A

GUIDANCE DOCUMENT

for

MEDICAL DEVICES

Draft version

2018

Indian Pharmacopoeia Commission

National Coordination Centre-Materiovigilance Programme of India

Ministry of Health & Family Welfare

Government of India

Disclaimer:

Guidance document for Medical Devices is neither a regulatory nor a legal document. This document has been framed on the basis of Medical Device Rules 2017 issued by Government of India. If there are any errors or omissions found in this guidance document, readers are advised to refer to original Medical Device Rules 2017. The information contained in this document should not be a substitute for Medical Device Rule 2017.

Message

I am happy to note that the Indian Pharmacopoeia Commission (IPC) has brought out the first edition of the "Standards for Medical Devices-A Reference Document" intended for the Indian Stakeholders. Though the country has made tremendous progress in health sector, framing laws and setting standards for medical devices remained a big challenge. This assumes importance especially when the medical devices impact health of the patients. Therefore, the Govt. of India, Ministry of Health & Family Welfare has recently notified the Medical Devices Rules, 2017 and made the same as part of the Drugs and Cosmetics Act, 1940. Medical devices are used as diagnostics and also for treatment of diseases. Therefore, like other pharmaceutical products, the quality of medical devices is also required to be monitored for ensuring efficacy and patient safety.

The efforts made by IPC for bringing out this manual indicating the standards for medical devices highlight the Government's intention to ensure the quality of medical devices for minimizing the patient safety risks. This is an important step in contextualizing and formalizing the country's commitment to ensuring quality of health care system by improving quality of medical devices.

This document is an essential reference manual for medical devices industries, policy makers and healthcare professionals for delivering their services by focusing on patient's wellbeing. I am sure that this document will help build public confidence in so far as the quality of medical devices is concerned. However, I seek continued support and participation of all stakeholders to revise/update the standards of medical devices, as and when required.

As the Chairperson of IPC, I expect this document will be widely used by the stakeholders for effectively addressing the challenges faced regarding the quality of medical devices in the country. I am thankful to all experts who contributed to the development of this guidance document.

(Ms. Preeti Sudan)

Secretary, Ministry of Health & Family Welfare
Government of India

Foreword

Medical devices are being widely used in all branches of medicines, surgery and community not only in India but across the globe. Keeping in view the broad objectives for ensuring protection of the health & safety of patients, healthcare professionals and others, the Ministry of Health & Family Welfare, Government of India has released the Medical Device Rules, 2017, effective from 1st January, 2018 for regulating Medical Devices being used in the country. As India is playing a major role in marketing of these devices in Asia, and beyond, regulating Medical Devices poses a real challenge, upon implementation of the Medical Device Rules, 2017 which ultimately aim at replacing the existing Rules of the Drugs and Cosmetics Act, 1940.

The Indian Pharmacopoeia Commission (IPC), under the aegis of the Ministry of Health and Family Welfare, has taken initiative to compile and publish the standards for medical devices as a Guidance Document for the benefit of the general public, patients and healthcare professionals as well. The primary objective and scope of this document is to provide necessary information to all the stakeholders of the country regarding the regulatory requirements, quality management systems and standards required to be followed for medical devices. This document will also serve as a reference manual for the licensing authority in the matters relating to medical devices.

Upon proper implementation of the guidelines and standards so given in this document, this will help improve the quality of medical devices and their proper management so as to build confidence among the population and minimize patient risk. I thank the Indian Pharmacopoeia Commission for preparing this document at the shortest possible time. Further, I also take this opportunity to thank other organizations such as CDSCO and stakeholders for their support and cooperation in developing this document. These efforts, I am sure, will go a long way for setting standards for and strengthening of the Medical devices used in the country.

(Dr. R. K Vats)

Additional Secretary
Ministry of Health & Family Welfare
Government of India

Preface

It gives me immense pleasure to present the first version of the "Standards for Medical Devices- A Reference Document" for the stakeholders. This is the first such document in so far as the quality of the medical devices in the country is concerned. On the basis of the recent guidelines issued by the Government of India, Ministry of Health & family Welfare for making separate rules on Medical Devices, effective from 1st January, 2018, the Indian Pharmacopoeia Commission (IPC) has made efforts to compile the requisite information relating to legal, regulatory requirements and standards prescribed for medical devices under one umbrella. This will serve as a reference manual for stakeholders such as Medical Device Manufacturers/ Licence Holders, Regulators, Healthcare Professionals etc.

This document has, inter alia, adopted regulatory requirements and quality management system as specified in the Drugs & Cosmetic Act, 1940 and Rules framed thereunder. The standards adopted in this document are from the Medical Device Rules 2017, the Indian Pharmacopoeia (I.P) 2018 and other Pharmacopoeia such as British Pharmacopoeia (BP), Japanese Pharmacopoeia (JP), European Pharmacopoeia (EP) etc and also the standards as prescribed by the Bureau of Indian Standards (BIS). This guidance document is intended to provide assistance to Medical Devices Industry, Regulators and Healthcare Professionals on how to comply with governing statutes and regulations for medical devices. This document is informative and for advisory purpose only; and, therefore, has no legal sanctity.

The IP Commission expresses its sincere thanks and gratitude to the Ministry of Health and family Welfare (MoHFW), Government of India (GOI) for its continued guidance, support and encouragement for bringing out this document.

(Dr. G.N. Singh)

Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare
Government of India

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AMC	Adverse Drugs Reaction Monitoring Centre
ANSI	American National Standards Institute
BSEs	Bovine Spongiform Encephalopathy
CDSCO	Central Drugs Standard Control Organization
CE	Conformité Européene
CEN	Comité Européen de Normalisation
CENELEC	European Committee for Electrotechnical Standardization
CLA	Central Licensing Authority
Class A	low risk
Class B	low moderate risk
Class C	Moderate high risk
Class D	High risk
CSA	Canadian Standards Association
CTC	Core Technical Committee
DCGI	Drugs Controller General of India
ELISA	Enzyme-linked Immunosorbent Assay
EP	Essential Principles
ETSI	European Telecommunication Standards Institute
GHTF	Global Harmonization Task Force
GoI	Government of India
HIV	Human Immunodeficiency Virus
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
IPC	Indian Pharmacopoeia Commission
ISO	International Organisation for Standardisation
ITU	International Telecommunication Union
IVD	*In-vitro* Diagnostic

MDAE	Medical Device Adverse Events
MDD	Medical Device Directive
MDQMS	Medical Device Quality Management System
MDR	Medical Devices Rules 2017
MoHFW	Ministry of Health and Family Welfare
MvPI	Materiovigilance programme of India
NBs	Notified Bodies
NCC	National Coordination Centre
NHSRC	National Health System Resource Centre
NRA	National Regulatory Authority
PvPI	Pharmacovigilance Programme of India
QMS	Quality Management System
SCC	Standards Council of Canada
SCTIMST	Sree Chitra Tirunal Institute for Medical Sciences & Technology
SLA	State Licensing Authority
TSEs	Transmissible Spongiform Encephalopathies
UNI	Italian National Standard

1. Introduction

Medical devices are an important part of health care, yet they are an extraordinarily heterogeneous class of products. The term "medical device" includes such technologically simple items as ice bags and tongue depressors on one end of the continuum and very sophisticated items such as cardiac pacemakers and proton therapy devices on the other end. Broadly based on the function of medical device they may be classified as preventive care device, assistive care device, diagnostic device and therapeutic device. Perhaps these are the unique challenges like safety concerns and diversity of products coupled with the sheer number of different devices in market that makes the development of an effective and efficient regulatory scheme a unique challenge for domestic as well as international regulatory bodies. Regulators and governments count on standards to help develop better regulation.

Background

The diagnosis and treatment of disease experienced relatively few breakthroughs until the 17th century. One major contribution in the field of medical devices was the invention of the thermometer. In 1603, Galileo invented a device to measure temperature and Sanatoria Santonio made improvements to the device, allowing him to measure the temperature of the human body. A second important contribution occurred in 1819, when the French physician René Laënnec is attributed with refining the "hearing tube" or stethoscope, a trumpet-shaped wooden tube. These inventions helped physicians to diagnose and treat patients with more confidence and better accuracy, making great contributions to health and quality of life. The real breakthrough in medical diagnostic equipment came in 1895 with the discovery of X-rays by the German physicist Wilhelm Conrad Röntgen. Wilhelm Einthoven's invention of the electrocardiograph in 1903 started the wave of physiological measuring instrumentation that is used in every hospital and doctor's office today. Since then, a number of medical devices including pacemaker, dialysis machine, disposable catheter, intraocular lens, artificial heart and liver etc. have appeared in the market and revolutionized the medical field.

Indian medical device sector, Asia's fourth largest market of approximate USD 5.5 Billion worth, presents an exciting business landscape and opportunities for both domestic as well as international manufacturers/entrepreneurs and expanding at a steady pace. Till the early 1990s, the medical device sector was significantly dominated by domestic players but after India

opened up its market post-New Economic Policy-1991, tables have turned in favor of Indian market. The technological advancement and expertise in the field of medical devices that the global market leaders offered has proved as an advantage. Today, India's medical device sector is dominated by multinational companies, which is evident from the fact that India relies on imports of medical devices (about 75-80% of the sales are generated by imported medical devices) to supply its healthcare system. Over the years, many multi-nationals have set up operations in India. However, the nature of majority of the operations is to only distribute imported devices and provide support function.

1.1 Purpose of the guidelines

- This Document aims to be informative in nature on medical device standards comprehensively, irrespective of usage i.e. whether on human beings and animals. Preparation of standards on medical devices nationally and internationally is an ongoing process, irrespective of regulation on same by National/State Medical Devices Regulator.
- This Document Provides guidance to assist manufacturers, traders/distributors, importers, clinical establishments, healthcare professionals and general public on nationally "recognized medical devices standards" and other regulatory requirements concerning medical device in India.
- This document serves as ready reference for medical devices standards preparation/adoptions, clinical care quality bodies, nomenclature of medical devices, claims on medical devices and validation mechanism, , existence of multiple regulatory bodies on medical devices and Law (ACT) directly governing medical devices in India.

1.2 Scope of the guidance document

It is a consolidated reference document made available for manufacturers, traders/distributors, importers, clinical establishments, healthcare professionals and general public about the standards, regulatory and other requirements for medical devices in India.

The guidelines describe the information to be supplied with applications to person who

- import;
- manufacture for sale or for distribution; and
- sale, stock, exhibit or offer for sale of medical devices in India

- Healthcare Professional
- Policy makers/Government organizations
- Medical devices Procurement persons or agencies/organizations
- Private and public hospitals or its representatives
- Medical devices testing, Quality monitoring organizations
- Associations of Industry, professionals, Hospital etc.
- General Public/Citizen of India

The guideline also describes post-market requirements for medical devices.

1.3 Definitions & Terminologies

As per the Gazette of India notification G.S.R. 78(E), dated 31st January 2017, unless the context otherwise requires,-

(a) "Act" means the Drugs and Cosmetics Act, 1940 (23 of 1940);

(b) "active diagnostic medical device" means any active medical device used, whether alone or in combination with other medical devices, to supply information for detecting, diagnosing or monitoring, or to provide support in the treatment of, any physiological condition, state of health, illness or congenital deformity;

(c) "active medical device" means a medical device, the operation of which depends on a source of electrical energy or any other source of energy other than the energy generated by human or animal body or gravity;

(d) "active therapeutic medical device" means any active medical device used, whether alone or in combination with any other medical device, to support, modify, replace or restore biological functions or structures, with a view to the treatment or alleviation of any illness, injury or handicap;

(e) "authorised agent" means a person including any firm or organisation who has been appointed by an overseas manufacturer through a power of attorney to undertake import of medical device in India;

(f) "body orifice" means any natural opening in a human body including the external surface of any eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy;

(g) "Central Licensing Authority" means the Drugs Controller General of India appointed by the Central Government;

(h) "central medical devices testing laboratory" means a medical devices laboratory established or designated by the Central Government under MDR 2017 and shall be deemed to be a Central Drug Laboratory established for the purpose of MDR 2017;

(i) "conformity assessment" means the systematic examination of evidence generated and procedures undertaken, by the manufacturer to determine that a medical device is safe and performs as intended by the manufacturer and therefore conforms to the essential principles of safety and performance for medical devices;

(j) "controlling officer" means the officer designated under MDR 2017;

(k) "custom made medical device" means a medical device made specifically in accordance with a written prescription of a registered medical practitioner, specialised in the relevant area, under his responsibility for the sole use of a particular patient, but does not include a mass production of such device;

(l) "intended use" means the use for which the medical device is intended according to the data supplied by the manufacturer on the labelling or in the document containing instructions for use of such device or in promotional material relating to such device, which is as per approval obtained from the Central Licensing Authority;

(m) "invasive device" means a device which, in whole or part, penetrates inside the body, either through a body orifice or through the surface of the body;

(n) "investigational medical device" in relation to a medical device, other than *in vitro* diagnostic medical device, means a medical device -

(i) which does not have its predicate device as defined in clause (z); or

(ii) which is licenced under MDR 2017 and claims for new intended use or new population or new material or major design change;

and is being assessed for safety or performance or effectiveness in a clinical investigation.

(o) "licence" means a licence granted by the State Licensing Authority or the Central Licensing Authority in FormMD-5, Form MD-6, Form MD-9, Form MD-10, Form MD-15, Form MD-17 or Form MD-19 as the case maybe;

(p) "long term use" means intended continuous use of a medical device for more than thirty days;

(q) "medical device grouping" means a set of devices having same or similar intended uses or commonality of technology allowing them to be classified in a group not reflecting specific characteristics;

(r) "Medical Device Officer" means an officer appointed or designated by the Central Government or the State Government, as the case may be, under MDR 2017;

(s) "medical devices testing laboratory" means any institute, organisation registered under MDR 2017 for carrying out testing or evaluation of any medical device on behalf of a licencee for manufacture for sale;

(t) "Medical Device Testing Officer" means an officer appointed or designated by the Central Government under MDR 2017;

(u) "new *in vitro* diagnostic medical device" means any medical device used for *in vitro* diagnosis that has not been approved for manufacture for sale or for import by the Central Licensing Authority and is being tested to establish its performance for relevant analyte or other parameter related thereto including details of technology and procedure required;

(v) "notified" means notified in the Official Gazette by the Central Government.

(w) "Notified Body" means a body corporate or other legal entity, registered under MDR 2017 as a body competent to carry out the audit of manufacturing site, assessment, and verification of specified category of medical devices for establishing conformity with standards;

(x) "performance evaluation" in relation to *in vitro* diagnostic medical device means any systematic investigation by which data is assessed and analysed to establish or verify performance of the *in vitro* diagnostic medical device for its intended use;

(y) "Post Marketing Surveillance" means systematic process to collect and analyse information gained from medical device that have been placed in the market;

(z) "predicate device" means a device, first time and first of its kind, approved for manufacture for sale or for import by the Central Licensing Authority and has the similar intended use, material of construction, and design characteristics as the device which is proposed for licence in India;

(za) "Quality Management System" means requirements for manufacturing of medical devices as specified in the MDR 2017;

(zb) "reagent" means a chemical, biological or immunological component, solution or preparation intended by the manufacturer to be used as *in vitro* diagnostic medical device;

(zc) "recall" means any action taken by its manufacturer or authorised agent or supplier to remove the medical device from the market or to retrieve the medical device from any person to whom it has been supplied, because the medical device,—

(i) is hazardous to health; or

(ii) fails to conform to any claim made by its manufacturer relating to its quality, safety or efficacy; or

(iii) does not meet the requirements of the Act and these rules;

(zd) "serious adverse event" means an untoward medical occurrence that leads to,—

(i) a death; or

(ii) a serious deterioration in the health of the subject that either-

(a) resulted in a life-threatening illness or injury; or

(b) resulted in a permanent impairment of a body structure or a body function; or

(c) required in-patient hospitalisation or prolongation of existing hospitalization; or

(d) resulted in medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function; or

(iii) foetal distress, foetal death or a congenital abnormality or birth defect;

(ze) "short term use" means intended continuous use of a medical device for not less than sixty minutes but not more than thirty days;

(zf) "specimen receptacle" means a device, whether vacuum type or not, specifically intended by its manufacturer for the primary containment of specimens derived from human or animal body;

(zg) "sponsor" includes a person, an investigator, a company or an institution or an organisation responsible for the initiation and management of a clinical investigation or clinical performance evaluation in India;

(zh) "State Licensing Authority" means the authority designated by the State Government under MDR 2017;

(zi) "transient use" means a device intended for continuous use for less than sixty minutes;

(zj) "transmissible agent", for the purpose of classification of in vitro diagnostic medical device, means an agent capable of being transmitted to a person, which causes communicable, infectious or contagious disease.

Words and expressions used but not defined in these rules, shall have the meanings respectively assigned to the min the Act and the Drugs and Cosmetics Rules, 1945.

1.4 What is a Medical Device?

There are as many different definitions for a medical device as there are regulatory and standards organisations. Though the definitions may differ in verbiage, they have a common thread of content. As per the Gazette of India notification G.S.R. 78(E), dated 31st January 2017, a **Medical device** means –

(A) substances used for *in vitro* diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i) [all medicine for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals including preparations applied on human body for the purpose of repelling insects like mosquitoes]

(B) Substances including mechanical contraceptives (condoms, intrauterine devices, and tubal rings), disinfectants and insecticides notified in the Official Gazette under sub-clause (ii) [such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermins or insects which cause disease or disorder in human beings or animals, as may be specified from time to time by the central government],

(C) Devices notified from time to time under sub-clause (iv) [such devices intended for internal or external use in the diagnostics, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government], of clause (b) of section 3 of the Act;

1.5 Regulation of Medical devices in India

The Central Drugs Standard Control Organization (CDSCO) under Directorate General of Health Services in Ministry of Health and Family Welfare (MoHFW), Government of India (GoI) is the National Regulatory Authority (NRA) responsible for approval of manufacturing, import, conduct of clinical trials, laying down standards, sale and distribution of medical devices through

enforcement and implementation of the Medical Devices Rules, 2017 released through Gazette of India notification G.S.R. 78(E), dated 31st January 2017 by the MoHFW, GoI.

The Medical Devices Rules, 2017 contains rules on the following:

Chapter	Chapter Title
I	Preliminary
II	Regulation of Medical Device
III	Authorities, Officers, and Bodies
IV	Import of Medical Devices
V	Labelling of Medical Devices
VI	Clinical Investigation of Medical Device and Clinical Performance Evaluation of new In Vitro Diagnostic Medical Device
VII	Import or Manufacture Medical Device Which Does not Have Predicate Device
VIII	Registration of Laboratory for Carrying out Test or Evaluation
IX	Sale of Medical Devices
X	Miscellaneous

The NRA is intended to ensure a high level of protection of public health and safety. As NRA, CDSCO has the responsibility to conduct Materiovigilance programme of India (MvPI). Indian Pharmacopoeia Commission functions as National Coordination Centre (NCC) for MvPI. Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram, shall act as National Collaborating Centre; National Health System Resource Centre (NHSRC), New Delhi, shall act as Technical support partner, and Central Drugs Standards Control Organisation (CDSCO), New Delhi, shall continue to function as regulator.

Materiovigilance Programme of India (MvPI) is meant to enable safety data collection in a systematic manner so that regulatory decisions and recommendations on safe use of medical devices being used in India could be based on data generated here. The programme is meant to monitor medical device-associated adverse events (MDAE), create awareness among healthcare

professionals about the importance of MDAE reporting in India and to monitor the benefit-risk profile of medical devices. It is also meant to generate independent, evidence-based recommendations on the safety of medical devices and to communicate the findings to all key stakeholders.

1.6 Roles and Responsibilities

1.6.1 Central Licensing Authority

The Drugs Controller General of India (DCGI) shall be the Central Licensing Authority, competent for the enforcement of these rules in matters relating to,-

- import of all Classes of medical devices;
- manufacture of Class C and Class D medical devices;
- clinical investigation and approval of investigational medical devices;
- clinical performance evaluation and approval of new *in vitro* diagnostic medical devices and;
- co-ordination with the State Licensing Authorities.

1.6.2 State Licensing Authority

The State Drugs Controller, by whatever name called, shall be the State Licensing Authority and shall be the competent authority for enforcement of these rules in matters relating to,-

- manufacture for sale or distribution of Class A or Class B medical devices;
- sale, stock, exhibit or offer for sale or distribution of medical devices of all classes.

*** Delegation of powers of Licensing Authorities**

(1) The Central Licensing Authority, may with the prior approval of the Central Government, by an order in writing, delegate all or any of its powers to any other officer of the Central Drugs Standard Control Organisation not below the rank of Assistant Drugs Controller.

(2) The officer to whom the powers have been delegated under sub-rule (1) shall exercise the powers of the Central Licensing Authority under its name and seal.

(3) The State Licensing Authority, may, with the prior approval of the State Government, by an order in writing, delegate all or any of its powers to any officer under its control.

(4) The officer to whom the powers have been delegated under sub-rule (3) shall exercise the powers of the State Licensing Authority under its name and seal.

1.6.3 National Accreditation Body

(1) The Central Government may, by notification, designate such institute, firm or a Government aided or Government organisation, which fulfills the criteria specified from time to time by the Government, as the National Accreditation Body:

Provided that the National Accreditation Board for Certification Bodies under the Quality Council of India, registered under the Societies Registration Act, 1860 (21 of 1860) set up by the Ministry of Commerce and Industry in the Government of India shall act as the National Accreditation Body for the purposes of accrediting Notified Bodies referred to in MDR 2017, till such time any other body for the purpose is notified, with immediate effect.

(2) The National Accreditation Body shall have the required number of competent persons for proper performance of its functions.

(3)The designated National Accreditation Body referred to in sub-rule (1) shall be responsible for carrying out the assessment of such entities who may apply for accreditation to become a Notified Body for the purpose of these rules.

(4) The National Accreditation Body referred to in sub-rule (1), shall, after carrying out the assessment of the entity which applied for accreditation, issue a certificate to such entity in respect of specified categories of standards for which such entity has been assessed and found qualified:

Provided that where the entity has been found not possessing the requisite qualification and other requirements, the National Accreditation Body, shall reject the application.

(5) The National Accreditation Body shall not act as a Notified Body.

Functions of National Accreditation Body:

The National Accreditation Body shall,-

(a) lay down the conformity assessment activities for accreditation of Notified Bodies and lay down standards for such accreditation;

(b) prepare norms and procedures for accreditation of Notified Body;

(c) audit a Notified Body periodically for assessing conformance with these rules and the norms laid down by it.

1.6.4 Notified body

(1) Any institute, organisation or body corporate may seek accreditation, after notification of these rules, as a Notified Body by applying to the National Accreditation Body in such form and manner as may be determined by the National Accreditation Body from time to time.

(2) The Notified Body accredited under sub-rule (1) shall be competent to carry out audit of manufacturing sites of Class A and Class B medical devices to verify conformance with the Quality Management System and other applicable standards as specified under these rules in respect of such medical devices as and when so advised by the State Licensing Authority.

(3) Any Notified Body accredited under sub-rule (1) shall, if it intends to carry out audit of a manufacturing site of Class A or Class B of medical devices in accordance with sub-rule (2), register with the Central Licensing Authority.

(4) Any Notified Body under sub-rule (3), with an experience of at least two years, may apply to the Central Licensing Authority for registration as a Notified Body for carrying out audit of Class C and Class D medical devices, provided it has personnel with requisite qualification and experience.

(5) With effect from the 1st day of the July, 2017, the Notified Body accredited in accordance with sub-rule (3) may make an application to the Central Licensing Authority for registration in Form MD-1 through online portal accompanied with a fee specified in the Second Schedule along with documents as specified in Part I of the Third Schedule.

(6) The Central Licensing Authority, on being satisfied, shall register the Notified Body and issue a registration certificate in Form MD-2.

(7) The Registration Certificate shall remain valid in perpetuity, unless, it is suspended or cancelled, provided the registration certificate holder deposits a registration retention fee as specified in the Second Schedule every five years from the date of its issue.

(8) If the registration certificate holder fails to pay the required registration certificate retention fee on or before due date as referred to in sub-rule (7), the registration certificate holder shall, in addition to the retention fee, be liable to pay a late fee calculated at the rate of two per cent. of the registration certificate retention fee for every month or part thereof within ninety days, and in the event of non-payment of such fee during that period, the registration certificate shall be deemed to have been cancelled.

(9) The Notified Body shall perform the functions as specified in Part II of the Third Schedule.

(10) The Central Licensing Authority, may, in cases where the requirement specified for registration of Notified Body have not been complied with, reject the application and shall inform the applicant of the reasons for such rejection.

(11) An applicant who is aggrieved by the decision of the Central Licensing Authority under sub-rule (10), may file an appeal within forty five days from the date of receipt of such rejection before the Central Government, which may after such enquiry and after giving an opportunity of being heard to the appellant, dispose of the appeal within a period of sixty days.

Documents to be furnished along with application in Form MD-1 for grant of certificate of registration

1. A Notified Body shall furnish duly signed copy of the following documents to the Central Licensing Authority.

(i) Constitution details of the Notified Body;

(ii) Brief profile of the organization and business profile related to audit of medical device manufacturing sites;

(iii) Accreditation Certificate issued by the National Accreditation Body referred to in the rule 11.

(iv) Quality manual of the organization;

(v) List of all Standard Operating Procedures;

(vi) List of all technical personnel including any outside experts along with their qualification, experience and responsibilities.

2. Undertaking to be submitted stating that the,-

(i) Notified body including its directors, executives and personnel responsible for carrying out evaluation and verification activities shall not be the designer, manufacturer, supplier or installer of devices within the product category for which the body has been designated, nor the authorised representative of any of those parties.

(ii) Directors, executives and personnel responsible for carrying out evaluation and verification activities shall be independent of both the manufacturers for whom the notified body conducts assessments and the commercial competitors of those manufacturers, during their employment by the notified body for the product range it is notified for.

(iii) Notified body personnel shall not be involved in consultancy activities relating to devices in question, their manufacturing control or test procedures, or their manufacturer.

Duties and functions of Notified Body

1. Duties:

1. Notified body shall perform the audit of manufacturer who applied under sub-rule (1) of rule 13. The specific application shall be allotted to the notified body by the State Licensing Authority through the portal of the Central Government. The audit shall relevant to domestic manufacturing site of Class A or Class B medical devices.

2. The notified body shall have standard operating procedure for identification, review and resolution of all cases where conflict of interest is suspected or proven. Record of such review and decision shall be maintained.

2. Functions:

A notified body shall,-

(i) impart training to its staff covering all the evaluation and verification operations for which the notified body has been designated;

(ii) ensure that staff has adequate knowledge and experience of the requirement of the control;

(iii) carry out the evaluation and verification operations with the highest degree of professional integrity independently with technical competence;

(iv) ensure that manufacturing site and products comply with prescribed standards referred in rule 7;

(v) not provide training or consultancy to the manufacturers whose site is being audited;

(vi) ensure that their auditors possess required qualification and expertise in the relevant field for carrying out assessments of manufacturing site and medical device that they are undertaking;

(vii) establish and maintain procedure and record which demonstrate its compliance with quality management system.

The notified bodies registered with CDSCO under provisions Medical Devices Rules, 2017 to carry out audit of manufacturing site under the provisions of said rules.

In this connection, following Notified Bodies have been registered with CDSCO:

1. **M/s Intertek India Pvt. Ltd.**
   E-20, Block B1, Mohan Cooperative, Industrial Area
   New Delhi (India) - 110044
   Telephone No.: 011-41595475, 9310412823
   Fax: 011-41595460
   E-Mail: kamal.gupta@intertek.com

2. **M/s TUV Rheinland India Pvt. Ltd.**
   82/A West Wing, 3rd Main Road 82/A West Wing,
   3rd Main Road Electronic City (India) - 560100
   Telephone No.: 080- 46498030
   Fax: 08046498042
   E-Mail: guruprasad.hc@ind.tuv.com

3. **M/s TUV Sud South Asia Pvt. Ltd.**
   TUV SUD House, Off Saki Vihar Road, Saki Naka
   Andheri (East), Mumbai-400072.
   Telephone No.: 022-49035508
   Fax: 022-49035508
   E-mail: info@tuv-sud.in

1.6.5 Central medical device testing laboratory

As per the Medical Devices Rule, 2017,

(1) the Central Government may, by notification, establish Central medical devices testing laboratory for the purpose of,—

(a) testing and evaluation of medical devices; or

(b) functioning as an appellate laboratory; or

(c) to carry out any other function as may be specifically assigned to it.

(2) Without prejudice to MDR 2017, the Central Government may also designate any laboratory having facility for carrying out test and evaluation of medical devices as central medical devices testing laboratory for the purposes specified in MDR 2017:

Provided that no medical devices testing laboratory, shall be so designated unless it has been duly accredited by the National Accreditation Body for Testing and Calibration Laboratories.

Government of India have designated the laboratories specified in column (2) of the Table below having facilities for carrying out test and evaluation of medical devices, as Central Medical Device Testing Laboratory for the purposes of -

(a) testing and evaluation;

(b) functioning as an appellate laboratory; and

(c) to carry out any other function as may be specifically assigned to it by the Central Government, in relation to the medical devices specified in column (3) of the said Table.

Serial Number	**Name of Laboratory**	**Category of Medical Device**
(1)	**(2)**	**(3)**
(1)	The National Institute of Biologicals, Noida	In-Vitro Diagnostics for human Immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus, Blood Grouping sera, Glucose Test Strip, Fully Automated Analyser Based Glucose Reagent
(2)	The Central Drugs Testing laboratory, Chennai	Condoms

(3)	The Central Drugs Laboratory, Kolkata	Surgical Dressings, Surgical Cotton, Surgical Bandages, Disinfectant
(4)	The Regional Drugs Testing Laboratory (RDTL), Guwahati	Disposable Hypodermic Syringes, Disposable Hypodermic Needle, Disposable Perfusion Sets, I.V. Cannulae
(5)	The Central Drugs Testing Laboratory, Mumbai	Intra Uterine Devices (IUD) and Falope Rings

1.6.6 Manufacturer of a medical device

1. The manufacturer of a medical device is the person who is responsible for the design, production, packaging and labelling of the device before it is supplied under the person's name, whether or not it is the person, or another person acting on the person's behalf, who carries out those operations.

2. If subsection (1) does not apply to a medical device, the manufacturer of the device is the person who, with a view to supplying the device under the person's name, does one or more of the following using readymade products:

- assembles the device;
- packages the device;
- processes the device;
- fully refurbishes the device;
- labels the device;
- assigns to the device its purpose by means of information supplied, by the person, on or in any one or more of the following:
  - the labelling on the device;
  - the instructions for using the device;
  - any advertising material relating to the device;
  - technical documentation describing the mechanism of the device.

