERMOTHERAPY, RF/MICROWAVE (BENIGN PROSTATIC HYPERPLASIA)
THIGH	89	A	ASSEMBLY, THIGH/KNEE/SHANK/ANKLE/FOOT, EXTERNAL
THORACOSCOPE	74	B	THORACOSCOPE
TIE	78 78	A	TIE GUN, DIALYSIS TIE, DIALYSIS

Keyword	Therapeutic Code	Class	Description
	79	B	LOOP, IDENTIFICATION, SURGICAL
TIMER	90	A	TIMER, RADIOGRAPHIC
	73 80	B	TIMER, FLOW TIMER, PHOTOTHERAPY
TIP	76 80	A	TIP, RUBBER, ORAL HYGIENE TIP, SUCTION, RIGID
	73 80 80 79 79	B	ATOMIZER AND TIP, ENT CATHETER AND TIP, SUCTION TIP, ENEMA TIP, SUCTION TUBE (YANKAUER, POOLE, ETC.) TIP, SUCTION, ELECTROSURGICAL
	78	C	TIP, VESSEL
TISSUE	74	D	TISSUE, HEART VALVE
TOE	87	C	PROSTHESIS, TOE
TOMOGRAPHIC	90 90	B	SYSTEM, TOMOGRAPHIC, NUCLEAR SYSTEM, X-RAY, TOMOGRAPHIC
TONGS	77 84	B	DEVICE, ANTICHOKE, TONGS SKULL TONG FOR TRACTION
TONOGRAPH	86	B	TONOGRAPH
TONOMETER	86 86	B	TONOMETER, AC -POWERED TONOMETER, MANUAL
TONSILLECTOME	77	A	TONSILLECTOME
TOOLS	74	A	TOOLS, PACEMAKER SERVICE
TOOTHBRUSH	76	A	TOOTHBRUSH, MANUAL
	76	B	TOOTHBRUSH, POWERED

TOURNIQUET	80	A	TOURNIQUET
	74		TOURNIQUET, CARDIOVASCULAR
	79		TOURNIQUET, GASTRO-UROLOGY
	79		TOURNIQUET, NONPNEUMATIC
	79	B	TOURNIQUET, AIR PRESSURE
	79		TOURNIQUET, PNEUMATIC
	74	C	TOURNIQUET, AUTOMATIC ROTATING
TOWEL	79	A	TOWEL, SURGICAL
TRABECULOTOME	86	A	TRABECULOTOME
TRACHEAL	79	C	PROSTHESIS, TRACHEAL
TRACHEOSTOMY	73	B	KIT, TRACHEOTOMY
TRACHEOTOME	73	A	TRACHEOTOME
TRACTION	89	A	ACCESSORIES, TRACTION
	87		ACCESSORIES, TRACTION (CART, FRAME, CORD, WEIGHT)
	87		APPARATUS, TRACTION, NON-POWERED
	87		COMPONENT, TRACTION, NON-INVASIVE
	87		INVERSION UNIT
	87		SYSTEM, TRACTION, ARTHROSCOPY
	87		UNIT, TRACTION, HIP, NON-POWERED, NON -PENETRATING
	87		UNIT, TRACTION, STATIC BED
	87		UNIT, TRACTION, STATIC, OTHER
	89	B	EQUIPMENT, TRACTION, POWERED
	87		UNIT, TRACTION, POWERED
	87	C	COMPONENT, TRACTION, INVASIVE
TRAINING	86	A	OCULO-MOTOR MOVEMENT TRAINING, OPH THALMIC
TRANSDUCER	80	B	DOME, PRESSURE TRANSDUCER
	74		TRANSDUCER, APEX CARDIOGRAPHIC
	74		TRANSDUCER, BLOOD FLOW, NON-INDWELLING