3. However, a person is not the manufacturer of a medical device if:

- the person assembles or adapts the device for an individual patient; and
- the device has already been supplied by another person; and

- the assembly or adaptation does not change the purpose intended for the device by means of information supplied by that other person, on or in any one or more of the following:
  - the labelling on the device;
  - the instructions for using the device;
  - any advertising material relating to the device.
  - technical documentation describing the mechanism of action of the device

4. A person is not the manufacturer of a medical device if the person is included in a class of persons prescribed by the regulations for the purposes of this subsection.

Responsibilities of a medical device manufacturer

Manufacturers must:

- for each medical device, determine the:
  - classification
  - intended purpose
  - appropriate Medical Device Nomenclature code
- select and apply appropriate conformity assessment procedures to demonstrate compliance with the Essential Principles
- ensure that they have appropriate processes in place and documentation to demonstrate this before they apply to the CDSCO or an Notified Body for conformity assessment evidence
- obtain the conformity assessment evidence and ensure the information on the certificate remains current and valid
- pay the application and assessment fees for obtaining the conformity assessment evidence
- prepare an Indian Declaration of Conformity that includes all the manufacturing details for the medical devices
- ensure that their conformity assessment procedures are appropriately maintained once they obtain the necessary conformity assessment evidence, and that the ongoing requirements are met (for example, reporting adverse events, regular quality systems audits)

- notify the CDSCO of substantial changes to the design, production or intended performance of the device.
- The legislation requires that the CDSCO must be notified in writing by the appropriate legal representative, within 3 months of the event occurring, if the manufacturer:
  - dies
  - is declared bankrupt
  - is a body corporate that is wound up

2. Classification of medical devices

2.1 Classification of medical devices & *in vitro* diagnostic medical devices

2.1.1 Medical devices other than *in vitro* diagnostic medical devices

Medical devices other than *in-vitro* diagnostic medical devices shall be classified on the basis of parameters specified in section A below, in the following classes, namely:

(i) Low risk - Class A;
(ii) Low moderate risk- Class B;
(iii) Moderate high risk- Class C;
(iv) High risk- Class D.

2.1.2 *In vitro* diagnostic medical devices

In-vitro diagnostic medical devices shall be classified on the basis of parameters specified in section B below, in the following classes, namely:—

(i) Low risk - Class A;
(ii) Low moderate risk- Class B;
(iii) Moderate high risk- Class C;
(iv) High risk- Class D.

2.2 Classification based on the intended use of the device and other parameters

Classification of medical devices other than *in vitro* diagnostic medical devices

Basic Principles for classification:

- Application of the classification provisions shall be governed by the intended purpose of the device.
- If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.
- Software, which drives a device or influences the use of a device, falls automatically in the same class.
- If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use.

- If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply.

Parameter for classification of medical devices

(Refer to figure 1-5)

Non-invasive medical devices which come into contact with injured skin

(a) A non-invasive medical device which comes into contact with injured skin shall be assigned to Class A, if it is intended to be used as a mechanical barrier, for compression or for absorption of exudates only, for wounds which have not breached the dermis and can heal by primary intention;

(b) Subject to clause (c), a non-invasive medical device which comes into contact with injured skin shall be assigned to Class B, if it is intended to be used principally with wounds which have breached the dermis, or is principally intended for the management of the microenvironment of a wound;

(c) A non-invasive medical device which comes into contact with injured skin shall be assigned to Class C, if it is intended to be used principally with wounds which have breached the dermis and cannot heal by primary intention.

Non-invasive medical devices for channeling or storing substances

(a) Subject to clauses (b) and (c), a non-invasive medical device shall be assigned to Class A, if it is intended for channeling or storing body liquids or tissues or liquids or gases for the purpose of eventual infusion, administration or introduction into a human body;

(b) A non-invasive medical device referred to in clause (a) shall be assigned to Class B, if it is intended to be connected to an active medical device which is in Class B, C or D or for channeling blood or storing or channeling other body liquids or storing organs, parts of organs or body tissues.

Provided, that the circumstances when a non-invasive medical device is connected to an active medical device include circumstances where the safety and performance of the active medical device is influenced by the non-invasive medical device, or vice versa; or

(c) A non-invasive medical device referred to in clause (a) shall be assigned to Class C, if it is a blood bag that does not incorporate a medicinal product.

Non-invasive medical devices for modifying compositions of substances

(a) Subject to clause (b), a non-invasive medical device shall be assigned to Class C, if it is intended for modifying the biological or the chemical composition of blood or other body liquids or other liquids intended for infusion into the body.

(b) A non-invasive medical device as referred to in clause (a) shall be assigned to Class B, if the intended modification is carried out by filtration, centrifuging or any exchange of gas or of heat.

Other non-invasive medical devices

A non-invasive medical device to which sub-paragraphs (i), (ii) and (iii) do not apply shall be assigned to Class A, if it does not come into contact with a person or comes into contact with intact skin only.

Invasive (body orifice) medical devices for transient use

(a) Subject to clause (b), an invasive (body orifice) medical device shall be assigned to Class A, if,-

- it is intended for transient use; and
- it is not intended to be connected to an active medical device; or
- it is intended to be connected to a Class A medical device only.

(b) An invasive (body orifice) medical device referred to in clause (a) shall be assigned to Class B, if,-

- it is intended for use on the external surface of an eyeball; or
- it is liable to be absorbed by the mucous membrane.

Invasive (body orifice) medical devices for short term use

(a) Subject to clause (b), an invasive (body orifice) medical device shall be assigned to Class B, if,-

- It is intended for short term use; and
- It is not intended to be connected to an active medical device; or
- It is intended to be connected to a Class A medical device only.

(b) An invasive (body orifice) medical device referred to in clause (a) shall be assigned to Class A, if,-

- It is intended for use in an oral cavity as far as the pharynx or in an ear canal up to the ear drum or in a nasal cavity; and
- It is not liable to be absorbed by the mucous membrane.

Invasive (body orifice) medical devices for long term use

(a) Subject to clause (b), an invasive (body orifice) medical device shall be assigned to Class C, if it is intended for long term use and, not intended to be connected to an active medical device or it is to be connected to a Class A medical device only.

(b) An invasive (body orifice) medical device referred to in clause (a) shall be assigned to Class B, if,-

- it is intended for use in an oral cavity as far as the pharynx or in an ear canal up to the ear drum or in a nasal cavity; and
- it is not liable to be absorbed by the mucous membrane.

Invasive (body orifice) medical devices for connection to active medical devices

An invasive (body orifice) medical device shall be assigned to Class B, regardless of the duration of its use, if it is intended to be connected to an active medical device which is in Class B, C or D.

Surgically invasive medical devices for transient use

(a) Subject to clauses (b) to (g), a surgically invasive medical device intended for transient use shall be assigned to Class B.

(b) Subject to clauses (c) to (g), a transient use surgically invasive medical device shall be assigned to Class A, if it is a reusable surgical instrument.

(c) A transient use surgically invasive medical device shall be assigned to the same class as the active medical device to which it is intended to be connected.

(d) A transient use surgically invasive medical device shall be assigned to Class C, if it is intended for the supply of energy in the form of ionising radiation.

(e) A transient use surgically invasive medical device shall be assigned to Class C, if it is intended to have a biological effect or to be wholly or mainly absorbed by the human body.

(f) A transient use surgically invasive medical device shall be assigned to Class C, if it is intended for the administration of any medicinal product by means of a delivery system and such administration is done in a manner that is potentially hazardous.

(g) A transient use surgically invasive medical device shall be assigned to Class D, if it is intended to be used specifically in direct contact with the central nervous system or for the diagnosis, monitoring or correction of a defect of the heart or of the central circulatory system through direct contact with these parts of the body.

Surgically invasive medical devices for short term use

(a) Subject to clause (b), (d) and (e), a surgically invasive medical device intended for short term use shall be assigned to Class B. (b) Subject to clause (c), a short term use surgically invasive medical device shall be assigned to Class C, if it is intended to undergo a chemical change in the body.

(c) A short term use surgically invasive medical device referred to in clause (b) shall be assigned to Class B, if it is intended to be placed into any tooth.
(d) A short term use surgically invasive medical device shall be assigned to Class C, if it is intended for the administration of any medicinal product or the supply of energy in the form of ionising radiation.

(e) A short term use surgically invasive medical device shall be assigned to Class D, if it is intended to have a biological effect or to be wholly or mainly absorbed by the human body or to be used specifically in direct contact with the central nervous system or for the diagnosis, monitoring or correction of a defect of the heart or of the central circulatory system through direct contact with these parts of the body.

Implantable medical devices and surgically invasive medical devices for long term use

(a) Subject to clauses (b), (c) and (d), an implantable medical device or a surgically invasive medical device intended for long term use shall be assigned to Class C.

(b) A long term use medical device shall be assigned to Class B, if it is intended to be placed into any tooth.

(c) A long term use medical device shall be assigned to Class D, if it is intended,-

- to be used in direct contact with the heart, the central circulatory system or the central nervous system;
- to be life supporting or life sustaining;
- to be an active medical device;
- to be wholly or mainly absorbed by the human body;
- for the administration of any medicinal product; or
- to be a breast implant.

(d) Subject to clause (b), a long term use medical device shall be assigned to Class D, if it is intended to undergo chemical change in the body.

Active therapeutic medical devices for administering or exchanging energy

(a) Subject to clause (b), an active therapeutic medical device shall be assigned to Class B, if it is intended for the administration or exchange of energy to or with a human body.

(b) An active therapeutic medical device referred to in (a) shall be assigned to Class C, if the administration or exchange of energy may be done in a potentially hazardous way (such as through the emission of ionising radiation), taking into account the nature, density and site of application of the energy and the type of technology involved.

(c) An active therapeutic medical device shall be assigned to Class C, if it is intended for the control or monitoring, or to be used to directly influence the performance, of a Class C active therapeutic device.

Active diagnostic medical devices

(a) Subject to clauses (b) and (c), an active diagnostic medical device shall be assigned to Class B, if it is intended,-
- to be used to supply energy which will be absorbed by the human body;
- to be used to capture any image of the *in vivo* distribution of radiopharmaceuticals; or
- for the direct diagnosis or monitoring of vital physiological processes.

(b) An active diagnostic medical device referred to in sub-clause (1) of clause (a) shall be assigned to Class A, if it is intended to be used solely to illuminate a patient's body with light in the visible or near infrared spectrum.

(c) An active diagnostic medical device referred to in clause (a) shall be assigned to Class C, if it is intended specifically for,-

- the monitoring of vital physiological parameters, where the nature of any variation is such that it could result in immediate danger to the patient (such as any variation in cardiac performance, respiration or activity of the central nervous system); or
- diagnosing in a clinical situation where the patient is in immediate danger.

(d) An active diagnostic medical device shall be assigned to Class C, if it is intended for the emission of ionising radiation and to be used in diagnostic or interventional radiology.

(e) An active diagnostic medical device shall be assigned to Class C, if it is intended for the control or monitoring, or to be used to directly influence the performance, of any active diagnostic medical device referred to in clause (d).

(f) Subject to clause (g), an active medical device shall be assigned to Class B, if it is intended for the administration, or removal of, any medicinal product, body liquid or other substance to or from a human body.

(g) An active medical device referred to in clause (f) shall be assigned to Class C, if the administration or removal of the medicinal product, body liquid or other substance is done in a manner that is potentially hazardous, taking into account,

- the nature of the medicinal product, body liquid or substance;
- the part of the body concerned; and
- the mode and route of the administration or removal.

Other active medical devices

An active medical device to which provisions of sub-paragraphs (xii) and (xiii) do not apply shall be assigned to Class A.

Medical devices incorporating medicinal products

(a) Subject to clause (b), a medical device shall be assigned to Class D, if it incorporates as an integral part a substance which,-

- if used separately, may be considered to be a medicinal product; and
- is liable to act on a human body with an action ancillary to that of the medical device.

(b) A medical device referred to in clause (a) shall be assigned to Class B, if the incorporated substance is a medicinal product exempted from the licensing requirements of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made there under.

Medical devices incorporating animal or human cells, tissues or derivatives

(a) Subject to clause (b), a medical device shall be assigned to Class D, if it is manufactured from or incorporates-

- Cells, tissues or derivatives of cells or tissues, or any combination thereof, of animal or human origin, which are or have been rendered non-viable; or
- Cells, tissues or derivatives of cells or tissues, or any combination thereof, of microbial or recombinant origin.

(b) A medical device referred to in clause (a) shall be assigned to Class A, if it is manufactured from or incorporates non-viable animal tissues, or their derivatives, that come in contact with intact skin only.

Medical devices for sterilization or disinfection

(a) Subject to clause (b), a medical device shall be assigned to Class C, if it is intended to be used specifically for,-

- the sterilization of any other medical device;
- the end-point disinfection of any other medical device; or
- the disinfection, cleaning, rinsing or hydration of contact lenses.

(b) A medical device shall be assigned to Class B, if it is intended for the disinfection of any other medical device before the latter is sterilized or undergoes end-point disinfection:

Provided, that "end-point disinfection" means the disinfection of a medical device immediately before its use by or on a patient.

Medical devices for contraceptive use

(a) Subject to clause (b), a medical device intended to be used for contraception or the prevention of the transmission of any sexually transmitted disease shall be assigned to Class C.

(b) A medical device referred to in clause (a) shall be assigned to Class D, if it is an implantable medical device or an invasive medical device intended for long term use.

Classification for *in vitro* diagnostic medical devices

1. Basic principles for classification of *in vitro* diagnostic medical devices:

(a) Application of the classification provisions shall be governed by the intended purpose of the devices.

(b) If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.

(c) Software, which drives a device or influences the use of a device, falls automatically in the same class.

(d) Standalone software, which are not incorporated into the medical device itself and provide an analysis based on the results from the analyser, shall be classified in to the same category that of the *in vitro* diagnostic medical device where it controls or influences the intended output of a separate *in vitro* diagnostic medical device.

(e) Subject to the clause (c) and (d), software that is not incorporated in an *in vitro* diagnostic medical device, shall be classified using the classification provisions as specified in paragraph

(f) Calibrators intended to be used with a reagent should be treated in the same class as the *in vitro* diagnostic medical device reagent.

(g) If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the stringent rules resulting in the higher classification shall apply.

2. The parameters for classification of *in vitro* diagnostic medical devices as follows:-

(i) *In vitro* diagnostic medical devices for detecting transmissible agents, etc.:

(a) An *in vitro* diagnostic medical device shall be assigned to Class D, if it is intended to be used for detecting the presence of, or exposure to, a transmissible agent that,-

(1) is in any blood, blood component, blood derivative, cell, tissue or organ, in order to assess the suitability of the blood, blood component, blood derivative, cell, tissue or organ, as the case may be, for transfusion or transplantation; or

(2) causes a life-threatening disease with a high risk of propagation.

(b) An *in vitro* diagnostic medical device shall be assigned to Class C, if it is intended for use in,-

(1) detecting the presence of, or exposure to, a sexually transmitted agent;

(2) detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation (*for example, Cryptococcus neoformans* or *Neisseria meningitidis*);

(3) detecting the presence of an infectious agent, where there is a significant risk that an erroneous result will cause death or severe disability to the individual or foetus being tested (*for example,* a diagnostic assay for *Chlamydia pneumoniae*, *Cytomegalovirus* or Methicillin-resistant *Staphylococcus aureus*)

(4) pre-natal screening of women in order to determine their immune status towards transmissible agents such as immune status tests for *Rubella* or *Toxoplasmosis*;

(5) determining infective disease status or immune status, 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 being tested (*for example, Cytomegalovirus, Enterovirus* or *Herpes simplex virus* in transplant patients);

(6) screening for disease stages, for the selection of patients for selective therapy and management, or in the diagnosis of cancer;

(7) human genetic testing, such as the testing for cystic fibrosis or Huntington's disease;

(8) monitoring levels of medicinal products, substances or biological components, where 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 being tested (*for example,* cardiac markers, cyclosporin or prothrombin time testing);

(9) management of patients suffering from a life-threatening infectious disease such as viral load of *Human immunodeficiency virus* or *Hepatitis C virus*, or genotyping and sub-typing *Hepatitis C virus* or *Human immunodeficiency virus);or*

(10) screening for congenital disorders in the foetus such as Down’s syndrome or spina bifida.

(ii) *In vitro* diagnostic medical devices for blood grouping or tissue typing:

(a) Subject to clause (b), an *in vitro* diagnostic medical device shall be assigned to Class C, if

it is intended to be used for blood grouping or tissue typing to ensure the immunological compatibility of any blood, blood component, blood derivative, cell, tissue or organ that is intended for transfusion or transplantation, as the case may be.

(b) An *in vitro* diagnostic medical device referred to in clause (a) shall be assigned to Class D, if it is intended to be used for blood grouping or tissue typing according to the ABO system, the, the Duffy system, the Kell system, the Kidd system, the rhesus system (*for example*, HLA, Anti-Duffy, Anti-Kidd).

(iii) *In vitro* diagnostic medical devices for self-testing:

(a) Subject to clause (b), an *in vitro* diagnostic medical device shall be assigned to Class C, if it is intended to be used for self-testing.

(b) An *in vitro* diagnostic medical device referred to in clause (a) shall be assigned to Class B, if it is intended to be used to obtain,-

- test results that are not for the determination of a medically-critical status; or
- preliminary test results which require confirmation by appropriate laboratory tests.

***(iv) In vitro* diagnostic medical devices for near-patient testing:**

An *in vitro* diagnostic medical device shall be assigned to Class C, if it is to be used for near-patient testing in a blood gas analysis or a blood glucose determination.

Illustration: Anticoagulant monitoring, diabetes management, and testing for C-reactive protein and Helicobacter pylori.

(v) *In vitro* diagnostic medical devices used in *in vitro* diagnostic procedures:
An *in vitro* diagnostic medical device shall be assigned to Class A:

- if it is a reagent or an article which possesses any specific characteristic that is intended by its product owner to make it suitable for an *in vitro* diagnostic procedure related to a specific examination;
- an instrument intended specifically to be used for an *in vitro* diagnostic procedure; or
- a specimen receptacle.

(vi) Other *in vitro* diagnostic medical devices:

(a) An *in vitro* diagnostic medical device shall be assigned to Class B, if sub-paragraphs (i) to (v) of paragraph 2 do not apply to it; or

(b) It is a substance or device used for the assessment of the performance of an analytical procedure or a part thereof, without a quantitative or qualitative assigned value.

2.3 Class wise list of medical devices:

(A) List of Medical Devices other than *In vitro* Medical Devices under provisions of sub-rule (1) rule 4 of the medical devices rules 2017

S. No.	Notified Device Category/Drug	Device Name	Risk Class	General/Intended Use
1.	Ablation Device	Vein Ablation Device	Class C	It is a non-thermal, minimally invasive choice for treating the source of varicose veins, providing patients with immediate recovery and a return to normal daily routines.
2.	Ablation Device	Thermal Ablation Device	Class C	Destruction of tissue by application of heat. Ablation of the endometrium as a treatment for menorrhagia is performed by placing a balloon filled with hot water in the uterine cavity.
3.	Ablation Device	Radiofrequency Ablation Device	Class D	A medical procedure in which part of the electrical conduction system of the heart, tumour or other dysfunctional tissue is ablated using the heat generated from high frequency alternating current.
4.	Ablation Device	Percutaneous Conduction Tissue Ablation	Class D	Clinical applications using hollow needles (cryoprobes) through which cooled, thermally conductive, fluids are circulated.
5.	Ablation Device	Suction Ablation Catheter System	Class D	Intended for use in inactivating Portions of the heart's conduction system to prevent abnormal heartbeat rates, comprises a tubular body having an open, distal end and a proximal aperture for applying suction through the catheter and through the distal end.
6.	Ablation Device	Uterine balloon therapy devices	Class C	System is a closed-cycle cryosurgical device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive bleeding) due to benign causes for whom childbearing is complete.
7.	Ablation Device	RF Conducte MR steerable electrode catheter	Class C	It is intended for intracardiac ablation.
8.	Bone Cements	Bone cement	Class C	Intended for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

9.	Cardiac Stents	Coronary stent	Class D	A coronary stent is a tube-shaped device placed in the coronary arteries that supply blood to the heart, to keep the arteries open in the treatment of coronary heart disease.
10.	Cardiac Stents	Bioresorbable Vascular Scaffold (BVS) System	Class D	An absorbable stent which is placed into a blood vessel (coronary artery) during angioplasty to help keep the coronary artery open.
11.	Cardiac Stents	Bifurcation Stent	Class C	Intended for improving the side branch luminal diameter of arterial bifurcation liaisons.
12.	Catheters	Fiberoptic Oximeter Catheter	Class B	Intended for monitoring the balance between oxygen delivery and consumption at the bedside.
13.	Catheters	A-V Shunt or Fistula Adapter	Class B	A blood access device and accessories is a device intended to provide access to a patient's blood for haemodialysis or other chronic uses.
14.	Catheters	Transcervical (Aminoscope) Endoscope and accessories	Class B	It is a device designed to permit direct viewing of the foetus and amniotic sac by means of an open tube introduced into the uterus through the cervix.
15.	Catheters	Forceps, endoscopic	Class B	Grasping Forceps device is intended to be used to grasp tissue, retrieve foreign bodies, and remove tissue from within the gastrointestinal tract.
16.	Catheters	Transabdominal (Fetoscope) Aminoscope and Accessories	Class C	It is a device designed to permit direct visual examination of the foetus by a telescopic system via abdominal entry. The device is used to ascertain foetal abnormalities.
17.	Catheters	Anaesthetic Conduction Kit	Class C	An anaesthesia conduction kit is a device used to administer to a patient conduction, regional, or local anaesthesia. The device may contain syringes, needles, and drugs.
18.	Catheters	Angiographic Guide Wire	Class D	It delivers radio opaque media and therapeutic agents to selected sites in the vascular system. It is also used to lead a guide wire or a catheter into the target site.
19.	Catheters	Cardiac Catherization Kit	Class D	Cardiac catheterization is a general term for a group of procedures that are performed using this method, such as coronary angiography and left ventricle angiography.
20.	Catheters	Vena Cava Filter Sets	Class C	It is indicated for the prevention of recurrent pulmonary embolism via placement in the vena cava to treat

				various disease conditions.
21.	Catheters	Vessel Dialator for percutaneous Catheterization	Class B	A vessel dilator for percutaneous catheterization is a device which is placed over the guide wire to enlarge the opening in the vessel, and which is then removed before sliding the catheter over the guide wire.
22.	Catheters	Tracheobronchial Suction Catheter	Class B	Clearing the airways of mucus, pus, or aspirated materials to improve oxygenation and ventilation
23.	Catheters	Cervical Drain	Class B	The device is used to avoid postoperative wound and respiratory complications such as excessive edema, hematoma, infection, reintubation, delayed extubation, or respiratory distress
24.	Catheters	Rectal Balloon	Class B	Reducing the intrafraction motion and improving the sparing of rectal wall by reducing the rectal volume in the high dose region, resulting in significant reduction in rectal toxicity.
25.	Catheters	Balloon for Cerebrovascular Occlusion	Class D	Balloon used to treat Blockage or closing of Cerebrovascular vessels/carotid arteries.
26.	Catheters	Intra-Aortic System Balloon and Control	Class D	It is a mechanical device that increases myocardial oxygen perfusion while at the same time increasing cardiac output.
27.	Catheters	Biliary Stone Retrieval Basket	Class B	Intend to extract stones in an antegrade fashion through an ampullary orifice previously treated by endoscopic sphincterotomy or less commonly with balloon dilation.
28.	Catheters	Tracheostomy Tube/Tracheal Tube	Class B	A breathing tube inserted into a tracheotomy used to obtain a closed circuit for ventilation.
29.	Catheters	Vial Adapter	Class B	It is indicated to allow multiple needleless access to injection medication vials for transfer or withdrawal of fluids from the vial.
30.	Catheters	Suprapubic, non-disposable Cannula	Class B	an emergency measure for the relief of acute urinary retention or condition which require temporary and permanent drainage of bladder.
31.	Catheters	Nasopharyngeal Catheter/Nasopharyngeal	Class A	A catheter (for adults) passed through the nares and advanced to the depth of the nasopharynx to remove air choke or obstruction. A Resuscitator.
32.	Catheters	Esophageal obturator	Class B	Inserted through a patient's mouth to aid ventilation of the patient during emergency resuscitation by occluding

				(blocking) the esophagus, thereby permitting positive pressure ventilation through the trachea.
33.	Catheters	Balloon Catheter for Retinal Reattachment	Class B	An instrument for reattachment of a detached retina to the inner wall of the eyeball. It can be inserted into the interior of the eyeball.
34.	Catheters	Gastric, Colonic etc. Irrigation and Aspiration Catheter	Class B	Used for instilling fluids into, withdrawing fluids from, splinting, or suppressing bleeding of the alimentary tract.
35.	Catheters	Suction Tip and Catheter	Class B	Suction Catheters feature a whistle tip and a thumb control port for precise and accurate suctioning.
36.	Catheters	Angiographic Catheter	Class B	Designed to provide a pathway for delivering contrast media to selected Catheter sites in the device vascular system including the carotid arteries.
37.	Catheters	Arterial Catheter	Class B	Intended to be used in conjunction with steerable guide wires in order to access discrete regions of the coronary and peripheral arterial vasculature.
38.	Catheters	Balloon Type Catheter	Class B	"Soft" catheter with an inflatable "balloon" at its tip which is used during a catheterization procedure to enlarge a narrow opening or passage within the body.
39.	Catheters	Balloon Dialation Vessel Catheter	Class B	Intended for use in Percutaneous Transluminal Angioplasty of the renal, tibial, popliteal, femoral and peroneal arteries. These catheters are not for use in coronary arteries.
40.	Catheters	Bartholin Gland Catheter	Class B	Catheter is used for the treatment of abscesses and cysts of the Bartholin gland.
41.	Catheters	Bronchography Catheter	Class B	Intended to deliver therapeutic and diagnostic agents that are indicated or labelled for airway and tracheal procedures.
42.	Catheters	Cholangiography Catheter	Class B	Diagnostic evaluation of the bile ducts during laparoscopic cholecystectomy procedures.
43.	Catheters	Anesthetic Conduction Catheter	Class B	An anesthesia conduction catheter is a flexible tubular device used to inject local anesthetics into a patient and to provide continuous regional anesthesia.
44.	Catheters	Anesthesia conduction filter	Class C	A microporous filter used while administering to a patient injections of local anesthetics to minimize particulate

				(foreign material) contamination of the injected fluid
45.	Catheters	Continuous Flush Catheter	Class B	Intended for the controlled and selective infusion of liquids for the purpose of eliminating clotting, back-leakage, and waveform damping.
46.	Catheters	Continuous Irrigation Catheter	Class B	Intended to be used to introduce fluids into body cavities other than blood vessels, drain fluids from body cavities, or evaluate certain physiologic conditions.
47.	Catheters	Coude Catheters	Class B	It is a urinary catheter, It may be used to inject liquids used for treatment or diagnosis of bladder conditions.
48.	Catheters	Depezzer Catheter	Class B	A tubular, flexible instrument, passed through body channels for withdrawal of fluids from a body cavity.
49.	Catheters	Double lumen Female Urethrographic Catheter	Class B	Intended for vascular access infusion and withdrawal of blood, blood products, and fluids, plasma pheresis, hyperalimentation, central venous blood sampling and continuous and intermittent drag infusion.
50.	Catheters	Epidural Catheter	Class B	Epidural catheter is a very thin, flexible tube that is implanted into spine.
51.	Catheters	Esophageal Balloon Catheter	Class B	intended for use in adult and adolescent populations.
52.	Catheters	Eustachian Catheter	Class B	It is used to test Eustachian tube patency.
53.	Catheters	Guiding Catheter	Class B	The guide catheter provides support for device advancement.
54.	Catheters	Haemodialysis Catheter	Class B	A catheter used for exchanging blood to and from the haemodialysis machine from the patient.
55.	Catheters	Central Venous Catheters	Class C	It is indicated for use in patients requiring administration of solutions, blood sampling, central venous pressure monitoring and injection of contrast media.
56.	Catheters	Intramuscular Pressure Monitoring Catheter	Class B	A modified fibre optic transducer-tipped catheter system for measuring intramuscular pressure during exercise was determined.
57.	Catheters	Introducer Sheath	Class C	Intended to provide easier access to the femoral, popliteal and infrapopliteal arteries.
58.	Catheters	Intravenous Catheter	Class B	A catheter that is inserted into a vein for supplying medications or nutrients directly into the bloodstream or for diagnostic purposes such as studying

				blood pressure.
59.	Catheters	Jejunostomy Catheter	Class B	Used for intraoperative feeding jejunostomy.
60.	Catheters	Multiple Lumen Catheter	Class B	Intended for monitoring central venous pressure (CVP), sampling blood, and simultaneous administration of multiple IV solutions or drugs.
61.	Catheters	Nasal Oxygen Catheter	Class B	It is a device used to deliver supplemental oxygen or increased airflow to a patient or person in need of respiratory help.
62.	Catheters	Embolic Filter system	Class D	It is indicated for general use as a guidewire and embolic protection system during angioplasty and stenting procedures in carotid arteries with reference vessel diameters of 2.5 to 5.5mm.
63.	Catheters	Carotid Filter System	Class C	Used while performing angioplasty and stenting procedures in carotid arteries.
64.	Catheters	RETRIEVAL SNARE	Class D	intended for use in the retrieval and manipulation of atraumatic foreign bodies located in the coronary and peripheral system and the extracranial neurovascular anatomy.
65.	Catheters	RETRIEVAL SNARE	Class D	intended for use in the retrieval and manipulation of atraumatic foreign bodies located in the coronary and peripheral system and the extracranial neurovascular anatomy.
66.	Catheters	Nephrostomy Catheter	Class B	A nephrostomy is a tube that's used to drain urine from a kidney into a bag outside the body
67.	Catheters	Peritoneal Dialysis Catheter	Class B	That allows dialysis fluid to enter the abdominal cavity, dwell inside for a while, and then drain back out again.
68.	Catheters	Radiographic (Non Vascular) Catheter	Class B	Interventional radiologists obtain images using needles and narrow tubes called catheters, rather than by making large incisions into the body as in traditional surgery.
69.	Catheters	Rectal Catheter	Class B	It is inserted into the rectum in order to relieve flatulence which has been chronic and which has not been alleviated by other methods.
70.	Catheters	Retention Type Catheter	Class B	This type of catheter is placed into the bladder and secured there for a period of time.
71.	Catheters	Retention Type Balloon Catheter	Class B	It has a balloon at the distal end, which is inflated with sterile water or saline to prevent the catheter from slipping out of

				the bladder.
72.	Catheters	Salpngography Catheter	Class B	Used for injection of contrast medium into the fallopian tube(s) for selective salpingography.
73.	Catheters	Single Needle Hemodialysis Catheter/Blood lines	Class B	The single-needle dialysis, in which case only one cannula or a single lumen catheter is used to access the blood.
74.	Catheters	Straight Catheter	Class B	It is used in patients with neurogenic bladder or spinal cord injury, lessens the risk of urinary tract infection.
75.	Catheters	Subclavian Catheter	Class B	Catheters can be placed in veins in the neck (internal jugular vein), chest (subclavian vein or auxiliary vein).
76.	Catheters	Suprapubic Catheter	Class B	A suprapubic catheter is a thin, sterile tube used to drain urine from bladder.
77.	Catheters	Umblical Artery Catheter	Class B	Umbilical artery catheterization provides direct access to the arterial blood supply and allows accurate measurement of arterial blood pressure, a source of arterial blood sampling, and intravascular access for fluids and medications.
78.	Catheters	Upper Urinary Tract Catheter	Class B	The catheter to the bladder and subsequently to the upper urinary tract.
79.	Catheters	Urethral Catheter/Nelaton Catheter/ Foley Catheter	Class B	A long, small gauge catheter designed for insertion directly into a ureter, either through the urethra and bladder or posteriorly via the kidney.
80.	Catheters	Urethrographic Male Catheter	Class B	A catheter used to pass into a man's bladder.
81.	Catheters	Chorionic Villus Sampling Catheter	Class B	An ultrasound guides a thin catheter through the cervix to your placenta. The chorionic villi cells are gently suctioned into the catheter.
82.	Catheters	Sclerotherapy Needle/ Catheter	Class B	Sclerotherapy Needles are designed to provide access for injection therapy applications and may also be used for polypectomy and endoscopic mucosal resection (EMR).
83.	Catheters	Water Jet Renal Catheter	Class B	A device used to dislodge stones from renal calyces (recesses of the pelvis of the kidney) by means of a pressurized stream of water through a conduit.
84.	Catheters	Hemodialysis Catheter (Long Term)	Class C	A dialysis catheter is a catheter used for exchanging blood to and from the hemodialysis machine from the patient. The dialysis catheter contains two lumens: Venous, Arterial.
85.	Catheters	Percuataneous	Class C	The device allows for repeated access to

		Intravascular Long Term Catheter		the vascular system for long-term use of 30 days or more, and it is intended for administration of fluids, medications, and nutrients; the sampling of blood.
86.	Catheters	Percutaneous Long Term Intraspinal Catheter	Class C	To conduct a preimplantintra spinal infusion screening trial procedure prior to implanting a pump.
87.	Catheters	Implanted Subcutaneous Intravascular Port & Catheter	Class C	The device allows for repeated access to the vascular system for the infusion of fluids and medications and the sampling of blood.
88.	Catheters	Subcutaneous Intraspinal Port & Catheter	Class C	Catheters used for both epidural Intrathecal infusion include short-term externalized catheters and long-term Catheter catheters that are tunnelled in the Subcutaneous tissue.
89.	Catheters	Peripheral, Transluminal Angioplasty Catheter	Class C	A catheter for treating peripheral vascular diseases.
90.	Catheters	Cardiac Thermo dilution Catheter	Class D	A catheter used in thermodilution for introduction of the cold liquid indicator into the cardiovascular system or for the assessment of a patient's hemodynamic condition through simultaneous right atrial, right ventricular, and pulmonary artery or wedge pressure monitoring, cardiac output determination, and for infusing solutions.
91.	Catheters	Cardiovascular Catheter	Class D	A thin, hollow tube called a catheter is inserted into a large blood vessel that leads to heart.
92.	Catheters	Cerebrospinal Catheter	Class D	For treatment or prevention of cranial/spinal cerebrospinal fluid fistula.
93.	Catheters	Atherectomy Coronary Catheter	Class D	A catheter containing a rotating cutter and a collecting chamber for debris, used for atherectomy and endarterectomy.
94.	Catheters	Electrode Recording Probe Electrode Recording Catheter	Class D	A cardiac catheter containing one or more electrodes; it may be used to pace the heart or to deliver high energy shocks.
95.	Catheters	Oximetry catheters, Oximetry Paceport catheter	Class B	It is indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination, continuous mixed venous oxygen saturation monitoring, and for infusing solutions.
96.	Catheters	Embolectomy	Class D	Indicated for the removal of fresh, soft

		Catheter		emboli.
97.	Catheters	Flow Directed Catheter	Class B	Used for venous sampling and catheter pressure monitoring.
98.	Catheters	Ultrasonic imaging Catheter	Class B	Intended for ultrasound examination of Catheter peripheral pathology only.
99.	Catheters	Intraaortic Balloon Catheter	Class D	It is indicated for use in patients undergoing cardiopulmonary bypass.
100.	Catheters	Intracardiac Mapping, High Density Array Catheter	Class D	A high density array catheter once used in the right atrium to map and diagnosis complex arrhythmias and assess the effectiveness of ablation treatment.
101.	Catheters	Coronary Dilation Catheter	Class C	It is intended for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.
102.	Catheters	Intravascular Occluding Catheter	Class D	It is a catheter with an inflatable or detachable balloon tip that is used to block a blood vessel to treat malformations, e.g., aneurysms of intracranial blood vessels.
103.	Catheters	Intravascular Diagnostic Catheter	Class D	Used to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels.
104.	Catheters	Occlusion Catheter	Class D	Insertion of a device or develop at any time during the course of intravenous (IV) therapy.
105.	Catheters	Percutaneous Catheter	Class D	A needle catheter getting access to a blood vessel, followed by the introduction of a wire through the lumen (pathway) of the needle.
106.	Catheters	Diagnostic Radiology Catheters	Class C	Angiography catheters are designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures.
107.	Catheters	Perfusion Catheter	Class D	Perfusion catheter allowing localised perfusion of drugs not only into the vessel lumen, but also directly into the vessel wall at low pressure, during coronary intervention.
108.	Catheters	Pericardium Drainage Catheter	Class D	Catheter drainage of the pericardium.
109.	Catheters	Atherectomy Peripheral Catheter	Class D	Intended for use in atherectomy of the Peripheral vasculature.
110.	Catheters	Septostomy Catheter	Class D	Used to enlarge interatrial openings.
111.	Catheters	Thrombectomy	Class D	Thrombectomy catheter is specifically

		Catheter		designed to treat deep vein thrombosis (DVT) in large-diameter upper and lower peripheral veins.
112.	Catheters	Transluminal Coronary Angioplasty Percutaneous Catheter	Class D	The catheter is placed in the opening or ostium of one the coronary arteries.
113.	Catheters	Ventrricular Catheter	Class C	It is used to monitor pressure in patients with brain injuries, intracranial bleeds or other brain abnormalities that lead to increased fluid build-up.
114.	Catheters	Balloon Repair Kit Catheter	Class C	A device used to repair or replace the balloon of a balloon catheter. The kit contains the materials, such as glue and balloons, necessary to affect the repair or replacement.
115.	Catheters	Micro-catheter	Class C	It is intended to access the peripheral and neurovasculature for the controlled selective infusion of physician specified therapeutic agents such as embolization materials and or diagnostic materials such as contrast media.
116.	Catheters	Imaging Catheter	Class C	Intended for use with the various medical imaging consoles.
117.	Catheters	Central Nervous System Shunt including Neurological catheters and other Components	Class D	It is a device or combination of devices used to divert fluid from the brain or other part of the central nervous system to an internal delivery site or an external receptacle for the purpose of relieving elevated intracranial pressure or fluid volume.
118.	Catheters	Endoscopic Ligation Devices	Class B	It is used for proximal and distal ligation of vessels during endoscopic vessel harvesting procedures.
119.	Catheters	Dialysate Tubing and Connector	Class B	A tubing connector adapted for peritoneal dialysis connections between tubing sets and containers of dialysate.
120.	Catheters	Urinary Drainage Unit	Class B	A closed urinary drainage system consists of a catheter inserted into the Unit urinary bladder and connected via tubing to a drainage bag.
121.	Catheters	Tympanostomy Tube	Class C	It is a small tube inserted into the eardrum in order to keep the middle ear aerated for a prolonged period of time, and to prevent the accumulation of fluid in the middle ear.
122.	Catheters	In-Vitro Fertilization/Embry	Class B	A cellular transfer catheter is provided for implantation of cellular material into the

		o Transfer Catheter		uterus of a patient.
123.	Catheters	Sclerotherapy Needle/Catheter	Class B	It is designed to provide access for injection therapy applications and may also be used for polypectomy and endoscopy.
124.	Catheters	Fluid Delivery tubing	Class B	Tube used to deliver fluid in body.
125.	Catheters	Colon Tube	Class B	Colon Tubes also called "Tips" or even Catheters are inserted from the anus, through the rectum to deliver your enema solution into the colon (large intestine).
126.	Catheters	Connecting Tube	Class B	Used to provide connection to a drainage bag.
127.	Catheters	Decompression Tube	Class B	Decompression using a rectal tube may assist in the treatment only if the sigmoid colon is involved.
128.	Catheters	Double Lumen for intestinal Decompression and/or Intubation Tube	Class B	Tracheal intubation, usually simply referred to as intubation, is the placement of a flexible plastic tube into the trachea (windpipe) to maintain an open airway or to serve as a conduit through which to administer certain drugs.
129.	Catheters	Closed Wound Drainage Tube or System	Class B	A surgical drain is a tube used to remove pus, blood or other fluids from a wound. They are commonly placed by surgeons or interventional radiologists.
130.	Catheters	Oesophageal Blakemore Tube	Class B	It is a medical device inserted through the nose or mouth and used occasionally in the management of upper gastrointestinal hemorrhage due to oesophageal varices.
131.	Catheters	Oesophageal Sengtaken Tube	Class B	It is used only in emergencies where bleeding from presumed varies is impossible to control with medication alone.
132.	Catheters	Feeding Tube	Class B	A feeding tube is a device that's inserted into your stomach through your abdomen. It's used to supply nutrition when you have trouble eating.
133.	Catheters	Gastro-Enterostomy Tube	Class B	Tube is placed through the abdominal wall into the stomach and then through the duodenum into the jejunum.
134.	Catheters	Gastrointestinal Tube	Class B	A gastrostomy tube (also called a G- tube) is a tube inserted through the abdomen that delivers nutrition directly to the stomach.
135.	Catheters	Heart-Lung Bypass Unit Tube	Class B	A tube will be placed in your heart to drain blood to the machine

136.	Catheters	Levine Tube	Class B	Used for the aspiration of gastric and intestinal contents and administration of tube feedings or medications.
137.	Catheters	NasoGastric Tube/Ryles Tube	Class B	It is a special tube that carries food and medicine to the stomach through the nose. It can be used for all feedings or for giving a person extra calories.
138.	Catheters	Nephrostomy Tube	Class B	The nephrostomy tube drains urine from kidney into a collecting bag outside the body.
139.	Catheters	Orthodontic Tube	Class B	An orthodontic small metal part welded on the outside of a molar bank, which contains slots to hold archwires, lip bu mpers, facebows and other devices used to move the teeth.
140.	Catheters	Rectal Tube	Class B	A rectal tube, also called a rectal catheter, is a long slender tube which is inserted into the rectum in order to relieve flatulence.
141.	Catheters	Stomach Evaculator (Gastric Lavage) Tube	Class B	Passage of a tube via the mouth or nose down into the stomach followed by sequential administration and removal of small volumes of liquid.
142.	Catheters	Tonsil Suction Tube	Class B	Used to suck out stones in tonsils.
143.	Catheters	Tracheal (Endotracheal) Tube	Class B	Inserts the tube with the help of a laryngoscope, an instrument that Tube permits to see the upper portion of the trachea, just below the vocal cords.
144.	Catheters	Closed Suction System	Class B	It is intended for endotracheal suctioning to provide a patient airway by removing excess fluids, secretions, exudates and transudate through the artificial airway.
145.	Catheters	Anastomosis Bypass Tube	Class C	It is anchored to mucosa and submucosa 3 centimetres proximal to a site of colocolonic anastomosis and later spontaneously evacuated by way of the rectum.
146.	Catheters	Endolymphatic Shunt Tube	Class B	During a surgical procedure in which it is placed in the membranous labyrinth of the inner ear to drain excess fluid.
147.	Catheters	Orthodontic Guide Wire	Class B	A wire conforming to the alveolar or dental arch that can be used with dental Wire braces as a source of force in correcting irregularities in the position of the teeth.
148.	Catheters	Intra-aortic balloon and control system	Class D	It is a medical device which is placed in the aorta to improve cardiovascular functioning during certain life threatening

				emergencies.
149.	Catheters	Ventricular bypass (assistive)	Class D	A ventricular bypass (assistive) device is a device that assists the left or right (assistive) ventricle in maintaining circulatory blood flow.
150.	Catheters	Catheter Guide Wire	Class D	It is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The PTCA Guide Wires are not to be used in the cerebral blood vessel.
151.	Catheters	Catheter Guide Wire	Class D	It is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The PTCA Guide Wires are not to be used in the cerebral blood vessel.
152.	Catheters	Wire	Class C	An esophageal stent is a stent (tube) placed in the oesophagus to keep a blocked area open so the patient can swallow soft food and liquids.
153.	Catheters	Biliary stents	Class C	Biliary stents provide bile drainage from the gallbladder, pancreas and bile ducts to the duodenum in conditions such as ascending cholangitis due to obstructing gallstone.
154.	Catheters	Duodenal stents	Class C	Duodenal Stent is indicated for the palliative treatment of gastroduodenal obstructions.
155.	Catheters	Colonic stent	Class C	A colonic stent is a flexible, hollow tube designed to keep a segment of the colon (large bowel) open when it has become blocked (obstructed). This blockage is commonly caused by a tumour inside the bowel or by outside pressure on the bowel wall.
156.	Catheters	Pancreatic stent	Class C	Pancreatic duct stents are often placed in patients who have chronic pancreatitis.
157.	Catheters	Carotid Stent System	Class D	Indicated for the treatment of patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization.
158.	Catheters	Peripheral Stent System	Class C	A Peripheral stent is a tube-shaped device Placed in the peripheral arteries that supply blood into body organ.
159.	Contraceptives	Tubal Rings/ Fallopian Rings	Class C	Contraception devices for female sterilization.

160.	Contraceptives	Male/Female Condoms	Class C	Condom with nonoxynol-9, micro-condom, prophylactic (condom) – latex sheath, non-latex, condoms with natural membrane, intra vaginal condoms etc.
161.	Contraceptives	Cu-T	Class D	Indicated for intrauterine contraception for up to 10 years.
162.	Disinfectants	Disinfectants	Class B	An agent that destroys pathogenic and other kinds of microorganisms by chemical or physical means. A disinfectant destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores. It is intended to disinfect a medical device.
163.	Disposable Hypodermic Needles	Aspiration Needle	Class B	Used for either laparoscopic aspiration or injection.
164.	Disposable Hypodermic Needles	Aspiration and Injection Needle	Class B	A thin needle is inserted into an area of abnormal-appearing tissue or body fluid. As with other types of biopsies, the sample collected during fine needle aspiration can help make a diagnosis or rule out conditions such as cancer.
165.	Disposable Hypodermic Needles	Insulin Needles /Pen Needles for insulin	Class B	Used to inject insulin for the treatment of diabetes.
166.	Disposable Hypodermic Needles	Medication Injector	Class B	A subcutaneous injection is a method of administering medication.
167.	Disposable Hypodermic Needles	Biopsy Needle Kit	Class B	A set of neurosurgical instruments designed to allow multiple biopsies from one or more targets in one trajectory.
168.	Disposable Hypodermic Needles	Angiographic Needle	Class B	Angiographic needle has a unique hub design with an ergonomic feel and a black triangle indicator to orient the bevel.
169.	Disposable Hypodermic Needles	Mammary Biopsy Needle	Class B	The growth sample is suctioned out through a needle or cut out using a surgical procedure.
170.	Disposable Hypodermic Needles	Blood Collecting Needle	Class B	Needle used to collect blood through syringe.
171.	Disposable Hypodermic Needles	Bone Marrow Needle	Class B	Needle inserted in Bone Marrow to collect sample.
172.	Disposable Hypodermic Needles	Gynaecological Cerclage Needle	Class B	It is a loop like instrument used to suture the cervix.
173.	Disposable Hypodermic	Cholangiography Needle	Class B	The aspirating needle is passed through the patient's skin and liver tissue until the

	Needles			tip penetrates one of the hepatic ducts.
174.	Disposable Hypodermic Needles	Anaesthetic Conduction Needle	Class B	An anaesthesia conduction needle is a device used to inject local anaesthetics into a patient to provide regional anaesthesia.
175.	Disposable Hypodermic Needles	Emergency Airway Needle	Class B	Emergency airway puncture is the placement of a hollow needle through the throat into the airway. It is done to treat life-threatening choking.
176.	Disposable Hypodermic Needles	Endoscopic Needle	Class B	Used to sample targeted submucosal gastrointestinal lesions through the accessory channel of an ultrasound endoscope.
177.	Disposable Hypodermic Needles	Fistula Needle	Class B	To connect blood lines with the blood vessels through needles when dialysis is carried out.
178.	Disposable Hypodermic Needles	Epidural Needle	Class B	Intended for transient delivery of anasthetics to provide regional anesthesia or to facilitate placement of an epidural catheter.
179.	Disposable Hypodermic Needles	Gastro-Urology Needle	Class B	Intended for gastroenterology biopsy.
180.	Disposable Hypodermic Needles	Single Lumen Hypodermic Needle	Class B	A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.
181.	Disposable Hypodermic Needles	Neurosurgical Suture Needle	Class B	A needle used in suturing during neurosurgical procedures or in the repair of nervous tissue.
182.	Disposable Hypodermic Needles	Oocyte Aspiration Needle	Class B	Mission to collect the maximum amount of undamaged oocytes in a short time as possible.
183.	Disposable Hypodermic Needles	Pneumoperitoneum Simple Needle	Class B	Inserting a Veress needle through the abdominal wall inside the peritoneal cavity.
184.	Disposable Hypodermic Needles	Prefillable Glass Barrel with needle	Class B	Intended for the automatic self administration of drugs and biologics from standard Glass Barrel.
185.	Disposable Hypodermic Syringes	Injector Type actuator syringe	Class C	A syringe actuator for an injector is an electrical device that controls the timing of an injection by an angiographic or indicator injector and synchronizes the injection with the electrocardiograph signal.
186.	Disposable Hypodermic Syringes	Aspiration Syringe	Class B	Used for either laparoscopic aspiration or injection

187.	Disposable Hypodermic Syringes	Irrigating Syringes	Class B	Cleaning debris away from the area the dentist is working on.
188.	Disposable Hypodermic Syringes	Insulin Syringes	Class B	Used to inject insulin for the treatment of diabetes.
189.	Disposable Hypodermic Syringes	Auto Disable Syringe for single use	Class B	Intend to inject fluids into or withdraw fluids from the body.
190.	Disposable Hypodermic Syringes	Traditional single use syringe without safety feature (Sterile hypodermic syringes for single use)	Class B	Intend to inject fluids into or withdraw fluids from the body.
191.	Disposable Hypodermic Syringes	Auto-disable (AD) syringes for immunization	Class B	Intend to inject fluids into or withdraw fluids from the body.
192.	Disposable Hypodermic Syringes	Re use Prevention (RUP) syringes for therapeutic injections (Syringes with re-use prevention feature)	Class B	Intend to inject fluids into or withdraw fluids from the body.
193.	Disposable Hypodermic Syringes	Sharps Injury Protection (SIP) Plastic needle shield to be added to a syringe	Class B	Intend to inject fluids into or withdraw fluids from the body.
194.	Disposable Perfusion Sets	Sharps Injury Blood Administration kits	Class B	It is used to administer blood from a container to a patient's vascular system through a needle or catheter inserted into a vein.
195.	Disposable Perfusion Sets	Measured Volume IV Set	Class B	It is intended for use in the administration of fluids from a container into the patient's vascular system through a vascular access device.
196.	Disposable Perfusion Sets	Transfusion or Perfusion sets for single use	Class B	Transfusion Set is used to administer blood/drugs to a patient's vascular system through a needle or catheter inserted into a vein.
197.	Disposable Perfusion Sets	Custom Perfusion System	Class C	Indicated for use in the extra corporeal circuit during cardio pulmonary bypass surgery procedure.
198.	Disposable Perfusion Sets	Manifolds	Class B	Indicated for fluid flow directional control and for providing access port/ports for administration of a solution.

199.	Disposable Perfusion Sets	3 way stop cock as an accessory to perfusion sets	Class B	It is indicated for fluid flow directional control and for providing access port for administration of solution, withdrawal of fluid and pressure monitoring.
200.	Disposable Perfusion Sets	Y-Connector as an accessory to perfusion sets	Class A	It can be used to connect to a perfusion sets or catheter for infusion of contrast media etc.
201.	Disposable Perfusion Sets	I V Flow regulator	Class B	An IV system and administration device offering precision care and consistent delivery.
202.	Disposable Perfusion Sets	Extension Sets	Class B	Extension sets are sterile devices for single use only. They are intended to be used as part of a system for the infusion of fluids/medications in medical applications.
203.	Disposable Perfusion Sets	Infusion Pump or Elastomeric Infusion Device	Class C	The Infusion Pumps intended for slow, continuous delivery through clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), and subcutaneous or epidural infusion of medications directly into an intra-operative site or subcutaneously for post operative pain management.
204.	Drug Eluting Stents	Drug eluting stent	Class D	Stent, coronary, drug-eluting - a metal scaffold with a drug coating placed via a delivery catheter into the coronary artery or saphenous vein graft to maintain the lumen. The drug coating is intended to inhibit restenosis.
205.	Heart Valves	Heart valve	Class D	A device intended to perform the function of any of the heart's natural valves.
206.	Internal Prosthetic Replacements	Tissue Expanders	Class C	Intended to be used in breast reconstruction or treatment of soft tissue deformities such as used following mastectomy or for treatment of underdeveloped breasts
207.	Internal Prosthetic Replacements	Bio Patches	Class C	Intended for reconstruction and repair of defects of pericardium.
208.	Internal Prosthetic Replacements	Vascular graft/occluders/Cardiac Patches	Class D	Intended to repair, replace, or bypass sections of native or artificial vessels, excluding coronary or cerebral vasculature, and to provide vascular access.
209.	Internal Prosthetic Replacements	Vascular embolizationdevice	Class D	It is an intravascular implant intended to control hemorrhaging due to, certain types of tumors.
210.	Internal	Voice / laryngeal	Class C	The device is intended to direct

	Prosthetic Replacements	Prothesis		pulmonary air flow to the pharynx in the absence of the larynx, for permitting esophageal speech.
211.	Internal Prosthetic Replacements	Cardiovascular prosthetic devices	Class D	An intra-cardiac patch or pledgete which is a medical device placed in the heart and is used to repair septal defects, for patch grafting, to repair tissue, and to buttress sutures.
212.	Internal Prosthetic Replacements	Hearing Prosthesis System	Class C	The prostheses are intended for partial ossicular replacement to restore functionality to the middle ear.
213.	Internal Prosthetic Replacements	Annuloplasty ring	Class C	An annuloplasty ring implanted around the mitral or tricuspid heart valve for reconstructive treatment.
214.	Internal Prosthetic Replacements	Total ossicular replacement prosthesis	Class D	It is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear.
215.	Internal Prosthetic Replacements	Ear, nose, and throat and facial synthetic polymer material or implant	Class C	It is a device material that is intended to be implanted for use as a space-occupying substance in the reconstructive surgery of the head and neck.
216.	Internal Prosthetic Replacements	Mandibular implant facial prosthesis	Class C	Intended to be implanted for use in the functional reconstruction of mandibular deficits.
217.	Internal Prosthetic Replacements	Sacculotomy tack (Cody tack)	Class C	Intended to be implanted to relieve the symptoms of vertigo.
218.	Internal Prosthetic Replacements	Endolymphatic shunt	Class C	Intended to be implanted to relieve the symptoms of vertigo.
219.	Internal Prosthetic Replacements	An endolymphatic shunt tube with valve	Class C	It is a device that consists of a pressure-limiting valve associated with a tube intended to be implanted in the inner ear to relieve symptoms of vertigo and hearing loss.
220.	Internal Prosthetic Replacements	Fallopian tube prosthesis	Class C	A device designed to maintain the patency (openness) of the fallopian tube and is used after reconstructive surgery.
221.	Internal Prosthetic Replacements	Vaginal stent	Class C	A device used to enlarge the vagina by stretching, or to support the vagina and to hold a skin graft after reconstructive surgery.
222.	Internal Prosthetic Replacements	Eye sphere implant	Class D	An eye sphere implant is a device intended to be implanted in the eyeball to occupy space following the removal of the contents of the eyeball with the sclera

				left intact.
223.	Internal Prosthetic Replacements	Keratoprosthesis	Class D	It is a device intended to provide a transparent optical pathway through an opacified cornea, either intraoperatively or permanently, in an eye.
224.	Internal Prosthetic Replacements	Bone heterograft	Class D	Intended to be implanted that is made from bovine bones and used to replace human bone following surgery in the cervical region of the spinal column.
225.	Internal Prosthetic Replacements	Intramedullary fixation rod	Class C	Intended to be implanted into the medullary (bone marrow) canal of long bones for the fixation of fractures.
226.	Internal Prosthetic Replacements	Endosseous dental implant	Class C	Intended to be surgically placed in the bone of jaw arches to provide support for prosthetic devices, such as artificial teeth.
227.	Internal Prosthetic Replacements	Dental implant	Class C	A dental implant is a surgical component that interfaces with the bone of the jaw or skull to support a dental prosthesis such as crown, bridge, denture, facial prosthesis or to act as an orthodontic anchor.
228.	Internal Prosthetic Replacements	Bone grafting material	Class C	Intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.
229.	Internal Prosthetic Replacements	Total temporomandibular joint prosthesis	Class D	Intended to be implanted in the human jaw to replace the mandibular condyle and augment the glenoid fossa to functionally reconstruct the temporomandibular joint.
230.	Internal Prosthetic Replacements	Glenoid fossa prosthesis	Class D	Intended to be implanted in the temporomandibular joint to augment a glenoid fossa or to provide an articulation surface for the head of a mandibular condyle.
231.	Internal Prosthetic Replacements	Mandibular condyle prosthesis	Class D	Intended to be implanted in the human jaw to replace the mandibular condyle and to articulate within a glenoid fossa.
232.	Internal Prosthetic Replacements	An interarticular disc prosthesis	Class D	Intended to be an interface between the natural articulating surface of the mandibular condyle and glenoid fossa.
233.	Internal Prosthetic Replacements	Penile inflatable implant	Class D	A penile inflatable implant is a device which is implanted in the penis, connected to a reservoir filled with radiopaque fluid implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum. This device is used in the treatment of erectile impotence.
234.	Internal Prosthetic	Penile rigidity implant	Class C	A device that is implanted in the corpora cavernosa of the penis to provide rigidity.

	Replacements			It is intended to be used in men diagnosed as having erectile dysfunction.
235.	Internal Prosthetic Replacements	Artificial Urinary Sphincters implants	Class C	It is used to prevent incontinence by occluding the urethra.
236.	Internal Prosthetic Replacements	Implanted mechanical/ hydraulic urinary continence device	Class C	An implanted mechanical/hydraulic urinary continence device is a device used to treat urinary incontinence by the application of continuous or intermittent pressure to occlude the urethra.
237.	Internal Prosthetic Replacements	Cochlear implant	Class D	A cochlear implant is an implanted electronic hearing device, designed to produce useful hearing sensations to a person with severe to profound nerve deafness by electrically stimulating nerves inside the inner ear.
238.	Internal Prosthetic Replacements	Retinal implant	Class D	The retinal implant is meant to partially restore useful vision to people who have lost their vision due to degenerative eye conditions.
239.	Internal Prosthetic Replacements	Breast implant	Class C	Breast implant is used to increase the breast size.
240.	Internal Prosthetic Replacements	Tracheal prosthesis	Class C	It is intended to be implanted to restore the structure and/or function of the trachea or tracheal bronchial tree.
241.	Internal Prosthetic Replacements	Polymeric Surgical Mesh	Class C	The polymeric mesh comprises an absorbable polymeric fibre and a non-absorbable polymeric fibre knitted together to form an interdependent, co-knit mesh structure.
242.	Internal Prosthetic Replacements	Endosseous dental implant abutment	Class C	Intended for use as an aid in prosthetic rehabilitation.
243.	Internal Prosthetic Replacements	A testicular prosthesis	Class D	A testicular prosthesis is an implanted device that consists of a solid or gel-filled silicone rubber prosthesis that is implanted surgically to resemble a testicle.
244.	Internal Prosthetic Replacements	Aneurysm Implant (detachable coils/clips)	Class D	It is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.
245.	Intra Ocular Lenses	Intraocular lens	Class C	Intraocular lenses (IOL) are lens implanted in the eye used to treat cataracts or myopia.
246.	IV Cannulae	Intravenous Cannula	Class B	The IV Cannula is a passive device to provide for the infusion of fluids, drugs,

				and/or blood components, or to facilitate the placement of Vascular Access devices.
247.	IV Cannulae	Arterial Cannula	Class B	Inserted into an artery, commonly the radial artery, and is used during major operations and in critical care areas to measure beat-to-beat blood pressure and to draw repeated blood samples.
248.	IV Cannulae	Coronary Artery Cannula	Class B	Cannulation technique for left-sided coronary artery surgery.
249.	IV Cannulae	Hemodialysis Cannula	Class B	Allowing the arterial blood to flow to the dialyzer and the dialyzed blood to return from the dialyzer to the circulation through the cannula in the vein.
250.	IV Cannulae	Vena Cava Cannula	Class B	Inserted into Vena Cava, taking deoxygenated blood to heart.
251.	IV Cannulae	Venous Cannula	Class B	It is intended for use as a single cannula for both venous drainage and reinfusion of blood via an internal jugular vein during extracorporeal life support procedures.
252.	IV Cannulae	Ventricular Cannula	Class B	For use in neurosurgical procedures. It is specially designed to penetrate delicate brain tissue and give continued access to brain's ventricular system.
253.	IV Cannulae	A-V Shunt Cannula	Class C	It is inserted into one of the client's blood vessels to facilitator repeated hemodialysis.
254.	IV Cannulae	Cannulact or Lymph Duct	Class B	A lymph duct is a great lymphatic vessel that empties lymph into one of the subclavian veins.
255.	Orthopaedic Implants	Intra Osseous Fixation Wire	Class C	Stabilization of fractured bony parts by direct fixation to one another with surgical wires.
256.	Orthopaedic Implants	Cortical Fixation Implant / rigidloop Adjustable Cortical Fixation System	Class C	Cortical Fixation System is a machined titanium implant designed to provide fixation in the repair of tendons and ligaments.
257.	Orthopaedic Implants	Intervertebral Body Fusion Device / Fuse Spinal System	Class C	It is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels.
258.	Orthopaedic Implants	Bone Wire	Class C	Intended to be used for bone stabilization in the hand and wrist.
259.	Orthopaedic Implants	Bone cap	Class C	Intended to be implanted to cover the end of a bone.
260.	Orthopaedic Implants	Orthopedic implant & accessories	Class C	Intended to replace a missing joint or bone or to support a damaged bone.