Keyword	Therapeutic Code	Class	Description
	80		TRANSDUCER, BLOOD PRESSURE
	74		TRANSDUCER, BLOOD PRESSURE, EXTRAVASCULAR
	80		TRANSDUCER, FORCE
	73		TRANSDUCER, GAS FLOW
	73		TRANSDUCER, GAS PRESSURE
	73		TRANSDUCER, GAS PRESSURE, DIFFERENTIAL
	74		TRANSDUCER, HEART SOUND
	89		TRANSDUCER, MINIATURE PRESSURE
	85		TRANSDUCER, PRESSURE, INTRAUTERINE
	73		TRANSDUCER, RESPIRATION RATE
	84		TRANSDUCER, TREMOR

	74	C	TRANSDUCER, ULTRASONIC
	90		TRANSDUCER, ULTRASONIC, DIAGNOSTIC
	85		TRANSDUCER, ULTRASONIC, OBSTETRIC
	74	D	TRANSDUCER, PRESSURE, CATHETER TIP
	74		TRANSDUCER, VESSEL OCCLUSION
TRANSFER	85	B	EQUIPMENT, IN -VITRO FERTILIZATION/EMBRYO TRANSFER
	80		SET, I.V. FLUID TRANSFER
TRANSFORMER	78	B	TRANSFORMER, ENDOSCOPE
TRANSFUSION	73	B	APPARATUS, AUTOTRANSFUSION
	80		BONE MARROW COLLECTION/TRANSFUSION KIT
	80		KIT, TRANSFUSION
TRANSILLUMINATOR	86	A	TRANSILLUMINATOR, AC -POWERED
	86		TRANSILLUMINATOR, BATTERY-POWERED
	80	B	PHANEROSCOPE
TRANSMITTER	74	B	TRANSMITTER AND RECEIVER, ELECTROCARDIOGRAPH, TELEPHONE
	74		TRANSMITTER AND RECEIVER, PHYSIOLOGICAL SIGNAL, RADIOFREQUENCY
	80		TRANSMITTER/RECEIVER SYSTEM, FETAL MONITOR, TELEPHONE
TRAP	73	B	DRAIN, TEE (WATER TRAP)
	74		TRAP, BUBBLE
TRAY	80	B	TRAY, SURGICAL, CUSTOM/SPECIAL PROCEDURE
TREPHINE	77	A	TREPHINE, SINUS
	86	B	ENGINE, TREPHINE, ACCESSORIES, AC -POWERED
	84		POWERED COMPOUND DRILLS, BURRS, TREPHINES & ACCESSORIES
	84		POWERED SIMPLE DRILLS, BURRS, TREPHINES & ACCESSORIES
	87		TREPHINE (DISPOSABLE)
	86		TREPHINE, MANUAL, OPHTHALMIC (DISPOSABLE)
TRICALCIUM PHOSPHATE	76	C	GRANULES, TRICALCIUM PHOSPHATE FOR DENTAL BONE REPAIR
TRIPSOR	78	B	TRIPSOR, STONE, BLADDER
TROCAR	78	B	CANNULA AND TROCAR, SUPRAPUBLIC, NON-DISPOSABLE
	74		TROCAR
	78		TROCAR, ABDOMINAL
	77		TROCAR, ANTRUM
	77		TROCAR, ENT
	78		TROCAR, GALLBLADDER
	78		TROCAR, GASTRO-UROLOGY
	77		TROCAR, LARYNGEAL
	85		TROCAR, OVARIAN
	77		TROCAR, SINUS
	74		TROCAR, THORACIC

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TRUSS	89	A	BELT, ABDOMINAL
	78		SUPPORT, HERNIA
	78		TRUSS, UMBILICAL