261.	Orthopaedic Implants	Intervertebral body fusion device	Class D	The device is inserted into the intervertebral body space of the cervical or lumbosacral spine, and is intended for intervertebral body fusion.
262.	Orthopaedic Implants	Pedicle screw spinal system	Class C	It is used to intend to provide immobilization and stabilization of spinal segments.
263.	Orthopaedic Implants	Ankle joint metal/composite semi-constrained cemented prosthesis	Class C	An ankle joint metal/composite semi-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint.
264.	Orthopaedic Implants	Ankle joint metal/polymer non-constrained cemented prosthesis	Class C	A device intended to be implanted to replace an ankle joint. The device limits minimally translation in one or more planes. It has no linkage across the-joint.
265.	Orthopaedic Implants	Elbow joint metal/polymer constrained cemented prosthesis	Class C	An elbow joint metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace an elbow joint.
266.	Orthopaedic Implants	Elbow joint metal/polymer semi-constrained cemented prosthesis	Class C	An elbow joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace an elbow joint.
267.	Orthopaedic Implants	elbow joint radial (hemi-elbow) polymer	Class C	An elbow joint radial (hemi-elbow) polymer prosthesis is a device intended to be implanted made of medical grade silicone elastomer used to replace the proximal end of the radius.
268.	Orthopaedic Implants	Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis	Class C	A device intended to be implanted made of alloys, such as cobalt-chromium-molybdenum, that is used to replace the distal end of the humerus formed by the trochlea humeri and the capitulumhumeri.
269.	Orthopaedic Implants	elbow joint humeral (hemi-elbow) metallic uncemented prosthesis	Class C	A device intended to be implanted made of alloys, such as cobalt-chromium-molybdenum, that is used to replace the distal end of the humerus formed by the trochlea humeri and the capitulumhumeri.
270.	Orthopaedic Implants	Finger joint metal/metal constrained	Class C	A device intended to be implanted toreplace a metacarpophalangeal or proximal interphalangeal (finger) joint.

		uncemented prosthesis		
271.	Orthopaedic Implants	Finger joint metal/metal constrained cemented prosthesis	Class C	A finger joint metal/metal constrained cemented prosthesis is a device intended to be implanted to replace a metacarpophalangeal (finger) joint.
272.	Orthopaedic Implants	Finger joint polymer constrained prosthesis	Class C	A device intended to be implanted toreplace a metacarpophalangeal or proximal interphalangeal (finger) joint.
273.	Orthopaedic Implants	hip joint metal constrained cemented or uncemented prosthesis	Class D	A hip joint metal constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint.
274.	Orthopaedic Implants	Hip joint metal/polymer constrained cemented or uncemented prosthesis	Class D	A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted toreplace a hip joint.
275.	Orthopaedic Implants	Hip joint metal/metal semi-constrained, with a cemented acetabular component prosthesis.	Class D	It is a prosthesis intended to be Implants implanted to replace a hip joint.
276.	Orthopaedic Implants	hip joint metal/metal semi-constrained with an uncemented acetabular component prosthesis	Class D	Intended to be implanted to replace a hip joint.
277.	Orthopaedic Implants	hip joint metal/composite semi-constrained cemented prosthesis	Class C	A hip joint metal/composite semi-constrained cemented prosthesis is a two-part device intended to be implanted to replace a hip joint.
278.	Orthopaedic Implants	Hip joint metal/ceramic/polymer semi constrained cemented or nonporous uncemented prosthesis	Class C	Intended to be implanted to replace a hip joint.

279.	Orthopaedic Implants	Hip joint metal/polymer/ metal semi-constrained porous-coated uncemented prosthesis.	Class C	Intended to be implanted to replace a hip joint.
280.	Orthopaedic Implants	A knee joint femorotibial metallic constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint	Class C	Intended to be implanted to replace part of a knee joint.
281.	Orthopaedic Implants	Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis	Class C	Intended to be implanted to replace a shoulder joint.
282.	Orthopaedic Implants	Wrist joint carpal lunate polymer prosthesis	Class C	Intended to be implanted to replace the carpal lunate bone of the wrist.
283.	Orthopaedic Implants	Wrist joint metal/polymer	Class C	Intended to be implanted to replace a wrist joint.
284.	Orthopaedic Implants	semi-constrained cemented prosthesis	Class C	Intended to be implanted to replace a wrist joint.
285.	Orthopaedic Implants	Wrist joint metal constrained cemented prosthesis	Class C	Intended to be implanted to replace a wrist joint.
286.	Orthopaedic Implants	Wrist joint carpal trapezium polymer prosthesis	Class C	Intended to be implanted to replace the carpal trapezium bone of the wrist.
287.	Orthopaedic Implants	Wrist joint carpal scaphoid polymer prosthesis	Class C	Intended to be implanted to replace the carpal scaphoid bone of the wrist.
288.	Orthopaedic Implants	Toe joint phalangeal (hemi toe) polymer prosthesis	Class C	Intended to be implanted to replace the base of the proximal phalanx of the toe.
289.	Orthopaedic Implants	Toe joint polymer constrained prosthesis	Class C	Intended to be implanted to replace the first metatarsophalangeal (big toe) joint.

290.	Orthopaedic Implants	Shoulder joint humeral (hemi shoulder) metallic uncemented prosthesis.	Class C	A shoulder joint humeral (hemishoulder) shoulder) metallic uncemented prosthesis.
291.	Orthopaedic Implants	Shoulder joint glenoid (hemi shoulder) metallic cemented prosthesis	Class C	It is intended to be implanted to replace part of a shoulder joint.
292.	Orthopaedic Implants	Shoulder joint metal/polymer/ metal nonconstrained or semi constrained porous-coated uncemented prosthesis	Class C	It is a device intended to be implanted to replace a shoulder joint.
293.	Orthopaedic Implants	Shoulder joint metal/polymer semi-constrained cemented prosthesis	Class C	Intended to be implanted to replace a shoulder joint.
294.	Orthopaedic Implants	shoulder joint metal/polymer non-constrained cemented prosthesis	Class C	Intended to be implanted to replace a shoulder joint.
295.	Orthopaedic Implants	Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint.
296.	Orthopaedic Implants	Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis	Class C	Intended to be implanted to replace the retropatellar articular surface of the patellofemoral joint.
297.	Orthopaedic Implants	knee joint femoral (hemi-knee) metallic uncemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint.
298.	Orthopaedic Implants	knee joint patellofemorotibial metal/polymer	Class C	Intended to be implanted to replace a knee joint.
299.	Orthopaedic	Knee joint	Class C	Intended to be implanted to replace a knee

	Implants	patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.		joint.
300.	Orthopaedic Implants	Knee joint patellofemorotibial polymer/metal/ metal constrained cemented prosthesis	Class C	Intended to be implanted to replace a knee joint.
301.	Orthopaedic Implants	knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis	Class C	It is intended to be implanted to replace part of a knee joint in the treatment of primary patellofemoral arthritis or chondromalacia.
302.	Orthopaedic Implants	Knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint.
303.	Orthopaedic Implants	Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint.
304.	Orthopaedic Implants	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint.
305.	Orthopaedic Implants	Knee joint femorotibial metal/polymer constrained cemented prosthesis	Class C	Knee joint femorotibial metal/polymer Constrained cemented prosthesis.
306.	Orthopaedic Implants	Knee joint femorotibial metal/polymer constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint.

307.	Orthopaedic Implants	Knee joint femorotibial metal/composite semi-constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint.
308.	Orthopaedic Implants	Knee joint femorotibial metal/composite non-constrained cemented prosthesis	Class C	Intended to be implanted to replace part of a knee joint.
309.	Orthopaedic Implants	Hip joint metal /polymer or ceramic /polymer semiconstrained resurfacing cemented prosthesis.	Class C	Intended to be implanted to replace the articulating surfaces of the hip while preserving the femoral head and neck.
310.	Orthopaedic Implants	Hip joint metal /metal semi-constrained with a cemented acetabular component prosthesis	Class D	Intended to be implanted to replace a hip joint.
311.	Orthopaedic Implants	Hip joint metal constrained cemented or uncemented prosthesis	Class D	Intended to be implanted to replace a hip joint.
312.	Orthopaedic Implants	Hip joint metal/polymer constrained cemented or uncemented	Class D	Intended to be implanted to replace a hip joint.
313.	Orthopaedic Implants	Hip joint femoral (hemi-hip) metallic resurfacing prosthesis	Class D	Intended to be implanted to replace a portion of the hip joint.
314.	Orthopaedic Implants	A hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis	Class D	Intended to be implanted to replace the head and neck of the femur.
315.	Orthopaedic Implants	A hip joint femoral (hemi-hip) trunnion-bearing	Class D	Intended to be implanted to replace the head and neck of the femur.

		metal/polyacetal cemented prosthesis		
316.	Orthopaedic Implants	Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis	Class D	Intended to be implanted to replace the head and neck of the femur.
317.	Orthopaedic Implants	A hip joint (hemi-hip) acetabular metal cemented prosthesis	Class D	Intended to be implanted to replace a portion of the hip joint.
318.	Orthopaedic Implants	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis	Class D	Intended to be implanted to replace a portion of the hip joint.
319.	Orthopaedic Implants	Plates, clippers Screws	Class C	Rigid, limb brace, lumbar, lumbo-sacral, rib fracture, sacroiliac, thoracic oethosis.
320.	Orthopaedic Implants	Spinal intervertebral body fixation orthosis	Class C	The device is used to apply force to a series of vertebrae to correct "sway back," scoliosis (lateral curvature of the spine), or other conditions.
321.	Orthopaedic Implants	Spinal interlaminal fixation orthosis	Class C	A device intended to be implanted made of an alloy that consists of various hooks and a posteriorly placed compression or distraction rod. The device is used primarily in the treatment of scoliosis.
322.	Orthopaedic Implants	Resorbable calcium salt bone void filler device	Class C	A resorbable calcium salt bone void filler device is a resorbable implant intended to fill bony voids or gaps of the extremities, spine, and pelvis.
323.	Orthopaedic Implants	Smooth or threaded metallic bone fixation fastener	Class C	It may be used for fixation of bone fractures, for bone reconstructions, as a guide pin for insertion of other implants, or it may be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system.
324.	Orthopaedic Implants	Sacroiliac joint fixation	Class C	The sacroiliac joints fixation may serve as protective mechanism for the lumbosacral region.
325.	Orthopaedic Implants	Cervical Artificial Disc	Class D	Cervical Artificial Disc is indicated for reconstruction of the disc.
326.	Scalp Vein Set	Scalp Vein Set	Class B	Intended to be used for insertion into the patient's vascular system (single use only) as an in-dwelling device to administer fluids intravenously or to sample blood.

327.	Surgical Dressings	Surgical Staples	Class B	Surgical staples are specialized staples used in surgery in place of sutures to close skin wounds, connect or remove parts of body during surgery.
328.	Surgical Dressings	Surgical Dressings	Class A	Dressing aerosol, non-adherent, dressing, periodontal, kit, dressing pad, dressing.
329.	Surgical Dressings	Surgical Dressings	Class B	Dressing-gel,dressing-permeable,moisture dressing, tracheostomy tube dressing, wound and burn dressings, hydrogel dressing, wound and burn, occlusive.
330.	Surgical Dressings	Cotton Grudges and bandages	Class B	Adhesive bandages, Gauge bandages, Pressure bandages, Traction bandages, and bandages Medical Absorbent (fiber) bandages.
331.	Surgical Dressings	Wound Dressings/Bacteriostatic Wound Dressings	Class C	Includes Beads, Hydrophilics For Wound Exudate Absorption for wound care.
332.	Surgical Dressings	Casting tapes/Splint Rolls	Class B	A prosthetic and orthotic accessory, intended for medical purposes to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis.
333.	Surgical Dressings	Haemostatic Gelatine Sponge /Haemostat	Class C	Intended for the control of surface bleeding from vascular access sites and percutaneous catheters or tube.
334.	Surgical Dressings	Surgical Dressings	Class C	Material dressing, surgical, polylactic acid dressings.
335.	Surgical Dressings	Absorable Hemostatic Based	Class D	An absorbable haemostatic agent or dressing is a device intended to produce haemostasis by accelerating the clotting process of blood. It is absorbable.
336.	Surgical Dressings	Umbilical occlusion device	Class A	These devices may be a clip, tie, tape,or other article used to close the blood vessels in the umbilical cord of a newborn infant.
337.	Surgical Dressings	Bolster Suture	Class A	Non-latex plastic bolsters are used to hinder pressure of any temporary suture against the body during surgery.
338.	Surgical Dressings	Suture Non Absorable Synthetic	Class C	Non-absorbable suture is comprised of surgical steel as well as synthetic non-absorbable sutures for use in general soft tissue approximation and ligation.
339.	Surgical Dressings	Suture Absorable	Class C	The device is intended for use in general soft tissue approximation and ligation.
340.	Surgical Dressings	Endovascular suturing system	Class C	It is a medical device intended to provide fixation and sealing between an endovascular graft and the native artery.
341.	Surgical Dressings	Fixation,non-absorbable for	Class C	Attaching suture or stapling ligaments of the pelvic floor.

		pelvic use		
342.	Surgical Dressings	Tissue adhesive for the topical use	Class C	Intended for topical closure of surgical incisions including laparoscopic incisions and simple traumatic lacerations.
343.	Surgical Dressings	Tissue adhesive for non-topical use	Class D	Intended for use in adhesion of internal tissues and vessels, for example; adhesives used in the embolization of brain arteriovenous malformation or for use in ophthalmic surgery.
344.	Surgical Dressings	Alcohol Swabs	Class A	It is a single use; sterile device containing 70% Isopropyl alcohol used for scrubbing and allowing drying and will disinfect needless access sites prior to use.
345.	Surgical Dressings	Ligature Wire	Class B	Offer a spot-welded auxiliary hook which may be added to any bracket by simply tying in the arch wire.
346.	Surgical Dressings	Surgical Sealant	Class B	For use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.
347.	Surgical Dressings	Wound Closure Device	Class B	Wound Closure Devices are indicated for soft tissue approximation.
348.	Surgical Dressings	Intracardiac patch	Class D	intracardiac patch or pledget made of polypropylene polyethylene terephthalate, or polytetrafluoroethylene is a fabric device placed in the heart that is used to repair septal defects, for patch grafting, to repair tissue, and to buttress sutures.

(B) List of *In Vitro* Diagnostics Medical Devices under provisions of the medical devices rules 2017

S. No.	Category	in vitro diagnostic medical device	Risk Class	Intended use
1.	Clinical Chemistry Reagents/Kits for estimation of various Parameters exemplified as:	Acid Phosphatase (total or prostatic) test reagents/kits	Class B	An acid phosphatase (total or prostatic) test reagent/kit is a medical device, intended for the estimation of acid phosphatase in serum /plasma.
2.		Albumin test reagents/kits	Class B	An albumin test reagent/kit is a medical device intended for the estimation of albumin in serum /plasma.
3.		Alkaline phosphatase or isoenzymes test reagents/kits	Class B	An alkaline phosphatase or isoenzymes test reagent/kit is a medical device intended for the estimation of alkaline phosphatase or its isoenzymes in serum/plasma.
4.		Ammonia test reagents/kits	Class B	An ammonia test reagent/kit is a medical device intended for the estimation of ammonia levels in blood, serum/plasma.
5.		Amylase test	Class B	An amylase test reagent/kit is a medical device

		reagents/kits		intended for the estimation of the enzyme amylase in serum, saliva / urine.
6.		Bicarbonate / carbon dioxide test reagents/kits	Class B	A bicarbonate/carbon dioxide test reagent/kit s a medical device for the estimation of bicarbonate/carbon dioxide in plasma, serum/whole blood.
7.		bilirubin (total and direct) test reagents/kits	Class B	A bilirubin (total and direct) test reagent/kit is a medical device intended for the estimation of bilirubin (total and direct) in serum/plasma.
8.		Calcium test reagents/kits	Class B	A calcium test reagent/kit is a medical device intended for the estimation of total calcium in serum.
9.		Chloride test reagents/kits	Class B	A chloride test reagent/kit is a medical device intended for the estimation of chloride in plasma, serum, sweat /urine.
10.		cholesterol (total) test reagents/kits	Class B	A cholesterol (total) test reagent/kit is a medical device intended for the estimation of cholesterol in serum or plasma.
11.		HDL cholesterol test reagents/kits	Class B	A HDL cholesterol test reagent/kit is a medical device intended for the estimation of HDL cholesterol in serum / plasma.
12.		LDL cholesterol test reagents/kits	Class B	A LDL cholesterol test reagent/kit is a medical device intended for the estimation of LDL cholesterol in serum/plasma.
13.		Lipoproteins test reagents/kits	Class B	A lipoprotein test reagent/kit is a medical device intended for the estimation of lipoproteins in serum /plasma.
14.		Cholinesterase test	Class B	A cholinesterase test reagent/kit is a medical device intended for the estimation of cholinesteral in serum /plasma. .
15.		Creatine Kinase and its isoenzymes test reagents/kits	Class B	A creatine phosphokinase/creatine kinase or isoenzymes including CKMB, CKBB and CKMM test reagent/kit is a medical device intended for the estimation of the enzyme creatine phosphokinase or its isoenzymes in serum / plasma.
16.		Copper test reagents/kits	Class B	Copper test reagent/kit is a medical device intended for the estimation of copper in plasma, serum / urine.
17.		Creatinine test reagents/kits	Class B	A creatinine test reagent/kit is a medical device intended for the estimation of creatinine in serum, plasma / urine.
18.		Gamma Glutamyl Transferase (GGT) and isoenymes test reagents/kits	Class B	A Gamma Glutamyl Transferase (GGT) and isoenzymes test reagent/kit is a medical device intended for the estimation of the enzyme Gamma Glutamyl Transferase (GGT) in serum / plasma.
19.		Glucose test reagents/kits	Class B	A Glucose test reagent/kit is a medical device intended for the estimation of glucose in

				blood/plasma/ body fluids.
20.		Glucose - 6 – Phosphate Dehydrogenase (G6PD) and its isoenzymes test reagents/kits	Class B	A Glucose – 6 – Phosphate Dehydrogenase (G6PD) test reagents/kit is a medical device intended for the estimation of Glucose - 6 - Phosphate Dehydrogenase or its isoenzymes in serum / plasma.
21.		Glycosylated Hemoglobin or its variants test reagents/kits	Class B	Glycosylated Hemoglobin or its variants test reagents/kits are medical devices intended for the estimation of glycosylated hemoglobin or its variants including A1a, A1b, and A1c in blood.
22.		Hemoglobin test reagents/kits	Class B	A hemoglobin test reagent/kit is a medical device intended for the estimation of hemoglobin in blood.
23.		Iron test reagents/kits	Class B	An iron test reagent/kit is a medical device intended for the estimation of iron in serum /plasma.
24.		Ferritin test reagents/kits	Class B	A Ferritin test reagent/kit is a medical device intended for the estimation of ferritin in serum /plasma.
25.		Iron -binding capacity test reagents/kits	Class B	Iron -binding capacity test reagents/kits are medical devices intended for the estimation of iron - binding capacity in serum / plasma.
26.		Lactate Dehydrogenase and its isoenzymes test reagents/kits	Class B	A Lactate Dehydrogenase and its isoenzymes test reagent/kit is a medical device intended for the estimation of enzyme Lactate Dehydrogenase and its isoenzymes in serum / plasma.
27.		Lipase test reagents/kits	Class B	A lipase test reagent/kit is a medical device intended for the estimation of lipase in serum / plasma.
28.		Magnesium test reagents/kits	Class B	A magnesium test reagent/kit is a medical device intended for the estimation of magnesium levels in serum / plasma.
29.		Phosphorus (inorganic) test reagents/kits	Class B	A phosphorus (inorganic) test reagent/kit is a medical device intended for the estimation of inorganic phosphorus in serum, plasma / urine.
30.		Potassium test reagents/kits	Class B	A potassium test reagent/kit is a medical device intended for the estimation of potassium in serum, plasma / urine.
31.		Aspartate Amino Transferase (AST/SGOT) test reagents/kits	Class B	An Aspartate Amino Transferase (AST/SGOT) test reagent/kit is a medical device intended for the estimation of the enzyme Aspartate Amino Transferase (AST/SGOT) in serum / plasma.
32.		Alanine Amino Transferase (ALT/SGPT) test reagents/kits	Class B	An Alanine Amino Transferase (ALT/SGPT) test reagent/kit is a medical device intended for the estimation of enzyme Alanine Amino Transferase (ALT/SGPT) in serum / plasma.

33.		Sodium test reagents/kits	Class B	A Sodium test reagent/kit is a medical device intended for the estimation of sodium in serum/ plasma / urine.
34.		Total protein test reagents/kits	Class B	A Total Protein test reagent/kit is a medical device intended for the estimation of total protein(s) in serum / plasma.
35.		Protein (fractionation) test reagents/kits	Class B	A Protein (fractionation) test reagent/kit is a medical device intended for the estimation of protein fractions in blood, urine, cerebrospinal fluid / other body fluids.
36.		Protein -bound iodine test reagents/kits	Class B	A Protein -bound iodine test reagent/kit is a medical device intended for the estimation of protein -bound iodine in serum / plasma.
37.		Triglycerides test reagents/kits	Class B	A Triglyceride test reagent/kit is a medical device intended for the estimation of triglycerides in serum / plasma.
38.		Urea (BUN) test reagents/kits	Class B	A Urea (BUN) test reagent/kit is a medical device intended for the estimation of urea/Blood Urea Nitrogen (BUN) in plasma/ serum / urine.
39.		Uric Acid test reagents/kits	Class B	A Uric Acid test reagent/kit is a medical device intended for the estimation of uric acid in serum/ plasma / urine.
40.		Micro-Protein test reagents/kits	Class B	A Micro-protein test reagent/kit is a medical device intended for the estimation of micro-proteins including micro-albumin in urine.
41.		Zinc test reagents/kits	Class B	A Zinc test reagent/kit is a medical device intended for the estimation of zinc in serum / plasma.
42.		Other clinical chemistry test reagents/kits	Class B*	Clinical chemistry test reagent/kit intended for the estimation of analytes/ parameters (other than listed above) in serum/ plasma/ urine or other body fluids.
43.	Hematology Reagents/ Kits for estimation of Complete Blood Counts exemplified as:	Blood cell Diluents	Class B	A blood cell Diluent is a medical device used to dilute blood for further testing, such as Complete Blood Count (CBC).
44.		Lyse reagents/kits for differential counts	Class B	A Lyse reagent/kit is a medical device used for lysing of cells for the estimation of Complete Blood Count (CBC).
45.		Rinse/Detergent/Cleaner s reagents/kits	Class B	A Rinse/Detergent/Cleaner reagent/kit is a medical device used for cleaning various parts of Hematology analyzers like probes, needles, baths, tubing etc.
46.	Reagents/ Kits for estimation of parameters in the urine exemplified	Ascorbic Acid/ Bilirubin /Blood Cells/Glucose/Ketone / Leukocyte peroxidase / Specific gravity/Urobilinogen Nitrite / pH / Protein	Class B	Ascorbic Acid/ Bilirubin /Blood Cells/Glucose/ Ketone / Leukocyte peroxidase / Specific gravity/Urobilinogen Nitrite / pH / Protein / Albumin & other urinary analytes test reagents /Strips/kits, are medical devices intended for the preliminary estimation of diagnostic markers in urine.

	as:	/ Albumin & other urinary analytes test reagents /Strips/kits		
47.	In - vitro Diagnostic Medical Devices for Self - Testing	Glucose test reagents/kits	Class B	A glucose test reagent/kit is a medical device intended for the preliminary self testing of glucose levels in blood/body fluids.
48.		Human Chorionic Gonadotropin (hCG) test reagents/kits	Class B	A human Chorionic Gonadotropin (hCG) test reagent/kit is a medical device intended for the preliminary self testing of hCG in urine/body fluids.
49.		Luteinizing Hormone (LH) test reagents/kits	Class B	A Luteinizing Hormone (LH) test reagent/kit is a medical device intended for the preliminary self testing of Luteinizing Hormone (LH) in urine/body fluids.
50.		Glycosylated hemoglobinor its variants Test reagents/kits	Class B	Glycosylated Hemoglobin or its variants test reagents/kits are medical devices intended for the preliminary self testing of Glycosylated Hemoglobin or its variants including A1a, A1b, and A1c in blood.
51.		Cholesterol test reagents/kits	Class B	A Cholesterol test reagent/kit is a medical device intended for preliminary self testing of cholesterol in blood /body fluids.
52.		Follicle Stimulating Hormone (FSH) test reagents/kits	Class B	A Follicle Stimulating Hormone (FSH) test reagent/kit is a medical device intended for the preliminary self testing of Follicle Stimulating Hormone (FSH) in urine /body fluids.
53.		Other In – vitro Diagnostic Medical Devices for Self - Testing	Class B*	
54.		Blood Gas Analysis test reagents/kits	Class C	A Blood Gas Analysis test reagent/kit for near patient testing is medical devices intended for the estimation of certain gases (such as oxygen and carbon dioxide etc.) dissolved in arterial blood.
55.		Anticoagulant monitoring test reagents/kits	Class C	An Anticoagulant monitoring test reagent/kit for near patient testing is a medical device intended for the estimation of coagulation parameters (such as PT, TT, APTT etc.) in plasma/blood.
56.		Diabetes management test reagents/kits	Class C	A Diabetes management test reagent/kit for near patient testing, is a medical device intended for the of monitoring of diabetes in body fluids.
57.		C- Reactive Protein (CRP)test reagents/kits	Class C	A C- Reactive Protein (CRP) test reagent/kit for near patient testing is a medical device intended for the estimation of C -Reactive Protein (CRP) in serum and other body fluids.

58.		H. pylori test reagents/kits	Class C	An H.pylori test reagent/kit for near patient testing is medical devices intended for the estimation of H. pylori in blood/body fluids.
59.		Troponin test reagents/kits	Class C	A Troponin test reagent/kit for near patient testing is a medical device intended for the estimation of Troponin T, I and its variants in blood/body fluids.
60.		Other in vitro Diagnostic Medical Devices for near patient test reagents/kits	Class C*	In vitro Diagnostic Medical Device for near patient test reagent/kit intended for the estimation of analytes/ parameters (other than listed above) in serum, plasma, urine or other body fluids.
61.	Reagents/ Kits for estimation of parameters of ToRCH& other infectious agents exemplified as under	Toxoplasma gondii test reagents/kits	Class C	A Toxoplasma gondii test reagent/kit is a medical device intended for the detection of Toxoplasma gondii in serum/body fluids.
62.		Rubella virus l test reagents/kits	Class C	A Rubella virus test reagent/kit is a medical device intended for the detection of Rubella virus in serum/body fluids.
63.		Cytomegalovirus test reagents/kits	Class C	A Cytomegalovirus test reagent/kit is a medical device intended for the detection of Cytomegalovirus in serum/body fluids.
64.		Herpes simplex virus reagents/kits	Class C	A Herpes simplex virus test reagent/kit is a medical device intended for the detection of Herpes simplex virus in serum/body fluids.
65.		Chlamydia pneumonia test reagents/kits	Class C	A Chlamydia pneumoniae test reagent/kit is a medical device intended for the detection of Chlamydia pneumonia in serum/body fluids.
66.		Methicillin-Resistant Staphylococcus aureus test reagents/kits	Class C	A Methicillin-Resistant Staphylococcus aureus test reagent/kit is a medical device intended for the detection of Methicillin-Resistant Staphylococcus aureus in serum/body fluids.
67.		Enterovirus test reagents/kits	Class C	An Enterovirus test reagent/kit is a medical device intended for the detection of enterovirus) in serum/body fluids.
68.	Reagents/ Kits for detection of Cancer Markers exemplified as :	Alpha-fetoprotein test reagents/kits	Class C	An Alpha-fetoprotein test reagent/kit is a medical device intended for the detection of Alpha-fetoprotein in serum/body fluids.
69.		Beta-2 microglobulin test reagents/kits	Class C	A Beta-2 microglobulin test reagent/kit is a medical device intended for the detection of Beta-2 microglobulin in serum/body fluids.
70.		Bladder tumour antigen (BTA) test reagents/kits	Class C	A Bladder tumour antigen (BTA) test reagent/kit is a medical device intended for the detection of Bladder tumour antigen (BTA)in serum/body fluids.
71.		CA15 -3 test reagents/kits	Class C	A CA15 - 3 antigens (BTA) test reagent/kit is a medical device intended for the detection of CA15 - 3 in serum/body fluids.
72.		CA27.29 test reagents/kits	Class C	A CA27.29 test reagent/kit is a medical device intended for the detection of CA27.29 in

				serum/body fluids.
73.		CA125 test reagents/kits	Class C	A CA125test reagent/kit is a medical device intended for the detection of CA125 in serum/body fluids.
74.		CA72 -4 test reagents/kits	Class C	A CA72 - 4 test reagent /kit is a medical device intended for the detection of CA72 -4 in serum/body fluids.
75.		CA19 -9 test reagents/kits	Class C	A CA19 - 9 test reagent /kit is a medical device intended for the detection of CA19 -9 in serum/body fluids.
76.		Calcitonin test reagents/kits	Class C	A Calcitonin test reagent/kit is a medical device intended for the detection of Calcitonin in serum/body fluids.
77.		Carcinoembryonic antigen (CEA) test reagents/kits	Class C	A Carcinoembryonic antigen (CEA) test reagent/kit is a medical device intended for the detection of Carcinoembryonic antigen (CEA) in serum/body fluids.
78.		Chromogranin A test reagents/kits	Class C	A Chromogranin A test reagent/kit is a medical device intended for the detection of Chromogranin A in serum/body fluids.
79.		Estrogen / Progesterone receptors test reagents/kits	Class C	A Estrogen / Progesterone test reagent/kit is a medical device intended for the detection of Estrogen / Progesterone in serum/body fluids.
80.		HER2 (Human Epidermal Growth Factor receptor, test reagents/kits	Class C	A HER2 (Human Epidermal Growth Factor receptor test reagent/kit is a medical device intended for the detection of HER2 (Human Epidermal Growth Factor receptor in serum/body fluids.
81.		human Chorionic Gonadotropin (hCG) test system test reagents/kits	Class C	A human Chorionic Gonadotropin (hCG) test reagent/kit is a medical device intended for the detection of human Chorionic Gonadotropin (hCG) in serum/body fluids.
82.		Lipid associated sialic acid test reagents/kits	Class C	A Lipid associated sialic acid test reagent/kit is a medical device intended for the detection of Lipid associated sialic acid in serum/body fluids.
83.		Neuron –Specific Enolase (NSE) test reagents/kits	Class C	A Neuron -Specific Enolase (NSE) test reagent/kit is a medical device intended for the detection of Neuron -Specific Enolase (NSE) in serum/body fluids.
84.		NMP22 test reagents/kits	Class C	A NMP22 test reagent/kit is a medical device intended for the detection of NMP22 in serum/body fluids.
85.		Prostate –Specific Antigen (PSA) test reagents/kits	Class C	A Prostate -Specific Antigen (PSA) test reagent/kit is a medical device intended for the detection of Prostate -Specific Antigen (PSA) in serum/body fluids.
86.		Prostatic Acid	Class C	A Prostatic Acid Phosphatase (PAP) test

		Phosphatase (PAP) test reagents/kits		reagents/kits test reagent/kit is a medical device intended for the detection of Prostatic Acid Phosphatase (PAP) test reagents/kits in serum/body fluids.
87.		Prostate Cancer Antigen 3 gene (PCA 3) test reagents/kits	Class C	A Prostate Cancer Antigen 3 gene (PCA 3) test reagent/kit is a medical device intended for the detection of Prostate Cancer Antigen 3 gene (PCA 3) in serum/body fluids.
88.		Prostate –Specific Membrane Antigen (PSMA) test reagents/kits	Class C	A Prostate -Specific Membrane Antigen (PSMA) test reagent/kit is a medical device intended for the detection of Prostate -Specific Membrane Antigen (PSMA) in serum/body fluids.
89.		S -100 test reagents/kits	Class C	A S -100 test reagent/kit is a medical device intended for the detection of S-100 in serum/body fluids.
90.		TA-90 test reagents/kits	Class C	A TA-90 test reagent/kit is a medical device intended for the detection of TA-90 in serum/body fluids.
91.		Thyroglobulin test reagents/kits	Class C	A Thyroglobulin test reagent/kit is a medical device intended for the detection of Thyroglobulin in serum/body fluids.
92.		Tissue Polypeptide Antigen (TPA) test reagents/kits	Class C	A Tissue Polypeptide Antigen (TPA) test reagent/kit is a medical device intended for the detection of Tissue Polypeptide Antigen (TPA) in serum/body fluids.
93.		Other Reagents/ Kits for detection of Cancer Markers	Class C*	
94.	Reagents/ Kits for estimation of Coagulation parameters exemplified as:	PT (Prothrombin Time) test reagents/kits	Class C	A Prothrombin Time (PT) test reagent/kit is a medical device intended for the estimation of prothrombin time in plasma/body fluids.
95.		TT (Thrombin Time) test reagents/kits	Class C	A Thrombin Time (TT) test reagent/kit is a medical device intended for the estimation of Thrombin Time in plasma/body fluids.
96.		Activated Partial Thromboplastin Time(APTT) tests reagents/kits	Class C	A Activated Partial Thromboplastin Time (APTT) test reagent/kit is a medical device intended for the estimation of Activated Partial Thromboplastin Time in plasma/body fluids.
97.		Activated whole blood clotting time tests reagents/kits		A Activated whole blood clotting time test reagent/kit is a medical device intended for the estimation of Activated whole blood clotting Time in plasma/body fluids.
98.		Fibrinogen/Fibrin degradation products tests reagents/kits	Class C	A Fibrinogen/Fibrin degradation products test reagent/kit is a medical device intended for the estimation of fibrinogen/fibrin degradation products in plasma/body fluids.
99.		D-Dimer tests reagents/kits	Class C	A D-Dimer test reagent/kit is a medical device intended for the estimation of D-Dimer test in

				plasma/body fluids.
100.		Other Reagents/ Kits for estimation of Coagulation parameters	Class C*	
101.	Reagents/ Kits for monitoring of drug levels used for therapy or abuse exemplified as under	Aminoglycoside antibiotics test reagents/kits	Class C	Aminoglycoside antibiotics test reagents/kits are medical devices intended for the estimation of Aminoglycoside antibiotics in serum/body fluids.
102.		Antiepileptics test reagents/kits	Class C	Antiepileptics test reagents/kits are medical devices intended for the estimation of Antiepileptics in serum/body fluids
103.		Antipsychotics test reagents/kits	Class C	Antipsychotics test reagents/kits are medical devices intended for the estimation of Antipsychotics in serum/body fluids.
104.		Mood stabilisers, test reagents/kits	Class C	Mood stabilisers test reagents/kits are medical devices intended for the estimation of Mood stabilisers in serum/body fluids.
105.		Biologic monoclonal antibody drugs test reagents/kits	Class C	Biologic monoclonal antibody drugs test reagents/kits are medical devices intended for the estimation of Biologic monoclonal antibody drugs in serum/body fluids.
106.		Buprenorphine (BUP) test reagents/kits	Class C	Buprenorphine (BUP) test reagents/kits are medical devices intended for the estimation of Buprenorphine (BUP) in serum/body fluids.
107.		Amphetamine (AMP) test reagents/kits	Class C	Amphetamine (AMP) test reagents/kits are medical devices intended for the estimation of Amphetamine (AMP) in serum/body Fluids.
108.		Barbiturates (BAR) test reagents/kits	Class C	Barbiturates (BAR) test reagents/kits are medical devices intended for the estimation of Barbiturates (BAR) in serum/body fluids.
109.		Opiate test system test reagents/kits	Class C	Opiate test reagents/kits are medical devices intended for the estimation of opiates in serum/body fluids.
110.		Benzodiazepines (BZO)Test reagents /kits	Class C	Benzodiazepines (BZO) test reagents/kits are medical devices intended for the estimation of Benzodiazepines (BZO) in serum/body fluids.
111.		Cocaine (COC) Test reagents /kits	Class C	Cocaine (COC) test reagents/kits are medical devices intended for the estimation of Cocaine (COC) in serum/body fluids.
112.		Cotinine (COT) Test reagents /kits	Class C	Cotinine (COT) test reagents/kits are medical devices intended for the estimation of Cotinine (COT) in serum/body fluids.
113.		Ketamine (KET)Test reagents /kits	Class C	Ketamine (KET) test reagents/kits are medical devices intended for the estimation of Ketamine (KET) in serum/body fluids.
114.		Ecstasy (MDMA) Test reagents /kits	Class C	Ecstasy (MDMA) test reagents/kits are medical devices intended for the estimation of Ecstasy (MDMA) in serum/body fluids.

115.		Methamphetamine (MET)Test reagents /kits	Class C	Methamphetamine (MET) test reagents/kits are medical devices intended for the estimation of Methamphetamine (MET) in serum/body fluids.
116.		Morphine (MOP)Test reagents /kits	Class C	Morphine (MOP) test reagents/kits are medical devices intended for the estimation of Morphine (MOP) in serum/body fluids.
117.		Methaqualone (MQL)Test reagents /kits	Class C	Methaqualone (MQL) test reagents/kits are medical devices intended for the estimation of Methaqualone (MQL) in serum/body fluids.
118.		Methadone (MTD) Test reagents /kits	Class C	Methadone (MTD) test reagents/kits are medical devices intended for the estimation of Methadone (MTD) in serum/body fluids.
119.		Oxycodone (OXY)Test reagents /kits	Class C	Oxycodone (OXY) test reagents/kits are medical devices intended for the estimation of Oxycodone (OXY) in serum/body fluids.
120.		Phencyclidine (PCP) Test reagents /kits	Class C	Phencyclidine (PCP) test reagents/kits are medical devices intended for the estimation of Phencyclidine (PCP) in serum/body fluids.
121.		Propoxyphene (PPX) Test reagents /kits	Class C	Propoxyphene (PPX) test reagents/kits are medical devices intended for the estimation of Propoxyphene (PPX) in serum/body Fluids.
122.		Tricyclic Antidepressants (TCA)Test reagents /kits	Class C	Tricyclic Antidepressants (TCA) test reagents/kits are medical devices intended for the estimation of Tricyclic Antidepressants (TCA) in serum/body fluids.
123.		Marijuana (THC)Test reagents /kits	Class C	Marijuana (THC) test reagents/kits are medical devices intended for the estimation of Marijuana (THC) in serum/body fluids.
124.		Tramadol (TRA) Test reagents /kits	Class C	Tramadol (TRA) test reagents/kits are medical devices intended for the estimation of Tramadol (TRA) in serum/body fluids.
125.		Fentanyl (FEN)Test reagents /kits	Class C	Fentanyl (FEN) test reagents/kits are medical devices intended for the estimation of Fentanyl (FEN) in serum/body fluids.
126.		Methadone Metabolite (EDDP)Test reagents /kits	Class C	Methadone Metabolite (EDDP) test reagents /kits are medical devices intended for the estimation of Methadone Metabolite (EDDP)in serum/body fluids.
127.		Other Reagents/ Kits for monitoring of drug levels used for therapy or abuse	Class C*	
128.	Reagents/ Kits for detection of autoimmune disorders exemplified	Anti Nuclear Antibodies test reagents/kits	Class B	Anti Nuclear Antibodies test reagent/kit is a medical device for the screening of auto-antibodies to nuclear antigens in human specimens.
129.		Anti Transglutaminase	Class B	Anti Transglutaminase Antibodies test reagent/kit is a medical device for the screening

	as	Antibodies test reagents/kits		of auto-antibodies to Transglutaminase in human Specimens.
130.		Anti Ganglioside Antibodies test reagents/kits	Class B	Anti Ganglioside Antibodies test reagent/kit is a medical device for the screening of auto-antibodies to Ganglioside in human specimens.
131.		Anti-Cyclic Citrullinated Peptide (CCP) Antibodies test reagents/kits	Class B	Anti Cyclic Citrullinated Peptide (CCP) Antibodies test reagent/kit is a medical device for the screening of CCP auto-antibodies in human specimens.
132.		Rheumatoid Factor (RF) immunological test reagents/kits	Class B	Rheumatoid Factor (RF) immunological test reagent/kit is a medical device for the screening of Rheumatoid Factor in human specimens.
133.		Anti Smooth Muscle Antibody test reagents/kits	Class B	Anti Smooth Muscle Antibody test reagent/kit is a medical device for the screening of auto-antibodies to smooth muscles in human specimens.
134.		Glutamic Acid Decarboxylase (GAD) Antibody test reagents/kits	Class B	Glutamic Acid Decarboxylase (GAD) Antibody test reagent/kit is a medical device for the screening of auto antibodies to Glutamic Acid Decarboxylase (in human specimens.
135.		Anti ovary antibodies test reagents/kits	Class B	Anti ovary antibodies test reagent/kit is a medical device for the screening of auto-antibodies to ovarian antigens in human specimens.
136.		Anti sperm Antibodies test reagents/kits	Class B	Anti sperm antibodies test reagent/kit is a medical device for the screening of auto-antibodies to spermatozoa in human specimens.
137.		Anti-IA2 test reagents/kits	Class B	Anti IA-2 antibodies test reagent/kit is a medical device for the screening of auto-antibodies to IA-2 (tyrosine phosphatase) in human specimens.
138.		Anti-Acetylcholine Receptor test reagents/kits	Class B	Anti-Acetylcholine Receptor test reagent/kit is a medical device for the screening of auto-antibodies to Acetylcholine Receptor in human specimens .
139.		Anti Thyroid gland antibody test reagents/kits	Class B	Anti Thyroid gland antibodies test reagent/kit is a medical device for the screening of auto-antibodies to thyroid gland antigens in human specimens.
140.		ANCA test reagents/kits	Class B	The ANCA test reagent/kit is a medical device for the screening of Anti-Neutrophil Cytoplasmic Antibodies (ANCA) in human Specimens.
141.		Anti-double stranded DNA (anti-dsDNA)test reagents/kits	Class B	The Anti-double stranded DNA (Anti-dsDNA) test reagent/kit is a medical device for the screening of auto-antibodies to Double stranded DNA in human specimens.
142.		Anti-Extractable Nuclear	Class B	The Anti-Extractable Nuclear Antigen (Anti-ENA) test reagent/kit is a medical device for the

		Antigen(Anti-ENA)test reagents/kits		screening of auto-antibodies to Extractable Nuclear Antigens like Smith (Sm) Antigens, Ribonuclears Protein (RNP), anti SSA (Ro) etc. in human Specimens .
143.		Anti-Intrinsic Factor test reagents/kits	Class B	The Anti-Intrinsic Factor test reagent/kit is a medical device for the screening of antibodies against intrinsic factor in human specimens.
144.		Anti-Saccharomyces Cerevisiae Antibodies (ASCA) test reagents/kits	Class B	The Anti-Saccharomyces Cerevisiae Antibodies (ASCA) test reagent/kit is a medical device for the screening of antibodies against Saccharomyces Cerevisiae in human specimens.
145.		Other Reagents/ Kits for detection of autoimmune disorders	Class B*	
146.	Reagents/Kits for detection of markers for Congenital disorders exemplified as under			
147.		Triple Screen Test reagents/kits for Down's Syndrome	Class C	Triple Screen Test reagent/kit for Down's Syndrome is a medical device intended for the screening of Down's Syndrome in serum/plasma.
148.		Quadruple Screen Test reagents/kits for Down's Syndrome	Class C	Quadruple Screen Test reagent/kit for Down's Syndrome is a medical device intended for the screening of Down's Syndrome in serum/plasma.
149.		Chorionic Villus Sample Test reagents/kits for Down's Syndrome	Class C	Chorionic Villus Sample Test reagent/kit for Down's Syndrome is a medical device intended for the detection of Down's Syndrome in body fluids.
150.		Maternal Serum Alpha- Fetoprotein (MSAFP) test reagents/kits for spina bifida	Class C	Maternal Serum Alpha-Fetoprotein (MSAFP) Test reagents/kits for is a medical device intended for the screening of spina bifida in serum.
151.		Others Reagents/ Kits for detection of Congenital disorders	Class C*	
152.	Reagents/ Kits for detection of Cardiac Markers exemplified as under	Creatine Kinase (CK) and CKMB test reagents/kits	Class B	Creatine Kinase (CK) and CKMB test reagent/kit are medical devices intended for the estimation of Creatine Kinase (CK) and CKMB in blood / body fluids.
153.		Myoglobin test reagents/kits	Class B	Myoglobin Test reagent/kit for is a medical device intended for the estimation of myoglobin in blood /body fluids.
154.		Troponin test reagents/kits	Class C	A Troponin test reagent/kit for near patient testing, is a medical device intended for the estimation of Troponin T, I and its variants in blood /body fluids.
155.		BNP &NT pro BNP test reagents/kits	Class C	BNP &NT pro BNP Test reagent/kit for is a medical device intended for the estimation of

				BNP &NT pro BNP in blood / body fluids.
156.	Reagents/ Kits for human Genetic testing exemplified as:	Genetic test reagents/kits for Cystic Fibrosis	Class C	Genetic test reagent/kit for Cystic Fibrosis is a medical device intended for the detection of Cystic Fibrosis in human specimens.
157.		Genetic test for Huntington's chorea	Class C	Genetic test reagent/kit for Huntington's chorea is a medical device intended for the detection of Huntington's chorea in human specimens.
158.		Other Reagents/ Kits for human Genetic testing	Class C*	
159.	Reagents/ Kits for the management of life threatening infections exemplified as under	HIV Viral Load test reagents/kits	Class C	HIV Viral Load test reagent/kit is a medical device intended for the estimation of HIV Viral Load in blood/body fluids.
160.		HBV Viral Load test reagents/kits	Class C	HBV Viral Load test reagent/kit is a medical device intended for the estimation of HBV Viral Load in blood/body fluids.
161.		HCV Viral Load test reagents/kits	Class C	HCV Viral Load test reagent/kit is a medical device intended for the estimation of HCV Viral Load in blood/body fluids.
162.		CD4 Count & % test reagents/kits	Class C	CD4 Count & % test reagent/kit is a medical device intended for the estimation of CD4 Count & % in blood/body fluids.
163.		CD8 Count & % test reagents/kits	Class C	CD8 Count & % test reagent/kit is a medical device intended for the estimation of CD8 Count & % in Blood/body fluids.
164.		CD4/CD8 Ratio test reagents/kits	Class C	CD4/CD8 Ratio test reagent/kit are a medical device intended for the estimation of CD4 /CD8 Ratio in blood/body fluids.
165.		Other Reagents/ Kits for the management of life threatening infections	Class C*	
166.	Reagents/ Kits for the detection of sexually transmitted agent exemplified as under:	Treponema pallidum test reagents and kits	Class C	Treponema pallidum test reagent/kit is a medical device intended for the detection of Treponema pallidum in blood/body fluids.
167.		Neisseria gonorrhoeae test reagents and kits	Class C	Neisseria gonorrhoeae test reagent/kit is a medical device intended for the detection of Neisseria gonorrhoeae in blood/body fluids.
168.		Human Papilloma Virus (HPV) test reagents and kits	Class C	Human Papilloma Virus (HPV) test reagent/kit is a medical device intended for the detection of Human Papilloma Virus in blood/body fluids.
169.		Chlamydia test reagents and kits	Class C	Chlamydia test reagent/kit is a medical device intended for the detection of Chlamydia in blood/body fluids.
170.		Herpes Virus test reagents and kits	Class C	Herpes Virus test reagent/kit is a medical device intended for the detection of Herpes Virus in blood/body fluids.

171.		Other Reagents/ Kits for the detection of sexually transmitted agent	Class C*	Malaria Antigen test reagent/kit is a medical device intended for the detection of Malaria Antigen in blood/body fluids.
172.	Reagents/ Kits for the Antigen detection of infectious agents with a risk of limited propagation exemplified as:			
173.		Malaria Antigen test reagents and kits	Class C	Dengue virus Antigen test reagent/kit is a medical device intended for the detection of Dengue virus Antigen in blood/body fluids.
174.		Dengue virus Antigen test reagents and kits	Class C	Dengue virus Antigen test reagent/kit is a medical device intended for the detection of Dengue virus Antigen in blood/body fluids.
175.		Chikungunya Antigen test reagents and kits	Class C	Chikungunya Antigen test reagent/kit is a medical device intended for the detection Chikungunya Antigen of in blood/body fluids.
176.		Leptospira Antigen test reagents and kits	Class C	Leptospira Antigen test reagent/kit is a medical device intended for the detection of Leptospira Antigen in blood/body fluids.
177.		Japanese Encephalitis Antigen test reagents and kits	Class C	Japanese Encephalitis Antigen test reagent/kit is a medical device intended for the detection of Japanese Encephalitis Antigen in blood/body fluids.
178.		Typhoid Antigens test reagents and kits	Class C	Typhoid Antigens Test reagent/kit is a medical device intended for the detection of Typhoid Antigens in blood/body fluids.
179.		Influenza A Antigen test reagents and kits	Class C	Influenza A Antigen test reagent/kit is a medical device intended for the detection of Influenza A Antigen in blood/body fluids.
180.		Influenza B Antigen test reagents and kits	Class C	Influenza B Antigen test reagent/kit is a medical device intended for the detection of Influenza B Antigen in blood/body fluids.
181.		Strep A Antigen test reagents and kits	Class C	Strep A Antigen test reagent/kit is a medical device intended for the detection of Strep A Antigen in blood/body fluids.
182.		Strep B Antigen test reagents and kits	Class C	Strep B test Antigen reagent/kit is a medical device intended for the detection of Strep B Antigen in blood/body fluids.
183.		Chagas Antigen test reagents and kits	Class C	Chagas disease Antigen test reagent/kit is a medical device intended for the detection of Chagas disease Antigen in blood/body fluids.
184.		Filariasis Antigen test reagents and kits	Class C	Filariasis test Antigen reagent/kit is a medical device intended for the detection of Filariasis Antigen in blood/body fluids.
185.		Kala Azar Antigen test reagents and kits gen	Class C	Kala Azar Antigen test reagent/kit is a medical device intended for the detection of Kala Azar Antigen in blood/body fluids.
186.		Rotavirus Antigen test reagents and kits	Class C	Rotavirus Antigen test reagent/kit is a medical devices intended for the detection of rotavirus antigen in blood/body fluids.
187.		S. pneumonia	Class C	S. pneumonia Antigen test reagent/kit is a

		Antigen test reagents and kits		medical device intended for the detection of S. pneumonia Antigen in blood/body fluids.
188.		H. pylori Antigen Antigen test reagents and kits Antigen	Class C	H. pylori Antigen test reagent/kit is a medical device intended for the detection of H. pylori Antigen in blood/body fluids.
189.		Other Reagents/ Kits for the detection of infectious agents with a risk of limited propagation	Class C*	Reagents/ Kits, other than above, for the Antigen detection of infectious agents with a risk of limited propagation.
190.	Reagents/ Kits for the detection of Antibodies to infectious agents with a risk of limited propagation exemplified as under			
191.		Malaria Antibody test reagents and kits	Class B	Malaria Antibody test reagent/kit is a medical device intended for the detection of Malaria Antibody in blood/body fluids.
192.		Dengue Antibody test reagents and kits	Class B	Dengue Antibody test reagent/kit is a medical device intended for the detection of Dengue Antibody in blood/body fluids.
193.		Chikungunya Antibody test reagents and kits	Class B	Chikungunya Antibody test reagent/kit is a medical device intended for the detection of Chikungunya Antibody in blood/body fluids.
194.		Leptospira Antibody test reagents and kits	Class B	Leptospira Antibody test reagent/kit is a medical device intended for the detection of Leptospira Antibody in blood/body fluids.
195.		Japanese Encephalitis Antibody test reagents and kits	Class B	Japanese Encephalitis Antibody test reagent/kit is a medical device intended for the detection of Japanese Encephalitis Antibody in blood/body fluids.
196.		Typhoid Antibody test reagents and kits	Class B	Typhoid Antibody test reagent/kit is a medical device intended for the detection of Typhoid Antibody in blood/body fluids.
197.		Cryptococcus neoformans Antibody test reagents and kits	Class B	Cryptococcus neoformans Antibody test reagent/kit is a medical device intended for the detection of Cryptococcus neoformans Antibody in blood/body fluids.
198.		Neisseria meningitides Antibody test reagents and kits	Class B	Neisseria meningitides Antibody test reagent/kit is a medical device intended for the detection of Neisseria meningitides Antibody in blood/body fluids.
199.		Vibrio cholera Antibody test reagents and kits	Class B	Vibrio cholera Antibody test reagent/kit is a medical device intended for the detection of Vibrio cholera Antibody in blood/body fluids.
200.		Influenza A Antibody test reagents and kits	Class B	Influenza A Antibody test reagent/kit is a medical device intended for the detection of Influenza A Antibody in blood/body fluids.
201.		Influenza B Antibody test reagents and kits	Class B	Influenza B Antibody test reagent/kit is a medical device intended for the detection of Influenza B Antibody in blood/body fluids.
202.		Strep A Antibody test reagents and kits	Class B	Strep A Antibody test reagent/kit is a medical device intended for the detection of Strep A

				Antibody in blood/body fluids.
203.		Strep B Antibody test reagents and kits	Class B	Strep B Antibody test reagents/kits are a medical device intended for the detection of Strep B Antibody in blood/body fluids.
204.		Chagas Antibody test reagents and kits	Class B	Chagas Antibody test reagent/kit is a medical device intended for the detection of Chagas Antibody in blood/body fluids.
205.		Filariasis Antibody test reagents and kits	Class B	Filariasis Antibody test reagent/kit is a medical device intended for the detection of Filariasis Antibody in blood/body fluids.
206.		Kala Azar Antibody test reagents and kits	Class B	Kala Azar Antibody test reagents/kits is a medical device intended for the detection of Kala Azar Antibody in blood/body fluids.
207.		Rotavirus Antibody test reagents and kits	Class B	Rotavirus Antibody test reagents/kits is a medical device intended for the detection of Rotavirus Antibody in blood/body fluids.
208.		S. pneumonia Antibody test reagents and kits	Class B	S. pneumonia Antibody test reagent/kit is a medical device intended for the detection of S. pneumonia Antibody in blood/body fluids.
209.		H. pylori Antibody test reagents and kits	Class B	H. pylori Antibody test reagent/kit is a medical device intended for the detection of H. pylori Antibody in blood/body fluids.
210.		Other Reagents/ Kits for the detection of Antibodies to infectious agents with a risk of limited propagation	Class B*	
211.	In vitro Diagnostic Medical Devices for Blood Grouping or Tissue Typing	All other than, the ABO system; the Duffy system; the Kell system; the Kidd system; the Rhesus system, test reagents/kits.	Class C	
212.	in vitro Diagnostic Medical Devices for Blood Grouping or Tissue Typing	ABO System test reagents/kits	Class D	Intended for blood grouping or tissue typing.
213.		Rhesus (D) System test reagents/kits	Class D	
214.		The Duffy system test reagents/kits	Class D	
215.		The Kell system test reagents/kits	Class D	
216.		The Kidd system test reagents/kits	Class D	
217.		HLA test reagents/kits	Class D	

218.	Reagents/ Kits for the detection of transmissible agents - screening & confirmatory	HIV test reagents/kits	Class D	HIV test reagents/kits is a medical device intended for the detection of HIV in blood/body fluids.
219.		HBV test reagents/kits	Class D	HBV test reagents/kits is a medical device intended for the detection of HBV in blood/body fluids.
220.		HCV test reagents/kits	Class D	HCV test reagents/kits is a medical device intended for the detection of HCV in blood/body fluids.
221.		Syphilis screening reagents/kits	Class D	Syphilis test reagents/kits is a medical device intended for the screening of Syphilis in blood/body fluids.
222.		Malaria screening reagents/kits	Class D	Malaria test reagents/kits is a medical device intended for the screening of Malaria in blood/body fluids.
223.	Other in vitro Medical Devices	TSH test reagents/kits	Class B	TSH test reagent/kit is a medical device intended for the estimation TSH in blood/body fluids.
224.		Total /Free triiodothyronine (T3) test reagents/kits	Class B	Total /Free triiodothyronine (T3) test reagent/kit is a medical device intended for the estimation Total /Free triiodothyronine (T3) in blood/body fluids.
225.		Total / Free thyroxine (T4) test reagents/kits	Class B	Total / Free thyroxine (T4)test reagent/kit is a medical device intended for the estimation of Total / Free thyroxine (T4)in blood/body fluids.
226.		Dehydroepiandrosterone (DHEA -S) (free and sulfate) test reagents/kits	Class B	Dehydroepiandrosterone (DHEA -S) (free and sulfate) test reagent/kit is a medical device intended for the estimation of DHEA - S (free and sulfate) in blood/body fluids.
227.		Estrogen test reagents/kits	Class B	Estrogen test reagent/kit is a medical device intended for the estimation of Estrogen in blood/body fluids.
228.		Progesterone test reagents/kits	Class B	Progesterone test reagent/kit is a medical device intended for the estimation of Progesterone in blood/body fluids.
229.		Testosterone (Free and Total) test reagents/kits	Class B	Progesterone test reagent/kit is a medical device intended for the estimation of Progesterone in blood/body fluids.
230.		Sex Hormone Binding Globulin (SHBG) test reagents/kits	Class B	Sex Hormone Binding Globulin (SHBG) test reagent/kit is a medical device intended for the estimation of Sex Hormone Binding Globulin (SHBG) in blood/body fluids.
231.		Cortisol test reagents/kits	Class B	Cortisol test reagent/kit is a medical device intended for the estimation of Cortisol in blood/body fluids.
232.		Insulin test reagents/kits	Class B	Insulin test reagent/kit is a medical device intended for the estimation of Insulin in blood/body fluids.
233.		Luteinizing	Class B	Luteinizing Hormones (LH) test reagent/kit is a

		Hormone(LH) test reagents/kits		medical device intended for the estimation of Luteinizing Hormone (LH) in blood/body fluids.
234.		Follicle Stimulating Hormone(FSH) test reagents/kits	Class B	Follicle Stimulating Hormone (FSH) test reagent/kit is a medical device intended for the estimation of Follicle Stimulating Hormone (FSH) in blood/body fluids.
235.		Prolactin test reagents/kits	Class B	Prolactin test reagent/kit is a medical device intended for the estimation of Prolactin in blood/body fluids.
236.		Other test reagents/kits for hormones	Class B	Test reagents/kits for the estimation of other than above hormones in blood/body fluids.
237.		Vitamin B test reagents/kits	Class B	Vitamin B test reagent/kit is a medical device intended for the estimation of Vitamin B in blood/body fluids.
238.		Vitamin D test reagents/kits	Class B	Vitamin D test reagent/kit is a medical device intended for the estimation of Vitamin B in blood/body fluids.
239.		Vitamin A test reagents/kits	Class B	Vitamin A test reagent/kit is a medical device intended for the estimation of Vitamin A in blood/body fluids.
240.		Vitamin E test reagents/kits	Class B	Vitamin E test reagent/kit is a medical device intended for the estimation of Vitamin E in blood/body fluids.
241.		Vitamin K test reagents/kits	Class B	Vitamin K test reagent/kit is a medical device intended for the estimation of Vitamin K in blood/body fluids.
242.		Other test reagents/kits for vitamins	Class B	Test reagents/kits for the estimation of other than above vitamins in blood/body fluids.
243.		Homocystein test reagents/kits	Class B	Homocystein test reagent/kit is a medical device intended for the estimation of Homocystein in blood/body fluids.
244.		allergens test reagents/kits	Class B	Test reagents/kits intended for the estimation of allergens in blood/body fluids.
245.	calibrators/controls for above all in vitro diagnostic medical devices	Calibrators	-	Calibrators intended to be used with a reagent should be treated in the same class as the In vitro diagnostic medical device reagent.
246.		Controls	-	Controls intended to be used with a reagent should be treated in the same class as the In vitro diagnostic medical device reagent.

3. The Essential Principles

This guidance document describes fundamental design and manufacturing requirements, referred to as "Essential Principles for Safety and Performance" that, when met, indicate a medical device including *in-vitro* diagnostic medical device (hereafter referred as IVD medical device) is safe and performs to its specification.