Keyword	Therapeutic Code	Class	Description
TUBE	73	A	AIRWAY, NASOPHARYNGEAL
	87		TUBE, CEMENT VENTILATION
	77		TUBE, EAR SUCTION
	87		TUBE, INTRAMEDULLARY, FLUSHING
	77		TUBE, TOYNBEE DIAGNOSTIC
	73	B	DRAIN, THORACIC (CHEST)
	74		KIT, CATHETER REPAIR, NON-BALLOON
	78		SET, GAVAGE, INFANT, STERILE
	77		TUBE, ASPIRATING, BRONCHOSCOPE, RIGID
	80		TUBE, ASPIRATING, FLEXIBLE, CONNECTING
	73		TUBE, BRONCHIAL (W/WO CONNECTOR)
	78		TUBE, CALIBRATION, GRASTROPLASTY
	78		TUBE, COLON
	80		TUBE, CONNECTING
	80		TUBE, DECOMPRESSION
	78		TUBE, DOUBLE LUMEN FOR INTESTINAL DECOMPRESSION AND/OR INTUBATION
	78		TUBE, DRAINAGE
	78		TUBE, ESOPHAGEAL, BLAKEMORE
	78		TUBE, ESOPHAGEAL, SENGSTAK EN
	78		TUBE, FEEDING
	78		TUBE, GASTRO-ENTEROSTOMY
	78		TUBE, GASTROINTESTINAL (AND ACCESSORIES)
	74		TUBE, HEART-LUNG BYPASS UNIT
	90		TUBE, IMAGE AMPLIFIER, X-RAY
	77		TUBE, LARYNGECTOMY
	78		TUBE, LEVINE
	78		TUBE, NASOGASTRIC
	78		TUBE, NEPHROSTOMY
	76		TUBE, ORTHODONTIC
	78		TUBE, RECTAL
	78		TUBE, SINGLE LUMEN, W MERCURY WT BALLOON FOR INTES. INTUB. &/OR DECOMPRESSION
	78		TUBE, STOMACH EVACUATOR (GASTRIC LAVAGE)
	77		TUBE, TONSIL SUCTION
	73		TUBE, TRACHEAL (ENDOTRACHEAL) (W/WO CONNECTOR)
	73		TUBE, TRACHEAL/BRONCHIAL, DIFFERENTIAL VENTILATION
	73		TUBE, TRACHEOSTOMY
	90	C	ASSEMBLY, TUBE HOUSING, X-RAY, DIAGNOSTIC
	90		ASSEMBLY, TUBE HOUSING, X-RAY, THERAPEUTIC
	78		TUBE, ANASTOMOSIS BYPASS
	78		TUBE, FEEDING, GASTROSOTOMY/JEJUNOSTOMY
	77		TUBE, SHUNT, ENDOLYMPHATIC

	77		TUBE, SHUNT, ENDOLYMPHATIC WITH VALVE
	77		TUBE, TYMPANOSTOMY
	90		TUBE, X-RAY
TUBING	76	A	DENTAL UNIT, TUBING AND ACCESSORIES
	80		TUBING, NONINVASIVE
	80		TUBING, PLASTIC
	74	B	CATHETER, CANNULA AND TUBING, VASCULAR, CARDIOPULMONARY BYPASS
	80		KIT, INTRAVENOUS EXTENSION TUBING
	78		KIT, TUBING HEMODIALYSIS, HEMOPERFUSION, HEMOFILTRATION
	73		SET, TUBING AND SUPPORT, VENTILATOR (W HARNESS)
	78		SET, TUBING, BLOOD WITH AND WITHOUT ANTI-REGURGITATION VALVE
	80		TUBING, CONDUCTIVE

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	80		TUBING, CONNECTOR/ADAPTOR
	80		TUBING, CORRUGATED
	78		TUBING, DIALYSATE (AND CONNECTOR)
	80		TUBING, FLUID DELIVERY
	77		TUBING, INSTRUMENTATION, BRONCHOSCOPE (BRUSH SHEATH A/O ASPIRATING)
	80		TUBING, LATEX
	80		TUBING, NON-CONDUCTIVE
	80		TUBING, OXYGEN CONNECTING
	80		TUBING, POLYETHYLENE
	80		TUBING, POLYVINYL, CHLORIDE
	73		TUBING, PRESSURE AND ACCESSORIES
	74		TUBING, PUMP, CARDIOPULMONARY BYPASS
	86		TUBING, REPLACEMENT, PHACOFRAGMENTATION UNIT
	80		TUBING, RUBBER
	80		TUBING, SILICONE
	80		TUBING, VINYL
TUCKER	76	A	INSTRUMENT, LIGATURE TUCKING, ORTHODONTIC
	86		TUCKER, TENDON/MUSCLE, STRABISMUS
TUNNELER	79	B	TUNNELER, SURGICAL (DISPOSABLE)
TWEEZER	80	A	TWEEZERS
TWISTER	89	A	TWISTER, BRACE SETTING
	87		TWISTER, WIRE
TYING	79	B	INSTRUMENT, LIGATURE PASSING AND KNOT TYING
TYMPANOSCOPE	77	A	TYMPANOSCOPE