There are seven general requirements of safety and performance that apply to all medical devices including IVD medical devices as specified in MDR 2017 of this document. There are further design and manufacturing requirements of safety and performance, some of which are relevant to each medical device. The design and manufacturing requirements in this document are grouped in following categories.

- Chemical, physical and biological properties;
- Infection and microbial contamination;
- Manufacturing and environmental properties;
- Devices incorporating a substance considered to be a medicinal product or drug;
- Devices incorporating materials of biological origin;
- Devices with a diagnostic or measuring function;
- Devices that incorporate software and standalone medical device software;
- Active medical devices and devices connected to them;
- Environmental properties;
- Protection against radiation;
- Protection against mechanical risks;
- Protection against the risks posed to the patient by supplied energy or substances;
- Protection against the risks posed to the patient for devices for self-testing or self-administration or intended by the manufacturer for use by lay persons;
- information supplied by the manufacturer i.e. Label and Instruction for Use;
- Performance evaluation including analytical performance and where appropriate, clinical evaluation.

In addition to the general essential principles as specified in the section 3.1 of this document, above listed additional essential principles for safety and performance which

need to be considered during the design and manufacturing process are further specified separately for,-

(i) Medical devices other than IVD medical devices, and
(ii) IVD medical devices.

Note: ***The manufacturer will select which of the design and manufacturing requirements are relevant to a particular medical device, documenting the reasons for excluding the others.***

Applicable standards used to meet essential principles for safety and performance

(A) A standard is a document, established by consensus and approved by a recognised body that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. Primarily, there are three types of standards:

(i) **Basic Standards or Horizontal Standards :** Standard indicating fundamental concepts, principles and requirements, with regard to general safety and performance aspects which are applicable to all kinds or a wide range of products and/or processes (e.g., standards concerning risk management, clinical investigation and the quality management system for the manufacture of medical devices).

(ii) **Group Standards or Semi-Horizontal Standards :** Standard indicating aspects applicable to families of similar products and/or processes making reference as far as possible to basic standards (e.g., standards concerning sterile medical devices, electrically-powered medical devices, stability of *in vitro* diagnostics reagents).

(iii) **Product Standard or Vertical Standard :** Standard indicating necessary safety and performance aspects of specific products and/or processes, making reference, as far as possible, to basic standards and group standards (e.g., standards for infusion pumps, for anaesthetic machines or for blood glucose meters for self-testing).

(B) Source of standards

Selection of Medical Devices Standards, as referred to in clause (A), which are used to establish conformity with the essential principles laid down in this document shall be as per the provisions of rule 7 of the Medical Devices Rules, 2017.

Definitions:

(i) "Analytical performance" means the ability of an IVD medical device to detect or measure a particular analyte.

(ii) "Clinical data" means safety or performance information that is generated from the clinical use of a medical device.

(iii) "Clinical evaluation" means 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.

(iv) "Clinical performance of an IVD medical device" means the ability of an IVD medical device to yield results that are correlated with a particular clinical condition or physiological state in accordance with target population and intended user.

(v) "Harm" means injury or damage to the health of people or damage to property or the environment.

(vi) "Hazard" potential source of harm.

(vii) "Lay person" means an individual that does not have formal training in a relevant field or discipline.

(viii) "Risk" means combination of the probability of occurrence of harm and the severity of that harm.

(ix) Words and expressions used but not defined in this document shall have the meanings respectively assigned to them in the Medical Devices Rules, 2017.

3.1 Essential Principles applicable to all medical devices including IVD medical devices – "General Principles"

3.1.1 Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

3.1.2 The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk(s) reduction is required, the manufacturer should control the risk(s) so that the residual risk associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed:

- Identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse;
- Eliminate risks as far as reasonably practicable through inherently safe design and manufacture;
- Reduce as far as reasonably practicable the remaining risks by taking adequate protection measures, including alarms; and
- Inform users of any residual risks.

3.1.3 Medical devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that, during normal conditions of use, they are suitable for their intended purpose.

3.1.4 The characteristics and performances referred to in clauses (3.1.1), (3.1.2) and (3.1.3) should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised

during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

3.1.5 Medical devices should be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.

3.1.6 All known and foreseeable risks, and any undesirable effects, should be minimised and be acceptable when weighed against the benefits of the intended performance of medical devices during normal conditions of use.

3.1.7 Every medical device requires clinical evidence, appropriate for its intended use and classification of the medical device, demonstrating that the device complies with the applicable provisions of the essential principles.

3.2 Essential Principles applicable to medical devices other than IVD medical devices

The design and manufacturing principles listed in this Section are additional to the general principles of safety and performance listed in Section 3.1.

3.2.1 Chemical, physical and biological properties:

A. The devices should be designed and manufactured in such a way as to ensure the characteristics and performance. Particular attention should be paid to,-

(a) The choice of materials used, particularly as regards toxicity, biodegradability and, where appropriate, flammability;

(b) The compatibility between the materials used and biological tissues, cells, and body fluids taking account of the intended purpose of the device;

(c) The choice of materials used, reflecting, where appropriate, matters such as hardness, wear and fatigue strength.

B. The devices should be designed, manufactured and packaged in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the device. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure.

C. The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products, they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.

D. The devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction.

E. Devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the device taking into account the device and the nature of the environment in which it is intended to be used.

3.2.2 Infection and microbial contamination:

A. The devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate

the risk of infection to patients, users and, where applicable, other persons. The design should,-

(a) Allow easy handling, and, where necessary;
(b) Reduce as far as reasonably practicable and appropriate any microbial leakage from the device and/or microbial exposure during use;
(c) Prevent microbial contamination of the device or specimen, where applicable, by the patient, user or other person.

B. Devices labelled as having a special microbiological state should be designed, manufactured and packaged to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.

C. Devices delivered in a sterile state should be designed, manufactured and packaged in a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.

D. Devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.

E. Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.

F. Packaging systems for non-sterile devices should maintain the integrity and cleanliness of the product and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the manufacturer.

G. The packaging or labelling of the device should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.

3.2.3 Medical devices incorporating a substance considered to be a medicinal product or drug:

A. Where a medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product or drug as defined in the Drugs and Cosmetics Act, 1940 and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and performance of the device as a whole should be verified, as well as the safety, quality and efficacy of the substance in the specific application.

3.2.4. Medical devices incorporating materials of biological origin:

A. Where a medical device incorporates substances of biological origin, the risk of infection must be reduced as far as reasonably practicable and appropriate by selecting appropriate sources, donors and substances and by using, as appropriate, validated inactivation, conservation, test and control procedures.

B. For medical devices incorporating non-viable tissues, cells and substances of animal origin should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. The manufacturer is required to retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

Explanation: For the purpose of this clause, veterinary controls shall also include that an animal source should be tested and to be free from Transmissible spongiform encephalopathies (TSEs) and Bovine spongiform encephalopathy (BSEs).

C. For medical devices incorporating cells, tissues and derivatives of microbial or recombinant origin, the selection of sources or donors, the processing, preservation, testing and handling of cells, tissues and derivatives of such origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

D. For medical devices incorporating non-viable human tissues, cells and substances, the selection of sources, donors or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

3.2.5. Manufacturing and Environmental properties:

A. If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system should be safe and should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer or mechanical coupling, should be designed and constructed in such a way as to minimize all possible risks from incorrect connection.

B. Devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate:

(i) The risk of injury to the patient, user or other persons in connection with their physical and ergonomic features;

(ii) The risk of use error due to the ergonomic features, human factors and the environment in which the device is intended to be used;

(iii) Risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature or variations in pressure and acceleration;

(iv) The risks associated with the use of the device when it comes into contact with materials, liquids, and gases to which it is exposed during normal conditions of use;

(v) The risk associated with the possible negative interaction between software and the environment within which it operates and interacts;

(vi) The risks of accidental penetration of substances into the device;

(vii) The risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.

C. Devices should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.

D. Devices should be designed and manufactured in such a way that adjustment, calibration, and maintenance, where such is necessary to achieve the performances intended, can be done safely.

E. Devices should be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.

3.2.6. Devices with a diagnostic or measuring function:

A. Diagnostic devices should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended use, based on appropriate scientific and technical methods. In particular the design should address sensitivity, specificity, trueness, repeatability, and reproducibility, control of known relevant interference and limits of detection, as appropriate.

B. Where the performance of devices depends on the use of calibrators or control materials, the traceability of values assigned to such calibrators or control materials should be assured through a quality management system.

C. Any measurement, monitoring or display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.

D. Wherever possible values expressed numerically should be in commonly accepted, standardized units, and understood by the users of the device.

3.2.7. Protection against radiation:

A. General:

Devices should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should be reduced as far as reasonably practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

B. Intended radiation:

Where devices are designed to emit hazardous, or potentially hazardous, levels of visible or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within acceptable tolerance. Where devices are intended to emit potentially hazardous,

visible or invisible radiation, they should be fitted, where reasonably practicable, with visual displays or audible warnings of such emissions.

C. Unintended radiation:

Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as reasonably practicable and appropriate.

D. Ionizing radiation:

(a) Devices intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where reasonably practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.

(b) Devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.

(c) Devices emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.

E. The operating instructions for a medical device that emits radiation must include detailed information about the following matters:

(a) The nature of the radiation emitted;

(b) The means by which patients and users can be protected from the radiation;

(c) Ways to avoid misusing the device; and

(d) Ways to eliminate any risks inherent in the installation of the device.

3.2.8. Medical devices that incorporate software and standalone medical device software:

A. Devices incorporating electronic programmable systems including software or standalone software that are devices in themselves, should be designed to ensure repeatability, reliability and performance according to the intended use. In the event of a single fault condition, appropriate means should be adopted to eliminate or reduce as far as reasonably practicable and appropriate consequent risks.

B. For devices which incorporate software or for standalone software that are devices in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, verification and validation.

3.2.9. Active medical devices and devices connected to them:

A. For active medical devices, in the event of a single fault condition, appropriate means should be adopted to eliminate or reduce as far as reasonably practicable and appropriate consequent risks.

B. Devices where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.

C. Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.

D. Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

E. Devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks of creating

electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.

F. Devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.

G. Devices should be designed and manufactured in such a way as to avoid, as far as reasonably practicable, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.

3.2.10. Protection against mechanical risks:

A. Devices should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

B. Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

C. Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

D. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.

E. Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level, the risk of error when certain parts within the device are intended to be connected or reconnected before or during use.

F. Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal conditions of use.

3.2.11. Protection against the risks posed to the patient or user by supplied energy or substances:

A. Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.

B. Devices should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.

C. The function of the controls and indicators should be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.

3.2.12. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons:

A. Devices for use by lay persons should be designed and manufactured in such a way that they perform appropriately for their intended purpose

taking into account the skills and the means available to lay persons and the influence resulting from variation that can reasonably be anticipated in the layperson's technique and environment. The information and instructions provided by the manufacturer should be easy for the lay person to understand and apply.

B. Devices for use by lay persons should be designed and manufactured in such a way as to reduce as far as reasonably practicable the risk of error during use by the lay person in the handling of the device and also in the interpretation of results.

C. Devices for use by lay persons should, where reasonably possible, include a procedure by which the lay person can verify that, at the time of use, the product will perform as intended by the manufacturer.

3.2.13. Label, direction or Instructions for Use (IFU):

A. Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge.

B. This information should be easily understood and detailed information for labelling should be incorporated as provided in the Chapter VI: labelling of Medical device, of the Medical Device Rules, 2017.

3.2.14. Clinical evaluation:

A. For all medical devices, the demonstration of conformity with essential principles includes a clinical evaluation. The clinical evaluation should review clinical data in the form of any,

(a) Clinical investigation reports; or

(b) Literature reports/reviews; or

(c) Clinical experience,

to establish that a favorable benefit-risk ratio exists for the device.

B. Clinical investigations:

Clinical investigations on human subjects should be carried out in accordance with the provisions of Medical Devices Rules, 2017. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.

3.3. Essential Principles applicable to IVD medical devices

The design and manufacturing principles listed in this Section are additional to the general principles of safety and performance listed in Section 3.1.

3.3.1 Chemical, physical and biological properties:

A. The IVD medical devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Section 3.1. Particular attention should be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the specimens and/or analyte (measurand) to be detected (such as biological tissues, cells, body fluids and microorganisms), taking account of its intended purpose.

B. The IVD medical devices should be designed, manufactured and packaged in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the device.

C. The IVD medical devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the IVD medical device. Special attention should be given to substances which are carcinogenic, mutagenic or toxic to reproduction.

D. IVD medical devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the IVD

medical device taking into account the device and the nature of the environment in which it is intended to be used.

3.3.2 Infection and microbial contamination:

A. The IVD medical devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to user, professional or lay, or, where applicable, other person. The design should:

(a) Allow easy and safe handling;

and, where necessary:

(b) Reduce as far as reasonably practicable and appropriate any microbial leakage from the IVD medical device and/or microbial exposure during use; and

(c) Prevent microbial contamination of the IVD medical device or specimen where applicable, by the user, professional or lay, or other person.

B. IVD medical devices labelled either as sterile or as having a special microbiological state should be designed, manufactured and packaged to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer, until the protective packaging is damaged or opened.

C. IVD medical devices labelled either as sterile or as having a special microbiological state should have been processed manufactured and, if applicable, sterilized by appropriate, validated methods.

D. IVD medical devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.

E. Packaging systems for non-sterile IVD medical devices should maintain the integrity and cleanliness of the device.

3.3.3 IVD medical devices incorporating materials of biological origin:

A. Where IVD medical devices include tissues, cells and substances originating from animals, the processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety for user, professional or lay, or other person. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.

B. Where IVD medical devices include human tissues, cells and substances, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety for user, professional or lay, or other person. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.

C. Where IVD medical devices include cells and substances of microbial origin, the processing, preservation, testing and handling of cells and substances should be carried out so as to provide optimal safety for user, professional or lay, or other person. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the IVD medical device or when such

elimination or inactivation process would compromise the performance of the IVD medical device.

3.3.4 Environmental properties:

A. If the IVD medical device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use.

B. IVD medical devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate:

(i) The risk of injury to user, professional or lay, or other person in connection with their physical and ergonomic features;

(ii) the risk of use error due to the ergonomic features, human factors and the environment in which the IVD medical device is intended to be used;

(iii) Risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations thereof;

(iv) the risks associated with the use of the IVD medical device when it comes into contact with materials, liquids, and gases to which it is exposed during normal conditions of use;

(v) The risk associated with the possible negative interaction between software and the environment within which it operates and interacts;

(vi) The risks of accidental penetration of substances into the IVD medical device;

(vii) The risk of incorrect identification of specimens or samples;

(viii) The risks of reasonably foreseeable interference with other devices such as carry over between IVD medical devices.

C. IVD medical devices should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to IVD medical devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.

D. IVD medical devices should be designed and manufactured in such a way that adjustment, calibration, and maintenance, where such is necessary to achieve the performances intended, can be done safely.

E. IVD medical devices should be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.

3.3.5 Performance Evaluation:

A. IVD medical devices should be designed and manufactured in such a way that the performance evaluation supports the intended use, based on appropriate scientific and technical methods. In particular, where appropriate, the design should address sensitivity, specificity, accuracy which is trueness and precision (repeatability and reproducibility), control of known relevant interference and limits of detection.

These performance evaluation need to be maintained during the lifetime of the IVD medical device as indicated by the manufacturer.

B. Where the performance of devices depends on the use of calibrators and/or control materials, the traceability of values assigned to such calibrators and/or control materials should be assured through available reference measurement procedures and/or available reference materials of a higher order.

C. Wherever possible values expressed numerically should be in commonly accepted, standardized units, and understood by the users of the device.

3.3.6 Protection against radiation:

A. IVD medical devices should be designed, manufactured and packaged in such a way that exposure of user, professional or lay, or other person to the emitted radiation (intended, unintended, stray or scattered) is reduced as far as reasonably practicable and appropriate.

B. When IVD medical devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should as far as reasonably practicable and appropriate be:

(a) Designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and

(b) Fitted with visual displays and/or audible warnings of such emissions.

3.3.7 IVD medical devices that incorporate software and standalone IVD medical device software:

A. For IVD medical devices which incorporate software or for standalone software that are IVD medical devices in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, verification and validation.

3.3.8 IVD medical devices connected to, or equipped with, an energy source:

A. IVD medical devices where the safety of the patient depends on an internal power supply in the IVD medical device, should be equipped with a means of determining the state of the power supply.

B. IVD medical devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.

C. IVD medical devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.

D. IVD medical devices should be designed and manufactured in such a way as to avoid, as far as reasonably practicable, the risk of accidental electric shocks to the user, professional or lay, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the IVD medical device is installed and maintained as indicated by the manufacturer.

3.3.9 Protection against mechanical and thermal risks:

A. IVD medical devices should be designed and manufactured in such a way as to protect the user, professional or lay, or other person against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

B. Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means must be incorporated.

C. IVD medical devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

D. IVD medical devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source.

E. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user, professional or lay, or other person has to

handle should be designed and constructed in such a way as to minimize all possible risks.

F. IVD medical devices should be designed and manufactured in such a way as to reduce to the lowest practicable level, the risk of error when certain parts within the device are intended to be connected or reconnected before or during use.

G. Accessible parts of the IVD medical devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal use.

3.3.10 Protection against the risks posed by IVD medical devices for self-testing:

A. IVD medical devices for self-testing should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can reasonably be anticipated in the layperson's technique and environment. The information and instructions provided by the manufacturer should be easy for the lay person to understand and apply.

B. IVD medical devices for self-testing should be designed and manufactured in such a way as to reduce as far as reasonably practicable the risk of error by the lay person in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.

C. IVD medical devices for self-testing should, where reasonably possible, include a procedure by which the lay person can verify that, at the time of use, the product will perform as intended by the manufacturer.

3.3.11 Label and Instructions for Use:

A. Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge. This information should be easily understood.

3.3.12 Performance evaluation including analytical performance and, where appropriate, clinical performance:

A. For an IVD medical device a performance evaluation should be conducted in accordance with provisions of Medical Device Rules, 2017. The performance evaluation should be reviewed for, but not limited to, analytical performance data and, where appropriate, clinical performance data in the form of any:

(i) Literature;

(ii) Performance study reports; and

(iii) Experience gained by routine diagnostic testing to establish that the IVD medical device achieves its intended performance during normal conditions of use and that the known, and foreseeable risks, and any undesirable effects, are minimized and acceptable when weighed against the benefits of the intended performance.

B. For new *in vitro* diagnostic medical devices, Clinical Performance Evaluation studies using specimens from human subjects should be carried out in accordance with the provisions of the Medical Devices Rules, 2017.

3.4 Technical Documentation

The manufacturer shall retain or be able to provide documentation to demonstrate that the device conforms to the selected standard or alternative means of meeting the Essential Principles.

4. Quality Management System – for Notified Medical Devices and *In-Vitro* Diagnostics

1. General Requirements:

1.1. This section (Fifth schedule of Medical Devices Rules 2017) specifies requirements for a quality management system that shall be used by the manufacturer for the design and development, manufacture, packaging, labelling, testing, installation and servicing of medical devices and *in-vitro* diagnostics. If the manufacturer does not carry out design and development activity, the same shall be recorded in the quality management system. The manufacturer shall maintain conformity with this Schedule to reflect the exclusions.

1.2. If any requirement in clause 7 (product realisation) of this Schedule is not applicable due to the nature of the medical device and *in-vitro* diagnostics for which the quality management system is applied, the manufacturer does not need to include such a requirement in its quality management system.

1.3. The processes required by this Schedule, which are applicable to the medical device and *in-vitro* diagnostic devices, but which are not performed by the manufacturer are the responsibility of the manufacturer and are accounted for in the manufacturer‘s quality management system.

1.4. If a manufacturer engages in only some operations subject to the requirements of this part, and not in others, that manufacturer need only to comply with those requirements which are applicable to the operations in which it is engaged.

1.5. It is emphasised that the quality management system requirements specified in this Schedule are in addition to complementary to technical requirements for products.

1.6. Manufacturers of components or parts of finished devices and *in-vitro* diagnostics are encouraged to use appropriate provisions of this regulation as guidance.

2. Applicability:

The provisions of this section shall be applicable to manufacturers of finished devices, *In-vitro* Diagnostics, mechanical contraceptives (condoms, intrauterine devices and tubal rings), surgical dressings, surgical bandages, surgical staplers, surgical sutures and ligatures, blood and blood components collection bags with or without anticoagulants intended for human or animal use.

3. Terms and definitions:

3.1 Active implantable medical device- Active medical device which is intended to be totally or partially introduced, surgically or medically, into the human or animal body or by medical intervention into a natural orifice and which is intended to remain after the procedure.

3.2 Active medical device- Medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human or animal body or gravity.

3.3 Advisory notice- Notice issued by the manufacturer, subsequent to delivery of the medical device and *in-vitro* diagnostic devices, to provide supplementary information or to advise what action should be taken in or both in:-

- the use of a medical device and *in-vitro* diagnostic devices;
- the modification of a medical device and *in-vitro* diagnostic devices;
- the return of the medical device and *in-vitro* diagnostic devices to the organization that supplied it; or
- the destruction of a medical device and *in-vitro* diagnostic devices.

3.4 Customer complaint. - Written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a medical device and *in-vitro* diagnostic devices that has been placed on the market.

3.5 Implantable medical device. - Medical device intended:-

- to be totally or partially introduced into the human or animal body or a natural orifice; or
- to replace an epithelial surface or the surface of the eye;
- by surgical intervention, and which is intended to remain after the procedure for at least thirty days, and which can only be removed by medical or surgical intervention.

3.6 Component means any raw material, substance, piece, part, software, firmware, labelling, or assembly which is intended to be included as part of the finished, packaged, and labelled device.

3.7 Design input means the physical and performance requirements of a device that are used as a basis for device design.

3.8 Design output means the results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labelling, and the device master record.

3.9 Design review means a documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.

3.10 Finished device means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labelled or sterilized.

3.11 Management with executive responsibility means those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy and quality system.

3.12 Medical device referred in this Schedule means devices that are notified.

3.13 Quality audit means a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.

3.14 Quality policy means the overall intention and direction of an organization with respect to quality, as established by management with executive responsibility.

3.15 Quality system means the organisational structure, responsibilities, procedures, processes, and resources for implementing quality management.

3.16 Rework means action taken on a nonconforming product that will fulfill the specified Device Master File requirements before it is released for distribution.

3.17 Specification means any requirement with which a product, process, service, or other activity must conform.

3.18 Validation means confirmation by examination and provision of objective evidence that the particular requirement for a specific intended use can be consistently fulfilled;

3.18.1 **Process validation** means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

3.18.2 **Design validation** means establishing by objective evidence that device specifications conform with user needs and intended use(s).

3.19 Verification means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

4. Quality management system

4.1 General:

The manufacturer shall establish, document, implement and maintain a quality management system and maintain its effectiveness in accordance with the requirements of this schedule.

The manufacturer shall;-

(a) identify the processes needed for the quality management system and their application throughout the organization;

(b) determine the sequence and interaction of these processes;

(c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective;

(d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes;

(e) monitor, measure and analyse these processes; and

(f) implement actions necessary to achieve planned results and maintain the effectiveness of these processes.

These processes shall be managed by the manufacturer in accordance with the requirements of this Schedule. Where a manufacturer chooses to outsource any process that affects product conformity with requirements, the manufacturer shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE: Processes needed for the quality management system referred to above shall include processes for management activities, provision of resources, product realization and measurement.

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include;-

a) documented statements of a quality policy and quality objectives;

b) a quality manual;

c) documented procedures required by this schedule;

d) documents needed by the manufacturer to ensure the effective planning, operation and control of its processes;

e) records required by this schedule, and

where this schedule specifies that a requirement, procedure, activity or special arrangement be "documented", it shall, in addition, be implemented and maintained.

For each type or model of medical device or *In-vitro* Diagnostics, the manufacturer shall establish and maintain a file either containing or identifying documents defining product specifications and quality management system requirements. These documents shall define the complete manufacturing process and, if applicable, installation.

The manufacture shall prepare documentation for device or *in-vitro* diagnostics in a form of a Device Master File containing specific information as referred to in Annexure-A appended to this Schedule.

Data may be recorded by electronic data processing systems or other reliable means, but documents and record relating to the system in use shall also be available in a hard copy to facilitate checking of the accuracy of the records. Wherever documentation is handled by electronic data processing methods, authorized persons shall enter or modify data in the computer. There shall be record of changes and deletions. Access shall be restricted by 'passwords' or other means and the result of entry of critical data shall be independently checked. Batch records electronically stored shall be protected by a suitable back-up. During the period of retention, all relevant data shall be readily available.

4.2.2 Quality manual

The manufacturer shall establish and maintain a quality manual that includes:-

a) the scope of the quality management system, including details of and justification for any exclusion or non-application or both;

b) the documented procedures established for the quality management system, or reference to them; and

c) a description of the interaction between the processes of the quality management system. The quality manual shall outline the structure of the documentation used in the quality management system.

The manufacturer shall prepare documentation in a form of a Plant Master File containing specific information about the facilities, personnel and other details as prescribed in Annexure B appended to this Schedule.

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in the control of records. Documents shall be approved, signed and dated by the appropriate and the authorised person.

A documented procedure shall be established to define the controls needed.-

(a) to review and approve documents for adequacy prior to issue;
(b) to review and update as necessary and re-approve documents;
(c) to ensure that changes and the current revision status of documents are identified;
(d) to ensure that relevant versions of applicable documents are available at points of use;
(e) to ensure that documents remain legible and readily identifiable;
(f) to ensure that documents of external origin are identified and their distribution controlled; and
(g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Changes to document shall be reviewed and approved. Change records shall be maintained which will include a description of the change, identification of the affected documents, the signature of the approving individual, the approval date, and when the change becomes effective.

The manufacturer shall ensure that changes to documents are reviewed and approved either by the original approving functionary or another designated functionary which has access to pertinent background information upon which to base its decisions.

The manufacturer shall define the period for which at least one copy of obsolete controlled documents shall be retained. This period shall ensure that documents to which medical devices or *in-vitro* diagnostics have been manufactured and tested are retained for at least

one year after the date of expiry of the medical device or *in-vitro* diagnostic as defined by the manufacturer.

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to the requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

The manufacturer shall retain the records for a period of time at least one year after the date of expiry of the medical device or *in-vitro* diagnostics as defined by the manufacturer, but not less than two years from the date of product release by the manufacturer.

5. Management responsibility

5.1 Management commitment:

Top management of the manufacturer shall provide evidence of its commitment to the development and implementation of the quality management system and maintaining its effectiveness by:-

a) communicating to the employees the importance of meeting customer as well as statutory and regulatory requirements;
b) establishing the quality policy;
c) ensuring that quality objectives are established;
d) conducting management reviews; and
e) ensuring the availability of resources.

5.2 Customer focus:

Top management of the manufacturer shall ensure that customer requirements are determined and are met.

5.3 Quality policy:

Top management of the manufacturer shall ensure that the quality policy:-

(a) is appropriate to the purpose of the manufacturing facility;

(b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system;

(c) provides a framework for establishing and reviewing quality objectives;

(d) is communicated and understood within the manufacturer‘s organization; and

(e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives:

Top management of the manufacturer shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the manufacturing organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality management system planning:

Top management of the manufacturer shall ensure that.-

(a) the planning of the quality management system is carried out in order to meet the specified requirements, as well as the quality objectives; and

(b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, authority and communication-

5.5.1 Responsibility and authority:

Top management of the manufacturer shall ensure that responsibilities and authorities are defined, documented and communicated within the manufacturing organisation.

Top management of the manufacturer shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks.

5.5.2 Management representative:

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes:-

(a) ensuring that processes needed for the quality management system are established, implemented and maintained;

(b) reporting to top management on the performance of the quality management system and any need for improvement; and

(c) ensuring the promotion of awareness of regulatory and customer requirements throughout the manufacturing organization.

5.5.3 Internal communication:

Top management shall ensure that appropriate communication processes are established within the Manufacturing organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review.-

5.6.1 General:

Top management shall review the organization‘s quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained.

5.6.2 Review input:

The input to management review shall include information on:-

(a) results of audits,

(b) customer feedback,

(c) process performance and product conformity,

(d) status of preventive and corrective actions,

(e) follow-up actions from previous management reviews,

(f) changes that could affect the quality management system,

(g) recommendations for improvement, and

(h) new or revised regulatory requirements as and when issued.

5.6.3 Review output:

The output from the management review shall include any decisions and actions related to improvements needed to maintain the effectiveness of the quality management system and its processes

(a) improvement of product related to customer requirements, and

(b) resource needs.

6 Resource management-

6.1 Provision of resources:

The manufacturing organization shall determine and provide the resources needed

a) to implement the quality management system and to maintain its effectiveness, and

b) to meet regulatory and customer requirements.

6.2 Human resources-

6.2.1 General:

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. Number of personnel employed shall be adequate and in direct proportion to the workload. Prior to employment, all personnel, shall undergo medical examination including eye examination, and shall be free from communicable or contagious diseases. Thereafter, they should be medically examined periodically, at least once a year. Records shall be maintained thereof.

6.2.2 Competence, awareness and training:

The manufacturer shall:-

(a) determine the necessary competence for personnel performing work affecting product quality,

(b) provide training or take other actions to satisfy these needs,

(c) evaluate the effectiveness of the actions taken,

(d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives,

(e) maintain appropriate records of education, training, skills and experience, and

(f) establish documented procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities.

6.3 Infrastructure:

The organisation shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:-

a) buildings, workspace and associated utilities.

b) process equipment (both hardware and software), and

c) supporting services (such as transport or communication).

The manufacturer shall establish documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality. Records of such maintenance shall be maintained.

6.4 Work environment:

The organisation shall determine and manage the work environment needed to achieve conformity to product requirements. The following requirements shall apply, namely:-

(a) the manufacturer shall establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product;

(b) if work environment conditions can have an adverse effect on product quality, the manufacturer shall establish documented requirements as per **Annexure-C** of this schedule for the work environment conditions and documented procedures or work instructions to monitor and control these work environment condition;

(c) the manufacturer shall ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained and supervised by a trained person;

(d) if appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel.

(e) all personnel shall bear clean body covering appropriate to their duties. Smoking, eating, drinking, chewing or keeping food and drink shall not be permitted in production, laboratory and storage areas.

7 Product realisation

7.1 Planning of product realization:

The manufacturer shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.

In planning product realisation, the manufacturer shall determine the following, as appropriate:-

(a) quality objectives and requirements for the product;

(b) the need to establish processes, documents, and provide resources specific to the product;

(c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;

(d) records needed to provide evidence that the realisation processes and resulting product meet requirements.

The output of this planning shall be in a form suitable for the manufacturer‘s method of operations.

The manufacturer organisation shall establish documented requirements for risk management (as per the IS or ISO 14971) throughout product realisation. Records arising from risk management shall be maintained.

7.2 Customer-related processes-

7.2.1 Determination of requirements related to the product:

The manufacturer shall determine:-

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

b) requirements not stated by the customer but necessary for specified or intended use, where known;

c) statutory requirements related to the product, and

d) any additional requirements determined by the manufacturer.

7.2.2 Review of requirements related to the product:

The manufacturer shall review the requirements related to the product. This review shall be conducted prior to the manufacturer's commitment to supply a product to the customer and shall ensure that:-

(a) product requirements are defined and documented;

(b) contract or order requirements differing from those previously expressed are resolved; and

(c) the manufacturer has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the manufacturer before acceptance.

Where product requirements are changed, the manufacturer shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Customer communication:

The manufacturer shall determine and implement effective arrangements for communicating with customers in relation to:-

(a) product information;

(b) enquiries, contracts or order handling, including amendments;

(c) customer feedback, including customer complaints; and

(d) advisory notices.

7.3 Design and development-

7.3.1 Design and development planning:

The manufacturer shall establish documented procedures for design and development. The manufacturer shall plan and control the design and development of product. During the design and development planning, the manufacturer shall determine:-

A. the design and development stages;
B. the review, verification, validation and design transfer activities that are appropriate at each design and development stage; and
C. the responsibilities and authorities for design and development.

The manufacturer shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be documented, and updated as appropriate, as the design and development progresses.

NOTE: Design transfer activities during the design and development process ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications.

7.3.2 Design and development inputs:

Inputs relating to product requirements shall be determined and records maintained. The design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patients. These inputs shall include:-

(a) functional, performance and safety requirements, according to the intended use;

(b) applicable statutory and regulatory requirements;

(c) where applicable, information derived from previous similar designs;

(d) other requirements essential for design and development; and

(e) output(s) of risk management.

These inputs shall be reviewed for adequacy and approved by designated individual. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and development outputs:

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be documented, reviewed, and approved prior to release.

Design and development outputs shall:-

(a) meet the input requirements for design and development;

(b) provide appropriate information for purchasing, production and for service provision;

(c) contain or reference product acceptance criteria; and

(d) specify the characteristics of the product that are essential for its safe and proper use.

Records of the design and development outputs shall be maintained.

Records of design and development outputs can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks.

7.3.4 Design and development review:

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements:-

(a) to evaluate the ability of the results of design and development to meet requirements; and

(b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage being reviewed, as well as other specialist personnel. Records of the results of the reviews and any necessary actions shall be maintained.

7.3.5 Design and development verification:

Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained.

7.3.6 Design and development validation:

Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use.

Design validation shall be performed under defined operating conditions on initial production units, lots, or batches or their equivalence. Design validation shall include software validation and risk analysis, where appropriate validation shall be completed prior to the delivery or implementation of the product.

Records of the results of validation and any necessary actions shall be maintained.

As part of design and development validation, the manufacturer shall perform clinical evaluations and/or evaluation of performance of the medical device or *In-vitro* Diagnostics.

NOTE 1- If a medical device or *In-vitro* Diagnostic can only be validated following assembly and installation at point of use, delivery is not considered to be complete until the product has been formally transferred to the customer.

NOTE 2- Provision of the medical device for purposes of clinical evaluations and/or evaluation of performance is not considered to be delivery.

7.3.7 Control of design and development changes:

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before

implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained.

Note.-Each manufacturer shall establish and maintain a Design History File for each type of device. The Design History File shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of design and development.

7.4 Purchasing

7.4.1 Purchasing process:

The manufacturer organisation shall establish documented procedures to ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realisation or the final product.

The manufacturer shall evaluate and select suppliers based on their ability to supply product in accordance with the manufacturer‘s requirements. Criteria for selection, evaluation and re-evaluation shall be established.

Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

7.4.2 Purchasing information:

Purchasing information shall describe the product to be purchased, including where appropriate:-

(a) requirements for approval of product, procedures, processes and equipment;

(b) requirements for qualification of personnel; and

(c) quality management system requirements.

The manufacturer shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

To the extent required for traceability, the manufacturer shall maintain documents and records of relevant purchasing information.

7.4.3 Verification of purchased product:

The manufacturer shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the manufacturer intends to perform verification at the supplier‘s premises, the manufacturer shall state the intended verification arrangements and method of product release in the purchasing information. Records of the verification shall be maintained.

7.5 Production and service provision

7.5.1 Control of production and service provision:

7.5.1.1 General requirements:

The manufacturer shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable:-

(a) the availability of information that describes the characteristics of the product,

(b) the availability of documented procedures, documented requirements, work instructions; and reference materials and reference measurement procedures as necessary;

(c) the use of suitable equipment;

(d) the availability and use of monitoring and measuring devices;

(e) the implementation of monitoring and measurement;

(f) the implementation of release, delivery and post-delivery activities; and

(g) the implementation of defined operations for labelling and packaging.

The manufacturer shall establish and maintain a record for each batch of medical device or *In-vitro* Diagnostic devices that provides traceability and identifies the amount manufactured and amount approved for distribution. The batch record shall be verified and approved.

7.5.1.2 Control of production and service provision — Specific requirements

7.5.1.2.1 Cleanliness of product and contamination control:

The manufacturer shall establish documented requirements for cleanliness of product if:-

(a) product is cleaned by the manufacturer prior to sterilisation or its use; or

(b) product is supplied non-sterile to be subjected to a cleaning process prior to sterilisation or its use; or

(c) product is supplied to be used non-sterile and its cleanliness is of significance in use; or

(d) process agents are to be removed from product during manufacture.

If the product is cleaned in accordance with (a) or (b) above, the requirements content in clause 6.4 (a) and (b) do not apply prior to the cleaning process

7.5.1.2.2 Installation activities:

If appropriate, the manufacturer shall establish documented requirements which contain acceptance criteria for installing and verifying the installation of the medical device or *In-vitro* Diagnostic device.

If the agreed customer requirements allow installation to be performed other than by manufacturer or its authorised agent, the manufacturer shall provide documented requirements for installation and verification. Records of installation and verification performed by the manufacturer or its authorized agent shall be maintained.

7.5.1.3 Particular requirements for sterile medical devices:

The manufacturer shall maintain records of the process parameters for the sterilisation process which was used for each sterilisation batch. Sterilisation records shall be traceable to each production batch of medical device.

7.5.2 Validation of processes for production and service provision-

7.5.2.1 General:

The manufacturer shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use. Validation shall demonstrate the ability of these processes to achieve planned results.

The manufacturer shall establish arrangements for these processes including, as applicable:-

A defined criteria for review and approval of the processes;

B approval of equipment and qualification of personnel

C use of specific methods and procedures,;

D requirements for records; and

E revalidation.

The manufacturer shall establish documented procedures for the validation of the application of computer software (and its changes to such software or its application) for production and service provision that affect the ability of the product conform to specified requirements. Such software applications shall be validated prior to initial use.

Records of validation shall be maintained.

7.5.2.2 Particular requirements for sterile medical devices:

The manufacturer shall establish documented procedures for the validation of sterilization processes. Sterilisation processes shall be validated prior to initial use. The records of validation of each sterilisation process shall be maintained.

7.5.3 Identification and traceability-

7.5.3.1 Identification:

The manufacturer shall identify the product by suitable means throughout product realization, and shall establish documented procedures for such product identification. The manufacturer shall establish documented procedures to ensure that medical devices and *In-vitro* Diagnostics returned to the manufacturer are identified and distinguished from conforming product.

7.5.3.2 Traceability

7.5.3.2.1 General:

The manufacturer shall establish documented procedures for traceability. Such procedures shall define the extent of product traceability and the records required.

Where traceability is a requirement, the manufacturer shall control and record the unique identification of the product.

NOTE- Configuration management is a means by which identification and traceability can be maintained.

7.5.3.2.2 Particular requirements for active implantable medical devices and implantable medical devices:

In defining the records required for traceability, the manufacturer shall include records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements.

The manufacturer shall require that its agents or distributors maintain records of the distribution of active implantable medical devices and implantable medical devices to allow traceability and that such record are available for inspection. Records of the name and address of the shipping package consignee shall be maintained.

7.5.3.3 Status identification:

The manufacturer shall identify the product status with respect to monitoring and measurement requirements. The identification of product status shall be maintained throughout production, storage, implant, usage and installation of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed.

7.5.4 Customer property:

The manufacturer shall exercise care with customer property while it is under the manufacturer‘s control or being used by the manufacturer. The manufacturer shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained.

NOTE- Customer property can include intellectual property or confidential health information.

7.5.5 Preservation of product:

The manufacturer shall establish documented procedures or documented work instructions for preserving the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

The manufacturer shall establish documented procedures or documented work instructions for the control of product with a limited shelf-life or requiring special storage conditions. Such special storage conditions shall be controlled and recorded.

7.6 Control of monitoring and measuring devices:

The manufacturer shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.

The manufacturer shall establish documented procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall be:-

(a) calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to Bureau of Indian Standards wherever available ; where no such standards exist, the basis used for calibration or verification shall be recorded;

(b) adjusted or re-adjusted as necessary;

(c) identified to enable the calibration status to be determined;

(d) safeguarded from adjustments that would invalidate the measurement result;

(e) protected from damage and deterioration during handling, maintenance and storage.

In addition, the manufacturer shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The manufacturer shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

8 Measurement, analysis and improvement-

8.1 General:

The manufacturer shall plan and implement the monitoring, measurement, analysis and improvement processes needed:-

(a) to demonstrate conformity of the product;

(b) to ensure conformity of the quality management system; and

(c) to maintain the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

Note- If relevant Indian standards are not available, International standards are applicable. In case no Indian or International standards are available, validated testing process of the manufacturer is applicable.

8.2 Monitoring and measurement

8.2.1 Feedback:

As one of the measurements of the performance of the quality management system, the manufacturer shall monitor information relating to whether the manufacturer has met customer or regulatory requirements. The methods for obtaining and using this information shall be determined.

The manufacturer shall establish a documented procedure for a feedback system to provide early warning of quality problems and for input into the corrective and preventive action processes.

8.2.2 Internal audit:

The manufacturer shall conduct internal audits at planned intervals to determine whether the quality management system:-

a) conforms to the planned arrangements, to the requirements of this schedule and to the quality management system requirements established by the manufacturer, and

b) is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

8.2.3 Monitoring and measurement of processes:

The manufacturer shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

8.2.4 Monitoring and measurement of product.-

8.2.4.1 General requirements:

The manufacturer shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realisation process in accordance with the planned arrangements and documented procedures.

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product. Product release shall not proceed until the planned arrangements have been satisfactorily completed.

8.2.4.2 Particular requirement for active implantable medical devices and implantable medical

Devices wherever applicable:

The manufacturer shall record the identity of personnel performing any inspection or testing.

8.3 Control of nonconforming product

The manufacturer shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The

controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

The manufacturer shall deal with nonconforming product by one or more of the following ways:

(a) by taking action to eliminate the detected nonconformity;

(b) by authorizing its use, release or acceptance under concession;

(c) by taking action to preclude its original intended use or application.

The manufacturer shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met. Records of the identity of the person authorisng the concession shall be maintained.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. When nonconforming product is detected after delivery or use has started, the manufacturer shall take action appropriate to the effects, or potential effects, of the non-conformity.

If product needs to be reworked (one or more times), the manufacturer shall document the rework process in a work instruction that has undergone the same authorisation and approval procedure as the original work instruction. Prior to authorisation and approval of the work instruction, a determination of any adverse effect of the rework upon product shall be made and documented.

8.4 Analysis of data:

The manufacturer shall establish documented procedures to determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate whether improvement of the effectiveness of the quality management system can be made.

This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to:-

(a) feedback

(b) conformity to product requirements;

(c) characteristics and trends of processes and products including opportunities for preventive action; and

(d) suppliers.

Records of the results of the analysis of data shall be maintained.

8.5 Improvement-

8.5.1 General:

The manufacturer shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

The manufacturer shall establish documented procedures for the issue and implementation of advisory notices. These procedures shall be capable of being implemented at any time. Records of all customer complaint investigations shall be maintained. If investigation determine that the activities outside the manufacturer‘s organisation contributed to the customer complaint, relevant information shall be exchanged between the organisations involved.

If any customer complaint is not followed by corrective or preventive action, the reason shall be recorded and approved. Manufacturer shall notify the adverse event to the regulatory authority and establish documented procedures for the same.

8.5.2 Corrective action:

The manufacturer shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for:-

(a) reviewing nonconformities (including customer complaints);

(b) determining the causes of nonconformities;

(c) evaluating the need for action to ensure that nonconformities do not recur

(d) determining and implementing action needed, including, if appropriate, updating documentation;

(e) recording of the results of any investigation and of action taken; and

(f) reviewing the corrective action taken and its effectiveness.

8.5.3 Preventive action:

The manufacturer shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for

1 determining potential nonconformities and their causes,

2 evaluating the need for action to prevent occurrence of nonconformities,

3 determining and implementing action needed,

4 recording of the results of any investigations and of action taken, and

5 reviewing preventive action taken and its effectiveness.

Annexure - A

(refer para 4.2.1)

The manufacturer shall prepare a succinct document in the form of Device Master File containing specific information about the device manufacturing in the premises.

1.0 Executive Summary:

An executive summary shall be provided by the manufacturer and shall contain:

Introductory descriptive information on the medical device or *In-vitro* Diagnostics, the intended use and indication for use, Class of Device, novel features of the device (if any), shelf life of the device and a synopsis on the content of the dossier information regarding sterilisation of the device (whether it is sterile or non-sterile; if sterile, mode of sterilisation)

2.0 Device Description and Product Specification, Including Variants and Accessories:

2.1 Device Description

2.2 Product Specification

2.3 Reference to predicate and/or previous generations of the device

3.0 Labelling

4.0 Design and Manufacturing Information

4.1 Device Design

4.2 Manufacturing Processes

5.0 Essential Principles (EP) Checklist

6.0 Risk Analysis and Control Summary

7.0 Product Verification and Validation

7.1 Biocompatibility

7.2 Medicinal Substances

7.3 Biological Safety

7.4 Sterilisation

7.5 Software Verification and Validation

7.6 Animal Studies

7.7 Shelf Life/Stability Data

7.8 Clinical Evidence

7.9 Post Marketing Surveillance Data (Vigilance Reporting)

8. Additional information in case of diagnostic kits: Product dossier showing the:

8.1 The details of source antigen or antibody as the case may be and characterization of the same.

Process control of coating of antigen or antibody on the base material like Nitrocellulose paper, strips or cards or enzyme-linked immunosorbent assay (ELISA) wells etc.

Detailed composition of the kit and manufacturing flow chart process of the kit showing the specific flow diagram of individual components or source of the individual components.

8.2 Test protocol of the kit showing the specifications and method of testing. In house evaluation report of sensitivity, specificity and stability studies.

8.3 The detailed test report of all the components used/packed in the finished kit.

8.4 Pack size and labelling.

8.5 Product inserts.

Specific evaluation report, if done by any laboratory in India, showing the sensitivity and specificity of the kit.

Specific processing like safe handling, material control, area control, process control, and stability studies, storage at quarantine stage and finished stage, packaging should be highlighted in the product dossier.

Annexure - B

(refer para 4.2.2)

The manufacturer shall prepare a succinct document in the form of Plant Master File containing specific information about the production and/or control of device manufacturing carried out at the premises. It shall contain the following information:

1. General Information:

(i) brief information on the site (including name and address), relation to other sites;

(ii) manufacturing activities;

(iii) any other operations carried out on the site

(iv) name and exact address of the site, including telephone, fax numbers, web site URL and e-mail address;

(v) type of medical devices handled on the site and information about specifically toxic or hazardous substances handled, mentioning the way they are handled and precautions taken;

(vi) short description of the site (size, location and immediate environment and other activities on the site);

(vii) number of employees engaged in Production, Quality Control, warehousing, and distribution;

(viii) use of outside scientific, analytical or other technical assistance in relation to the design, manufacture and testing;

(ix) short description of the quality management system of the company;

(x) devices details registered with foreign countries;

2. Personnel:

(i) organisation chart showing the arrangements for key personne;l

(ii) qualifications, experience and responsibilities of key personnel;

(iii) outline of arrangements for basic and in-service training and how records are maintained;

(iv) health requirements for personnel engaged in production

(v) personnel hygiene requirements, including clothing.

3. Premises and Facilities:

(i) layout of premises with indication of scale;

(ii) nature of construction, finishes/fixtures and fittings;

(iii) brief description of ventilation systems. More details should be given for critical areas with potential risks of airborne contamination (including schematic drawings of the systems). Classification of the rooms used for the manufacture of sterile products should be mentioned;

(iv) special areas for the handling of highly toxic, hazardous and sensitizing materials;

(v) brief description of water systems (schematic drawings of the systems are desirable) including sanitation;

(vi) maintenance (description of planned preventive maintenance programmes for premises and recording system);

4. Equipment:

(i) Brief description of major production and quality control laboratories equipment (a list of the equipment is required);

(ii) maintenance (description of planned preventive maintenance programmes and recording system);

(iii) qualification and calibration, including the recording system. Arrangements for computerized systems validation.

5. **Sanitation:**

Availability of written specifications and procedures for cleaning the manufacturing areas and equipments.

6. Production:

(i) Brief description of production operations using, wherever possible, flow sheets and charts specifying important parameters ;

(ii) arrangements for the handling of starting materials, packaging materials, bulk and finished products, including sampling, quarantine, release and storage;

(iii) arrangements for reprocessing or rework;

(iv) arrangements for the handling of rejected materials and products;

(v) brief description of general policy for process validation.

7. **Quality Assurance:**

Description of the Quality Assurance system and of the activities of the Quality Assurance Department. Procedures for the release of finished products.

8. Storage:

Policy on the storage of medical device.

9. Documentation:

Arrangements for the preparation, revision and distribution of necessary documentation, including storage of master documents.

10. Medical Device Complaints and Field Safety Corrective Action:

(i) Arrangements for the handling of complaints ;

(ii) Arrangements for the handling of field safety corrective action

11. **Internal Audit:**

Short Description of the internal audit system.

12. Contract Activities:

Description of the way in which the compliance of the contract acceptor is assessed.

Annexure - C

Environmental requirement for Notified medical devices and *in-vitro* diagnostics

Name of Device	Type of Operation	ISO Class (At rest)
Cardiac stent/ Drug Eluting Stent	Primary Packing and Crimping	5
	Washing, Ultrasonic cleaning &Drug Coating	7
	Assembly, Wrapping & Packaging	8
	Laser cutting, Descaling, Annealing & Electro polishing	9
Heart Valves	Valve Packing	5
	Ultrasonic Cleaning & Visual Inspection	7
	Frame & Disc Assembly	7
Intra Ocular Lenses	Packing & Sealing	5
	Final Inspection	7
	Power Checking& Final Cleaning	8
	Tumble Polishing & Lathe Cutting	9
Bone Cements	Final Product Filling	5
	Sieving & Calcinations	7
	Powder Preparation, Granulation &Drying	8
Internal Prosthetic Replacement	Packing	5
	Product Preparation	7
	Component Preparation	8
Orthopaedic Implants	Polishing &Cleaning & packaging (to be sterilized in factory premises)	7
	Polishing , cleaning & packaging (Non Sterile- to be sterilized in Hospital)	8
	Cutting, lathing	9

Catheters /Ablation Device / IV Cannulae / Scalp Vein Set/ Hypodermic Syringes/ Hypodermic Needles / Perfusion Sets	Assembly, Coating, Wrapping & Packing	7
	Component Preparation & Cleaning	8
	Moulding	9
Condom	Compounding	Well ventilated area with minimum 5 micron filter
	Moulding	Well ventilated area with minimum 5 micron filter
	Vulcanising	Normal air
	Packing	Air conditioned
Intra Uterine Devices	Moulding	Well ventilated area with minimum 5 micron filter
	Assembling	7
	Packaging	7
Tubal ring	Extrusion	7
	Cutting and Assembly	7
	Packaging	7
Blood bags	Moulding/Extrusion of components	8
	Assembly	7
	Filing	5
Suture	Extrusion	9
	Assembly	8
	Packing	8

Staplers	Staple formation	9
	Staple final pack	8
	Staple Primary pack	8

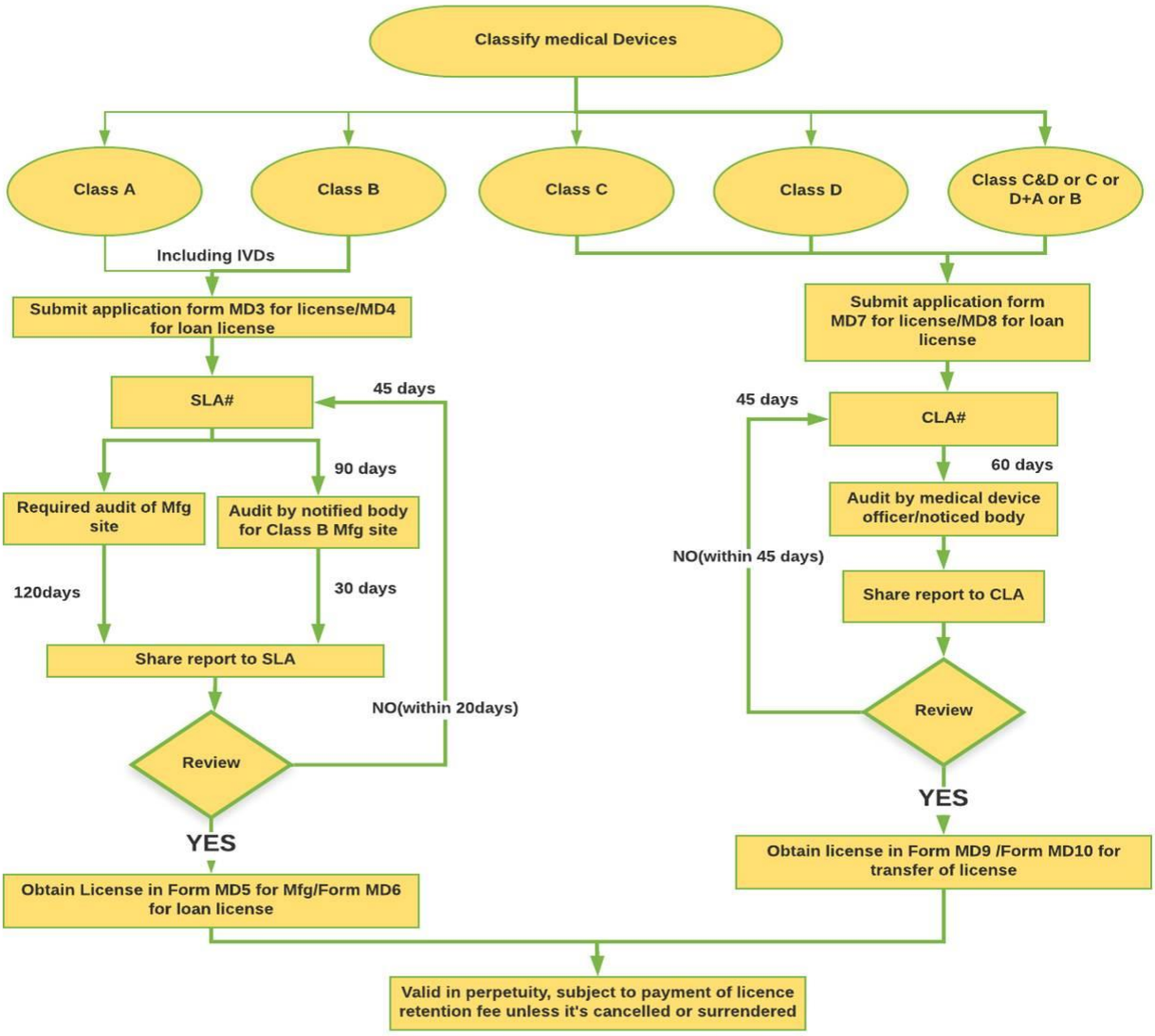
Ligatures	Extrusion	9
	Cutting and assembly	8
	Final Pack	8
Surgical dressings	Weaving	9
	Assembly and Gauzing	9
	Final pack	9
In-vitro diagnostics Kit/Reagents	Dry, Liquid Reagent Preparation	Well Lighted and Ventilated controlled temperature & humidity as per process or product Requirement
	Coating of sheets etc.	
	Assembly and primary packing	
	Filling	Well Lighted and Ventilated controlled temperature and humidity as per process or product requirement. Provision of Laminar hood if required, Clean Room class 8 or class 9 as per product/process Requirement
	Secondary Packing	Well Lighted and Ventilated controlled temperature if required
	Storage	As per recommended storage condition of the product.

5. Process for Registration of Medical Devices in India:

The State Drugs Controller serves as the State Licensing Authority (SLA) and shall be the competent authority for enforcement of the rules relating to the manufacture of Class A or Class B medical devices and the sale, stocking and exhibition of medical devices and other related functions.

Class C and Class D high-risk medical devices are regulated by the Central Licensing Authority (CLA), which oversees the clinical investigation and clinical performance evaluation of medical devices and has other related functions. If the manufacturer intends to manufacture a predicate medical device, the manufacturer must receive approval from the CLA before applying to the SLA. Diagrammatic representations given below detail the requirements for receiving manufacture for sale/distribution and import approval.

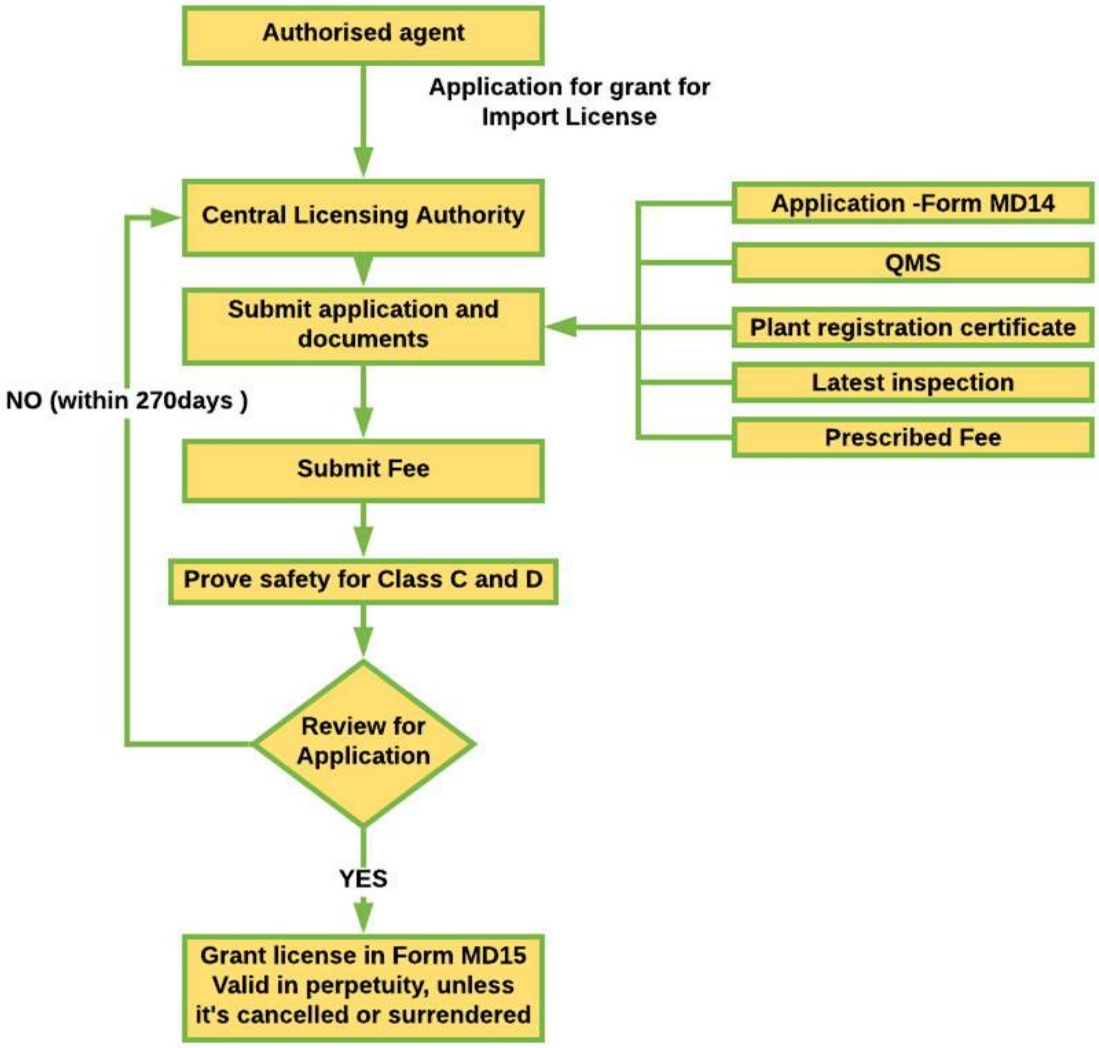
Regulatory approval process for manufacture for sale/distribution of medical devices:



State Licensing Authority (SLA), Central Licensing Authority (CLA)

* Audit of facility by notified body is conducted after approval of class A medical device.