ULTRASONIC	74 84 74 80	B	ECHOCARDIOGRAPH ECHOENCEPHALOGRAPH STETHOSCOPE, DIRECT (ACOUSTIC) WASHER/DISINFECTOR
ULTRASOUND	74 85 74 90 90 90 90 87	C B	DETECTOR, BLOOD FLOW, ULTRASONIC (DOPPLER) DETECTOR, FETAL HEART, ULTRASONIC (DOPPLER) MONITOR, BLOOD-PRESSURE, NEONATAL, ULTRASONIC/DOPPLER SCANNER, ULTRASONIC, GENERAL PURPOSE SYSTEM IMAGING, PULSED DOPPLER, ULTRASONIC SYSTEM, MAGING, PULSED ECHO, ULTRASONIC SYSTEM, IMAGING, ULTRASONIC, OPHTHALMIC STIMULATOR, BONE GROWTH, NON -INVASIVE
	85 74 90 86	C	DOPPLER ULTRASOUND FOR FETAL EVALUATION FLOWMETER, BLOOD, NON-INVASIVE ELECTROMAGNETIC OR DOPPLER SONOMETER, BONE UNIT, PHACOFRAGMENTATION AND ACCESSORIES
URETEROSCOPE	78	B	URETEROSCOPE
URETHROMETER	78	B	URETHROMETER
URETHROSCOPE	78 78	B	CYSTOURETHROSCOPE URETHROSCOPE
URETHROTOME	78	A	URETHROTOME
URINE	78 80	A	BAG, DRAINAGE, WITH ADHESIVE, OSTOMY KIT, MID -STREAM COLLECTION
	78 78	B	CATHETER, NEPHROSTOMY TRAY, CATHETERIZATION, STERILE URETHRAL, WITH OR WITHOUT CATHETER
URINOMETER	78 78	A	DEVICE, URINE FLOW RATE MEASURING, NON-ELECTRICAL, DISPOSABLE URINOMETER, MECHANICAL
	78	B	URINOMETER, ELECTRICAL
URODYNAMIC	78	B	DEVICE, CYSTOMETRIC, HYDRAULIC

Keyword	Therapeutic Code	Class	Description
UROFLOWMETER	78	B	UROFLOWMETER
VACUUM	80 85	B	GAUGE, PRESSURE SYSTEM, ABORTION, VACUUM

VAGINOSCOP E	85	B	VAGINOSCOPE AND ACCESSORIES
VALVE	74	A	PUMP, AIR, MANUAL CUFF INFLATING
	73 74 74 73 73 74 77 73 73	B	VALVE, BREATHING VALVE, CATHETER FLUSH, CONTINUOUS VALVE, CATHETER, FLUSH VALVE, NON -REBREATHING VALVE, POSITIVE END EXPIRATORY PRESSURE (PEEP) VALVE, PRESSURE RELIEF, CARDIOPULMONARY BYPASS VALVE, SPEAKING, TRACHEAL VALVE, SWITCHING VALVE, SWITCHING (PLOSS)
	85	C	DEVICE, OCCLUSION, TUBAL (TOD), CONTRACEPTIVE
	74 84 74	D	HEART-VALVE, MECHANICAL SHUNT, CENTRAL NERVOUS SYSTEM AND COMPONENTS TISSUE, HEART VALVE
VALVULOTOME	74	B	VALVULOTOME
VAPORIZER	73	C	VAPORIZER, ANESTHESIA, NON-HEATED
VARNISH	76	C	VARNISH, CAVITY
VASECTOMY	78	B	KIT, SURGICAL, VASECTOMY
VDT	86 79 79	A	AID, VISION IMAGE INTENSIFICATION CAMERA, TELEVISION, MICROSURGICAL, WITHOUT AUDIO CAMERA, TELEVISION, SURGICAL, WITHOUT AUDIO
	79 74	B	CAMERA, TELEVISION, ENDOSCOPIC, WITHOUT AUDIO (INVASIVE) SYSTEM, THERMAL REGULATING
VECTIS	85	A	VECTIS, OBSTETRICAL
VECTORCARDIOGRAPH	74	B	VECTORCARDIOGRAPH
VENEER	76	C	VENEER, DENTAL
VENTILATION	73	B	ATTACHMENT, INTERMITENT MANDATORY VENTILATION (IMV)
	77	C	TUBE, TYMPANOSTOMY
VENTILATOR	73 73	B	CIRCUIT, BREATHING, VENTILATOR VENTILATOR, EMERGENCY, MANUAL (RESUSCITATOR)
	73 73 73 73 73 73 73	C	RESPIRATOR, NEONATAL VENTILATOR VENTILATOR, ANESTHESIA UNIT VENTILATOR, CONTINUOUS (RESPIRATOR) VENTILATOR, CONTINUOUS, HYPERBARIC VENTILATOR, CONTINUOUS, NON-LIFE-SUPPORTING VENTILATOR, EMERGENCY, POWERED (RESUSCITATOR) VENTILATOR, EXTERNAL BODY, NEGATIVE PRESSURE, ADULT (CUIRASS) VENTILATOR, NON-CONTINUOUS (RESPIRATOR)

	73 73		VEN TILATOR, PRESSURE CYCLED (IPPB MACHINE) VENTILATOR, VOLUME (CRITICAL CARE)
VENTRICULAR	74	D	DEVICE, BYPASS, VENTRICULAR (ASSIST)
VERTIGO	77	C	TACK, SACCULOTOMY (CODY TACK)
VIBRATOR	80 89 89 85 89	B	DEVICE, COLIC TREATMENT MASSAGER, BATTERY-POWERED MASSAGER, THERAPEUTIC, ELECTRIC VIBRATOR FOR THERAPEUTIC USE, GENITAL VIBRATOR, THERAPEUTIC
VIDEOTAPE	78 79	A	TAPE, TELEVISION & VIDEO, CLOSED -CIRCUIT, USED DURING ENDOSCOPIC PROCEDURE VIDEOTAPE, CAMERA, SURGICAL

Keyword	Therapeutic Code	Class	Description
VISCOELASTIC	86	C	FLUID, INTRAOCULAR
VISE	87 77	A	VISE, ORTHOPEDIC VISE, OSSICULAR FINGER
VISION	86	A	GRID, AMSLER
	86	B	TESTER, BRIGHTNESS ACUITY
VISUAL	86	A	OCULO-MOTOR MOVEMENT TRAINING, OPHTHALMIC
VOICE	77 77	B	LARYNX, ARTIFICIAL, BATTERY POWERED VALVE, SPEAKING, TRACHEAL
	77	C	PROSTHESIS, LARYNX
VOLUMETER	73	B	SPIROMETER, MONITORING (W/WO ALARM)
WAFER	76	A	WAX, DENTAL, INTRAORAL
WALKER	89	A	WALKER, MECHANICAL
WARMER	80	B	INFUSION FLUID THERMAL WARMER
	80 80	C	WARMER, INFANT RADIANT WARMER, RADIANT, ADULT
WASHER	73 80 80	B	APPARATUS, AUTOTRANSFUSION STERILIZER/WASHER, ENDOSCOPE WASHER/DISINFECTOR
	87	C	WASHER, BOLT, NUT
WATERBED	80	B	TEMPERATURE REGULATED WATER MATTRESS

WAX	76	A	WAX, DENTAL, INTRAORAL
	89	B	BATH, PARAFFIN
	87	C	WAX, BONE
WEDGE	76	A	WEDGES
WEIGHT	89 80	A	UNIT, SUPPORT, AMBULATION WEIGHTS FOR STABILIZING MATERIAL DURING PROCEDURE
	78	B	EXTERNAL DEVICE FOR WEIGHT MANAGEMENT
WETTING	86	B	ACCESSORIES TO CONTACT LENSES - CLEANING AND WETTING AGENTS
WHEEL	76	A	WHEEL, POLISHING AGENT
WHEELCHAIR	89 89 89 89 89 89	A	STROLLER, ADAPTIVE VEHICLE, MOTORIZED C-WHEELED WHEELCHAIR, MECHANICAL WHEELCHAIR, POWERED WHEELCHAIR, STAIR CLIMBING WHEELCHAIR, STANDUP
WHIRLPOOL	89	A	BATH, HYDRO-MASSAGE
WICK	77	A	EAR WICK
WIRE	79	A	WIRE, SNARE
	78 74 74 76	B	GUIDE, CATHETER WIRE, GUIDE, ANGIOGRAPHIC AND ACCESSORIES WIRE, GUIDE, CATHETER WIRE, ORTHODONTIC
	76 90 79 87 76 79 87	C	LOCK, WIRE, AND LIGATURE, INTRAORAL SOURCE, WIRE, IRIDIUM, RADIOACTIVE SUTURE, NONABSORBABLE, STEEL, MONOFILAMENT AND MULTIFI LAMENT WIRE, BONE WIRE, FIXATION, INTRAOSSEOUS WIRE, LIGATURE WIRE, SURIGICAL
WRAP	89	A	PACK, HOT OR COLD, REUSABLE
	89	B	DEVICE, CRYOTHERAPY/COMPRESSION
	86	D	WRAP, IMPLANT, ORBITAL
WRENCH	87	A	WRENCH

Keyword	Therapeutic Code	Class	Description

WRIST	89 89	A	ASSEMBLY, SHOULDER/ELBOW/FOREARM/WRIST/HAND, MECHANICAL UNIT, WRIST, EXTERNAL LIMB COMPONENT, MECHANICAL
	87 87 87 87 87 87 87	C	PROSTHESIS, CARPAL PROSTHESIS, WRIST, B PART METAL -PLASTIC ARTICULATION, SEMI -CONSTRAINED PROSTHESIS, WRIST, C PART METAL -PLASTIC -METAL ARTICULATION, SEMI-CONSTRAINED PROSTHESIS, WRIST, CARPAL SCAPHOID PROSTHESIS, WRIST, CARPAL TRAPEZIUM PROSTHESIS, WRIST, CARPAL, LUNATE PROSTHESIS, WRIST, HEMI-, ULNAR
XENON	73	C	XENON SYSTEM
XRAY	90 90 90 90	A	APRON, LEADED APRON, PROTECTIVE DEVICE, SPOT FILM SCREEN, INTENSIFYING, RADIOGRAPHIC
	76 90 76	B	SYSTEM, IMAGING, DENTAL, DIGITIAL - FILMLESS SYSTEM, X-RAY, TOMOGRAPHIC UNIT, RADIOGRAPHIC, DIAGNOSTIC, DENTAL (X-RAY)
	90I 90 90 90I 90J 90 90 90J 90 90 90 90 90	C	ASSEMBLY, TUBE HOUSING, X-RAY, DIAGNOSITC ASSEMBLY, TUBE HOUSING, X-RAY, THERAPEUTIC CAMERA, MULTI-IMAGE SYSTEM, IMAGING, X-RAY, ELECTROSTATIC SYSTEM, THERAPEUTIC, X-RAY SYSTEM, X-RAY, ANGIOGRAPHIC SYSTEM, X-RAY, FLUOROSCOPIC, IMAGE-INTENSIFIED SYSTEM, X-RAY, FLUOROSCOPIC, NON-IMAGE-INTENSIFIED SYSTEM, X-RAY, MAMMOGRAPHIC SYSTEM, X-RAY, MOBILE, FLUOROSCO PIC SYSTEM, X-RAY, STATIONARY TUBE, X-RAY UNIT, X-RAY, MOBILE, EXPLOSION-SAFE
YOKE	73	B	YOKE ASSEMBLY, MEDICAL GAS
ZIPPER	79	A	ZIPPER, WOUND CLOSURE