Procedure to apply for import of medical devices:



List of applications forms required to apply for Medical Device approval

Description	Form No
Application for grant of certificate of registration of a notified body	Form MD1
Application for grant of license to manufacture for sale or for distribution for Class A or Class B medical device	Form MD3
Application for grant of loan license to manufacture for sale or for distribution of Class A or Class B medical device	Form MD4
Licence to manufacture for sale or for distribution of Class A or Class B Medical Device	Form MD5
Loan Licence to manufacture for sale or for distribution of Class A or Class B Medical Device	Form MD6
Application for grant of license to manufacture for sale or for distribution of Class C or Class D medical devices	Form MD7
Application for grant of loan license to manufacture for sale or for distribution of Class C or Class D medical device	Form MD8
Licence to manufacture for sale or for distribution of Class C or Class D Medical Device	Form MD9
Loan Licence to manufacture for sale or for distribution of Class C or Class D Medical Device	Form MD10
Form in which the audit or inspection book shall be maintained	Form MD11
Application for license to manufacture medical device for purpose of clinical investigations, test, evaluation, examination, demonstration, or training	Form MD12
Licence to manufacture Medical Device for the purpose of clinical investigations or test or evaluation or demonstration or training	Form MD13
Application for issue of import license to import medical device	Form MD14
Licence to import Medical Device	Form MD15
Application for license to import medical devices for the purposes of clinical investigations or test or evaluation or demonstration or training	Form MD16
Licence to import medical devices for the purposes of clinical investigations or test or evaluation or demonstration or training	Form MD17
Application for license to import investigational medical devices for the purposes by a government hospital or statutory medical institution for the treatment of patients	Form MD18
Licence to import investigational medical devices for the purposes by a government hospital or statutory medical institution for the treatment of patients	Form MD19
Application for permission to import small quantity of medical devices for personal use	Form MD20
Permission to import small quantity of medical devices for personal use	Form MD21
Application for grant of permission to conduct clinical investigation of an Investigational Medical Device	Form MD22
Permission to conduct clinical investigation of an Investigational Medical Device	Form MD23
Application for grant of permission to conduct clinical performance evaluation of New *In-Vitro* Diagnostic Medical Device	Form MD24
Permission to conduct clinical performance evaluation of New *In-Vitro* Diagnostic Medical Device	Form MD25
Application for grant of permission to import/manufacture for sale or for distribution of medical device which does not have a predicate medical device	Form MD26
Permission to import/manufacture for sale or for distribution of medical device which does not have a predicate medical device	Form MD27

Application for grant of permission to import or manufacture for sale or for distribution of a New *In-Vitro* Diagnostic Medical Device	Form MD28
Permission to import or manufacture New *In-Vitro* Diagnostic Medical Device	Form MD29
Memorandum to Central Medical Device Testing Laboratory	Form MD30
Certificate of Test or Evaluation by the Central Medical Device Testing Laboratory	Form MD31
Report of Test or Evaluation of Medical Devices by Medical Device Testing Officer	Form MD32
Application from a purchaser for test or evaluation of a medical device under section 26 of the Drugs and Cosmetics Act, 1940 (23 of 1940)	Form MD33
Memorandum to medical device testing officer	Form MD38

List of documents required with the application for grant of licence to manufacture or import of Medical Device

Class A *In -vitro* and Other than *In-vitro*	**Class B, Class C, and Class D *In -vitro* and Other than *In -vitro***	**Device Other than Predicate**
For Manufacturing		
• Device description • Intended use of device • Specifications including variants & accessories • Material of construction • Working principle and use of novel technology if any • Labels, package inserts, user manual, wherever applicable • Summary of serious ADR in India/other countries • Site/plant master file • Firm details • Signed undertaking agreement • Essential principles checklist • Analytical performance Summary for *in vitro* device	• Constitution details of domestic manufacturer or authorized agent • Site or plant master file • Device Master File • Essential principle checklist for demonstrating conformity for safety and performance • Test licence for testing and generation quality control data • Signed undertaking agreement stating manufacturing site is compliant with fifth schedule • *In-vitro* performance evaluation report for *in vitro* device	• Data analysis • Design input/output documents • Mechanical and electrical test results • Reliability test results • Validation of software • Performance test results • Biocompatibility test results • Risk management data • Animal performance data • Pilot and pivotal clinical investigation data • Regulatory status and restrictions in use • Proposed instructions for use
For import licence		
• Notarized copy of overseas manufacturing site and Free Sale Certificate (FSC) • Notarized copy of QMS or full Quality Assurance certificate • Self-attested copy of whole sale license or manufacturing licence • Copy of latest inspection/audit report carried out by Notified Bodies/NRA		

6. <u>Guidance on grouping of medical devices for product registration:</u>

Central Government notifies the following guidelines in respect to grouping of Medical Devices for a person who applies for licence to import or manufacture for sale or distribution of medical devices, namely,

Application for license:

(l) Application for licence to import or manufacture for sale or distribution, sell, stock or offer for sale or distribution of medical device shall be made as specified under respective form to the Appendix to Medical Devices Rules, 2017 or refer to chapter 5. Process for Registration of Medical Devices in India:

(2) The applicant may group medical devices having same or similar intended uses or commonality of technology and submitted in a single application. The grouping of medical devices is for purpose of submission of single application for license to import or manufacture in the following manner:

(i) <u>Single:</u>

a) A single medical device is a medical device sold as a distinct packaged entity and does not meet the criteria for family, IVD test kit, system, IVD cluster or a group. It may be sold in a range of package sizes.
b) The medical devices that cannot be assigned to family, IVD test kit, system, IVD cluster or a group must be licensed separately.
c) The medical devices which are a part of a group must be licensed separately before it sold separately as individual medical devices.

Illustration:

A. Condoms are sold in package of 3, 10 or 16 can be licensed a single medical device applications.

B. A company that assembles and licenced a first aid kit has now decided to also supply each of medical devices in the first aid kit individually. In such cases, each medical device supplied individually must be licensed as a single medical device.

(ii) <u>Family:</u>

a) A medical device family is a collection of medical devices and each medical device,

a. is from same license holder;
b. is of same risk classification class;
c. has a common intended use;
d. has the same design and manufacturing process;
e. have variations that are within the scope of the permissible variants.

b) The characteristics of a medical device may be considered as permissible variant under clause (1), if

a. the physical design and material of construction of the medical device are the same or very similar;
b. the manufacturing processes, including sterilisation method, for the medical devices are the same or very similar;
c. the intended purpose of medical devices are the same; and
d. the risk profile of the medical device, taking into account the above factors, is the same.

Illustration:

A. Condoms that differ in colour, size and texture but are manufactured from the same material and manufacturing process and share a common intended purpose can be licenced as a Family.

B. Spherical contact lens with additional features of UV protection can be licenced as part of a Family, as this feature does not affect the basic design or manufacturing of the lens.

C. Contact lens is available as toric lens and spherical lens. These products have different intended purposes and performances. They are designed and manufactured differently. Due to these differences, they shall not be considered as members of a Family.

(iii) *In vitro* diagnostics Test Kit:

a) An *in-vitro* diagnostics kit is a device that consists of reagents or articles which are,

i. from same license holder;
ii. intended to be used in combination to complete a specific intended purpose;
iii. sold under single proprietary test kit name; and
iv. compatible when used as a test kit;

b) An *in-vitro* diagnostics kit does not include the instruments, such as analysers, need to be perform the test.

c) Individual reagents or articles can be supplied separately as replacement items for kit. If the reagents or articles in a Test Kit are supplied for use in more than one Test Kit, such reagents or articles shall be included in the application of the other Test Kits.

Illustration:

A. Human Immunodeficiency Virus (HIV) Enzyme Linked Immunosorbent Assay (ELISA) Test Kit may contain controls, calibrators, and washing buffers. All the reagents and articles are used together to detect HIV and therefore can be licenced as Test Kit. These reagents and articles can be supplied separately as replacement items for that particular Test Kit.

(iv) System:

a. The medical devices comprises system, that are

a) From same license holder;
b) Intended to be used in combination to complete a common intended purpose;
c) Compatible when used as system; and
d) sold under single proprietary system name;

b. The constituent component in a system which is supplied for use in more than one system, such constituent components shall be included in the application for licence for each of other system.

c. If the several systems fulfill the conditions, as specified in clause (b), to be grouped as Family, they may be licenced as family.

Illustration:

A. A hip replacement system comprising of femoral and acetabular components can be licenced as system. The components must be used in combination to achieve a common intended purpose of total hip replacement. The size of component may vary.

B. A glucose monitoring System comprising of a glucose meter, test strips, control solutions and linearity solutions can be licenced as a System.

(v) *In vitro* diagnostics cluster:

An in-vitro diagnostics cluster comprises of a number of *in-vitro* diagnostics reagents or articles which are,

a) from same license holder;
b) of a common methodology;
c) sold under single proprietary name; and
d) compatible when used as a Test Kit.

(vi) Group:

a) A medical device Group is a collection of two or more medical devices, supplied in a single package by same license holder, which are,
    i. sold under single proprietary Group name; and
    ii. a common intended purpose.
b) The medical device in the Group may have different proprietary name and intended purpose and designed and sold by different license holder.
c) The collection of medical devices in a Group may differ in the number and combination of products that comprises each Group, while maintaining the same proprietary Group name and Group's intended purpose.

d) The medical device in a Group is supplied for use in another Group; such a medical device shall be included in the application of that other Group.

Illustration:

A first aid kit consisting of medical devices such as bandages, gauzes, drapes and thermometers, when assembled together as one package, can be licenced as a Group.

7. Fees and Charges for Medical devices:

7.1 Fee payable for license, permission and registration certificate

S. No.	Rule	Subject	In rupees (INR) except where specified in dollars ($)
1.	13(5)	Registration of Notified Body	25000
2.	13(7)	Registration retention fee of Notified Body.	25000
3.	20(2)	Manufacturing licence or loan licence to manufacture Class A or Class B medical device for,-	--------
4.		(a) one site; and	5000
5.		(b) each distinct medical device.	500
6.	21(2)	Manufacturing licence or loan licence to manufacture Class C or Class D medical device for,-	--------
7.		(a) one site; and	50000
8.		(b) each distinct medical device.	1000
9.	29(1)	Manufacturing licence or loan licence retention fee for,	--------
10.		(a) one site manufacturing Class A or Class B medical device; or	5000
11.		(b) one site of manufacturing Class C or Class D medical device;	50000
12.		(c) each distinct medical device of Class A or Class B; or	500
13.		(d) each distinct medical device of Class C or Class D.	1000
14.	31(1)	Test licence to manufacture for clinical investigations, test, evaluation, examination, demonstration or training for each distinct medical device.	500
15.	34(2)	Import licence for Class A medical device other than in vitro diagnostic medical device for,-	--------
16.		(a) one site; and	$1000
17.		(b) each distinct medical device.	$50
18.	34(2)	Import licence for Class B medical device other than *in vitro* diagnostic medical device for,-	--------
19.		(a) one site; and	$2000
20.		(b) each distinct medical device.	$1000
21.	34(2)	Import licence for Class A or Class B *in vitro* diagnostic medical device for,-	--------
22.		(a) one site; and	$1000

23.		(b) each distinct *in vitro* diagnostic medical device.	$10
24.	34(2)	Import licence for Class C or Class D medical device other than *in vitro* diagnostic medical device for,-	--------
25.		(a) one site; and	$3000
26.		(b) each distinct medical device.	$1500
27.	34(2)	Import licence for Class C or Class D *in vitro* diagnostic medical device for,-	--------
28.		(a) one site; and	$3000
29.		(b) each distinct *in vitro* diagnostic medical device.	$500
30.	35(2)	Inspection of the overseas manufacturing site.	$6000
31.	37	Import licence retention fee for,-	--------
32.		(a) one overseas site manufacturing Class A medical device other than in vitro diagnostic medical device; or	$1000
33.		(b) one overseas site manufacturing Class B medical device other than in vitro diagnostic medical device; or	$2000
34.		(c) one overseas site manufacturing Class C or Class D medical device other than in vitro diagnostic medical device; or	$3000
35.		(d) each distinct medical device of Class A other than *in vitro* diagnostic medical device; or	$50
36.		(e) each distinct medical device of Class B other than *in vitro* diagnostic medical device; or	$1000
37.		(f) each distinct medical device of Class C or Class D other than *in vitro* diagnostic medical device.	$1500
38.		(g) one overseas site manufacturing Class A or Class B in vitro diagnostic medical device;	$1000
39.		(h) one overseas site manufacturing Class C or Class D medical device other than in vitro diagnostic medical device;	$3000
40.		(i) each distinct in vitro diagnostic medical device of Class A or Class B in vitro diagnostic medical device;	$10
41.		(j) each distinct in vitro diagnostic medical device of Class C or Class D in vitro diagnostic medical device;	$500
42.	40(2)	Fee for Import licence for test, evaluation or demonstration or training for each distinct medical device.	$100

43.	42(1)	Fee for Import of investigational medical device by Government hospital or statutory medical institution for treatment of patient of each distinct medical device.	500
44.	51(2)(a)	Permission to conduct pilot clinical investigation.	100000
45.	51(2)(b)	Permission to conduct pivotal clinical investigation.	100000
46.	59(2)	Permission to conduct clinical performance evaluation.	25000
47.	63(1)	Permission to import or manufacture a medical device which does not have its predicate device	50000
48.	64(1)	Permission to import or manufacture new in vitro diagnostic medical device.	25000
49.	81(1)	Registration of medical device testing laboratory to carry out testing or evaluation of a medical device on behalf of manufacturer.	20000
50.	84	Registration retention fee for medical device testing laboratory	20000
51.	91	Certificate to export of each distinct medical device.	1000

7.2 Audit fee of Notified Bodies under Medical Devices Rules, 2017

The notified bodies (NBs) registered with CDSCO under provisions Medical Devices Rules, 2017, shall carry out audit of manufacturing sites as per Medical Devices Rules, 2017.

As per the provisions of Rule 16 of Medical Devices Rules, 2017, the fees chargable by notified bodies, as approved by competent authority of Ministry of Health & Family Welfare in the Central Government, are as under-

- Rs. 20, 000 per man/day for audit of manufacturing site including product assessment (on-site/off-site).
- Rs. 12,500 per man/day with package of Rs. 25,000 requiring 2 man/days. In case, if more man/day required, it would be charged other than this fee.
- Above fees are excluding travel cost which shall not normally be more than Rs. 12,000 per auditor/visit.
- Man/day calculation criteria to be followed for assessment by NBs, which is based on number of products, Risk Class and effective number of employees, and prior experience as per CE marking/ISO 13485 etc. as minimum as specified in Table-1.

- Annual surveillance assessment shall be 1/3 man/days of total initial assessment as specified in Table-1.
- Organization/Industry already certified to ISO 13485from a NB and or CE mark certified for the same product is considered for reduction in man- days as per the table given below:

Table-1: Man/day calculation for assessment as per MDR, 2017

Requirements of MDR, 2017	**Onsite audit YES/NO**	**Desk audit YES/NO**	**Number of Man Days (Having CE/MDD certification)**	**Number of Man Days (without CE/MDD certification)**	**Number of Man Days (without 13485/CE/MDD certification)**
I	II	III	IV	V	VI
Forth Schedule	N Y	Y Y	1.0	2.0	Pl refer Table-2
Fifth Schedule	Y	Y	1.0	1.0	As per Annex D of IAF MD* 9
Report writing as per CDSCO requirements	Y	Y	0.5	1.0	1.0

***** International Accreditation Forum- Mandatory Document

Note:

- Manufacturers holding a valid ISO 13485/MDD Certificate issued by a Notified Bodies are considered under column IV & V.
- The above review assumes one round of Technical File review, an additional round of reviews will require additional man days as applicable.
- The desktop assessments will be based on QMS and Product Certificate issued from Notified Bodies.
- The manufacturer will have to submit full technical file as per Forth schedule requirements for review with the Notified Body.
- The number of technical files to be reviewed will be derived from the CDSCO guideline document (Grouping of Medical Devices for submission of Applications) based on the client application categories (Single, Family, IVD test kit, System, IVD cluster, Group).

- The desktop assessments will be based on MDQMS accredited Certificate issued by Notified Bodies.

Table-2: Applicable for onsite assessment for schedule 4 requirements

No of products	1 to 5	6 to 10	11 to 15	More than 15 products
Man/days	2	3	4	5

8. Information about a Medical Device

8.1 Labelling of medical devices:

The following particulars shall be printed in indelible ink on the label, on the shelf pack of the medical device or on the outer cover of the medical device and on every outer covering in which the medical device is packed, namely,-

(a) name of the medical device;

(b) the details necessary for the user to identify the device and its use;

(c) the name of manufacturer and address of manufacturing premises where the device has been manufactured;

(d) the correct statement about the net quantity in terms of weight, measure, volume, number of units, as the case may be, and the number of the devices contained in the package expressed in metric system;

(e) the month and year of manufacture and expiry (alternately the label shall bear the shelf life of the product):

Provided that in case of sterile devices, the date of sterilization may be given as date of manufacture of the device

Provided further that where the device is made up of stable materials such as stainless steel or titanium, and supplied non-sterile or in case of medical equipment or instruments or apparatus, the date of expiry may not be necessary.

Explanation- For the purposes of this clause, the date of expiry shall be in terms of the month and the year and it shall mean that the medical device is recommended till the last day of the month and the date of expiry shall be preceded by the words "Expiry date" or "Shelf Life";

(f) to provide, wherever required, an indication that the device contains medicinal or biological substance;

(g) to provide, a distinctive batch number or lot number preceded by the word "Lot No." or "Lot" or "Batch No." or "B. No.";

(h) to indicate, wherever required, any special storage or handling conditions applicable to the device;

(i) to indicate, if the device is supplied as a sterile product, its sterile state and the sterilization method;

(j) to give, if considered relevant, warnings or precautions to draw the attention of the user of medical device;

(k) to label the device appropriately, if the device is intended for single use;

(l) to overprint on the label of the device, the words "Physician's Sample—Not to be sold", if a medical device is intended for distribution to the medical professional as a free sample;

(m) to provide, except for imported devices, the manufacturing licence number by preceding the words "Manufacturing Licence Number" or "Mfg. Lic. No." or "M. L";

(n) to provide on the label, in case of imported devices, by way of stickering, where such details are not already printed, the import licence number, name and address of the importer, address of the actual manufacturing premises and the date of manufacture:

Provided that the label may bear symbols recognised by the Bureau of Indian Standards or International Organisation for Standardisation (ISO) in lieu of the text and the device safety is not compromised by a lack of understanding on the part of the user, in case the meaning of the symbol is not obvious to the device user;

(o) in case of small sized medical devices on which information cannot be printed legibly, shall include the information necessary for product identification and safety such as information covered by clauses (a), (b), (c), (d), (e), (g), (k), and (m) shall be included.

Exemption of labelling requirements for export of medical devices:

The labels on packages or container of devices for export shall be adopted to meet the specific requirements of law of the country to which the device is to be exported, but the following particulars shall appear in a conspicuous manner on the label of the inner most pack or shelf pack of the medical device in which the device is packed and every other outer covering in which the container is packed:-

(a) name of the device;

(b) the distinctive batch number or lot number or serial number preceded by the word "Lot No." or "Lot" or "Batch No." or "B. No." or "Serial No.";

(c) date of expiry, if any;

(d) the name and address of manufacturer and address of actual premises where the device has been manufactured;

(e) licence number preceded by letters "Licence No. or Lic. No.";

(f) internationally recognised symbols in lieu of text, wherever required:

Provided that where a device is required by the consignee not to be labeled with the name and address of manufacturer, the label on the package or container shall bear a code number as approved by the Central Licensing Authority and the code number shall bear the name of the State or Union territory, in abbreviation, followed by the word "Device" and "manufacturing licence number":

Provided further that where a device is required by the consignee not to be labeled with the code number also, the label on the packages or container shall bear a special code number, as requested by the consignee, and approved by the Central Licensing Authority.

Unique device identification of the medical device:

With effect from 1st day of January, 2022, a medical device, approved for manufacture for sale or distribution or import, shall bear unique device identification which shall contain device identifier and production identifier.

Explanation- For the purposes of this rule,-

(i) "device identifier" means a global trade item number;.

(ii) "production identifier" means a serial number, lot or batch number, software as a medical device version, manufacturing and or expiration date.

Shelf life of medical devices:

The shelf life of the medical devices, shall be determined keeping in view the technical parameters and shall ordinarily not exceed sixty months from the date of manufacture to be reckoned from month to month (i.e. January to January), except in cases where satisfactory evidence is produced by the manufacturer to justify a shelf life of more than sixty months of a device to the satisfaction of the Central Licensing Authority:

Provided that any medical device, whose total shelf life claim is less than ninety days, shall not be allowed to be imported by the licensing authority if it has less than forty per cent residual shelf-life on the date of import:

Provided further that any medical device, whose total shelf life claim is between ninety days and one year, shall not be allowed to be imported by the licensing authority if it has less than fifty per cent residual shelf-life on the date of import:

Provided also that any medical device, whose total shelf life claim is more than one year, shall not be allowed to be imported by the licensing authority if it has less than sixty per cent residual shelf-life on the date of import.

Labelling medical device or a new in vitro diagnostic medical device for purpose of test, evaluation, clinical investigations, etc.:

Any medical device or new *in-vitro* diagnostic medical device imported or manufactured, for the purpose of clinical investigation or clinical performance evaluation, test, evaluation, demonstration and training, shall be kept in containers bearing labels, indicating the name of the product or code number, batch or lot number, serial number wherever applicable, date of manufacture, use before date, storage conditions, name and address of the manufacturer, and the purpose for which it has been manufactured.

8.2 Instructions for Use for Medical Devices other than IVD Medical Devices:

The instructions for use should contain the following particulars:

(a) The name or trade name of the medical device.

(b) The name and address of the manufacturer in a format that is recognisable and allows the location of the manufacturer to be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance.

(c) The device's intended use/purpose including the intended user (e.g. professional or lay person), as appropriate.

(d) The performance of the device intended by the manufacturer.

(e) Where the manufacturer has included clinical investigations as part of premarket conformity assessment to demonstrate conformity to Essential Principles, a summary of the investigation, outcome data and clinical safety information, or a reference as to where such information may be accessed.

(f) Any residual risks, contraindications and any expected and foreseeable side effects, including information to be conveyed to the patient in this regard.

(g) Specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it.

(h) If the device contains, or incorporates, a medicinal substance and/or material of biological origin, identification of that substance or material, as appropriate.

(i) Details of any preparatory treatment or handling of the device before it is ready for use (e.g. sterilization, final assembly, calibration, etc.).

(j) Any requirements for special facilities, or special training, or particular qualifications of the device user and/or third parties.

(k) The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:

- details of the nature, and frequency, of preventative and regular maintenance, and of any preparatory cleaning or disinfection;
- identification of any consumable components and how to replace them;
- information on any necessary calibration to ensure that the device operates properly and safely during its intended life span;
- methods of eliminating the risks encountered by persons involved in installing, calibrating or servicing medical devices.

(l) An indication of any special storage and/or handling condition that applies.

(m) If the device is supplied sterile, instructions in the event of the sterile packaging being damaged before use.

(n) If the device is supplied non-sterile with the intention that it is sterilized before use, the appropriate instructions for sterilization.

(o) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization. Information should be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses.

(p) For devices intended for use together with other medical devices and/or general purpose equipment:

- information to identify such devices or equipment, in order to obtain a safe combination, and/or
- information on any known restrictions to combinations of medical devices and equipment.

(q) If the device emits hazardous or potentially hazardous levels of radiation for medical purposes:

- detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation;
- the means of protecting the patient, user, or third party from unintended radiation during use of the device;

(r) Information that allows the user and/or patient to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. This information should cover, where appropriate:

- warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety;
- warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;
- warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g. electromagnetic interference emitted by the device affecting other equipment);
- if the device administers medicinal or biological products, any limitations or incompatibility in the choice of substances to be delivered;
- warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device;

- precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic reaction of the patient or user.

(s) Warnings or precautions to be taken related to the disposal of the device, its accessories and the consumables used with it, if any. This information should cover, where appropriate:

- infection or microbial hazards (e.g. explants, needles or surgical equipment contaminated with potentially infectious substances of human origin);
- environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation);
- physical hazards (e.g. from sharps).

(t) For devices intended for use by lay persons, the circumstances when the user should consult with a healthcare professional.

(u) Date of issue or latest revision of the instructions for use and, where appropriate, an identification number.

Instructions for Use for IVD Medical Devices:

The instructions for use should contain the following particulars:

(a) The name or trade name of the IVD medical device.

(b) The IVD medical device's intended use/purpose:

- what is detected;
- its function (e.g. screening, monitoring, diagnosis or aid to diagnosis);
- the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;
- whether it is automated or not;
- whether it is qualitative or quantitative;
- the type of specimen(s) required (e.g. serum, plasma, whole blood, tissue biopsy, urine); and

- testing population.

(c) An indication that it is for *in-vitro* diagnostic use.

(d) The intended user, as appropriate (e.g. lay person).

(e) Test principle.

(f) A description of the reagent, calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only).

Note: IVD medical device kits include individual reagents and articles that may be made available as separate IVD medical devices. In this situation, where appropriate, these IVD medical devices should comply with the instructions for use content in this section.

(g) A list of materials provided and a list of special materials required but not provided.

(h) For IVD medical devices intended for use together with other medical devices, including IVD medical devices, and/or general purpose equipment

- information to identify such devices or equipment, in order to obtain a safe combination, and/or
- information on any known restrictions to combinations of medical devices and equipment.

(i) An indication of any special storage (e.g. temperature, light, humidity, etc.) and/or handling conditions that apply.

(j) In use stability which may include, the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant.

(k) If the IVD medical device is supplied as sterile, instructions in the event of the sterile packaging being damaged before use.

(l) Information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the IVD medical device. This information should cover, where appropriate:

- warnings, precautions and/or measures to be taken in the event of malfunction of the IVD medical device or its degradation as suggested by changes in its appearance that may affect performance;
- warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;
- warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g. electromagnetic interference emitted by the device affecting other equipment);
- precautions related to materials incorporated into the IVD medical device that are carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic reaction.

(m) Any warnings and/or precautions related to potentially infectious material that is included in the IVD medical device.

(n) Where relevant, requirements for special facilities (e.g. clean room environment) or special training (e.g. radiation safety), or particular qualifications of the device user.

(o) Conditions for collection, handling, and preparation of the specimen.

(p) Details of any preparatory treatment or handling of the IVD medical device before it is ready for use (e.g. reconstitution, calibration, etc.).

(q) The information needed to verify whether the IVD medical device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:

- details of the nature, and frequency, of preventative and regular maintenance (including cleaning and disinfection);

- identification of any consumable components and how to replace them;
- information on any necessary calibration to ensure that the IVD medical device operates properly and safely during its intended life span;
- methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing IVD medical devices, e.g. contaminated surfaces.

(r) Where relevant, recommendations for quality control procedures.

(s) The metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and/or reference measurement procedures of higher order.

(t) Assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing should be considered.

(u) Analytical performance characteristics, such as sensitivity, specificity, and accuracy (which is a combination of trueness and precision).

(v) Where relevant, clinical performance characteristics, such as diagnostic sensitivity and diagnostic specificity.

(w) Where relevant, reference intervals.

(x) Information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of specimen/sample) that may affect the performance of the assay.

(y) Warnings or precautions to be taken related to the disposal of the device, its accessories, and the consumables used with it, if any. This information should cover, where appropriate:

- infection or microbial hazards (e.g. consumables contaminated with potentially infectious substances of human origin);
- environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation);
- physical hazards (e.g. explosion)

(z) For IVD medical devices intended for use by lay persons, the circumstances when the user should consult with a healthcare professional.

(aa) Where relevant, a bibliography.

(bb) The name and address of the manufacturer in a format that is recognisable and allows the location of the manufacturer to be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance.

(cc) Date of issue or latest revision of the instructions for use and, where appropriate, an identification number.

9. Quality Standards for Medical Devices

9.1 What are standards?

The formal definition of a standard that should be adopted in the medical device domain is given by the ISO:

Standards are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines or definitions of characteristics, to ensure that materials, products, process and services are fit for their purpose.

Types of specifications in standards

Standards can establish a wide range of specifications for products, processes and services

1. Prescriptive specifications obligate product characteristics, e.g. device dimensions, biomaterials, test or calibration procedures, as well as definitions of terms and terminologies.
2. Design specifications set out the specific design or technical characteristics of a product, e.g. operating room facilities or medical gas systems.
3. Performance specifications ensure that a product meets a prescribed test, e.g. strength requirements, measurement accuracy, battery capacity, or maximum defibrillator energy.
4. Management specifications set out requirements for the processes and procedures companies put in place, e.g. quality systems for manufacturing or environmental management systems.

A standard may contain a combination of specifications. Prescriptive, design and performance specifications have been common place in standards. Management specifications are also rapidly gaining prominence.

Recent years have seen the development and application of what are known as "generic management system standards", where "generic" means that the standards' requirements can be applied to any organization, regardless of the product it makes or the service it delivers, and "management system" refers to what the organization does to manage its processes. Two of the most widely known series of generic management system standards are the ISO 9000 series for

managing quality systems, and the ISO 14000 series for environmental management systems. Wide ranging information and assistance related to these standards and their application is available at www.iso.org. ISO13485 and ISO13488 are specific ISO quality systems standards for medical device manufacturing.

Terms such as outcome-oriented standards, objectives standards, function-focused standards and result-oriented standards are also employed. Essentially, these terms indicate that the standards specify the objectives (ends) to be achieved while leaving the methods (means) to the implementers. This can minimize possible constrictive effects of standards.

9.2 Why do we need standards?

Standards can serve different purposes. They can:

1. Provide reference criteria that a product, process or service must meet.
2. Provide information that enhances safety, reliability and performance of products, processes and services.
3. Assure consumers about reliability or other characteristics of goods or services provided in the marketplace.
4. Give consumers more choice by allowing one firm's products to be substituted for, or combined with, those of another.

With the world becoming a global village, the need and benefits of standardization are becoming more and more important internationally for manufacturing, trade and communications. Quality systems and other management standards can provide common references to the kind of process, service or management practice expected. The Internet functions effectively because globally agreed-upon interconnection protocols exist. Global communication would be very difficult without international standardization. Health care workers are well aware of incompatible consumables or replacement parts in medical devices of similar function that are made by different manufacturers (e.g. IV set, X-ray cassettes). The lack of available consumables and repair parts is an important cause of medical equipment problems that are constantly encountered in developing countries.

Most medical devices are used globally. The safety, performance and consistent quality of medical devices are, therefore, an international public health interest.

9.3 Voluntary and mandatory standards

Most standards are voluntary. However, a standard may be mandated by a company, professional society, industry, government or trade agreement. A standard may be called a regulation when it becomes mandatory. This mandate may, or may not, have a legal basis.

When a standard is mandated by a government or an international trade agreement, it normally becomes legally obligatory based on regulations or a law established by the government or the contracts between international bodies. Countries that are considering making standards mandatory should take into account the potential consequences under international agreements on technical barriers to trade.

9.4 Standards development process

Figure provides an example of the many steps used by standards development organizations. In general, good standards have the following attributes:

1. Their development has been overseen by a recognized body, thus ensuring that the process is transparent and not dominated by vested interests.
2. The development process has been open to input from all interested parties and the resulting document based on consensus. Consensus, in a practical sense, means that significant agreement among the stakeholders is reached in the preparation of the standard, including steps taken to resolve all objections. This process implies more than the votes of a majority, but not necessarily unanimity.
3. Good technical standards are based on consolidated results of science, technology and experience, and are aimed at the promotion of optimum community benefits.
4. Standards do not hinder innovations and must be periodically reviewed to remain in tune with technological advances.

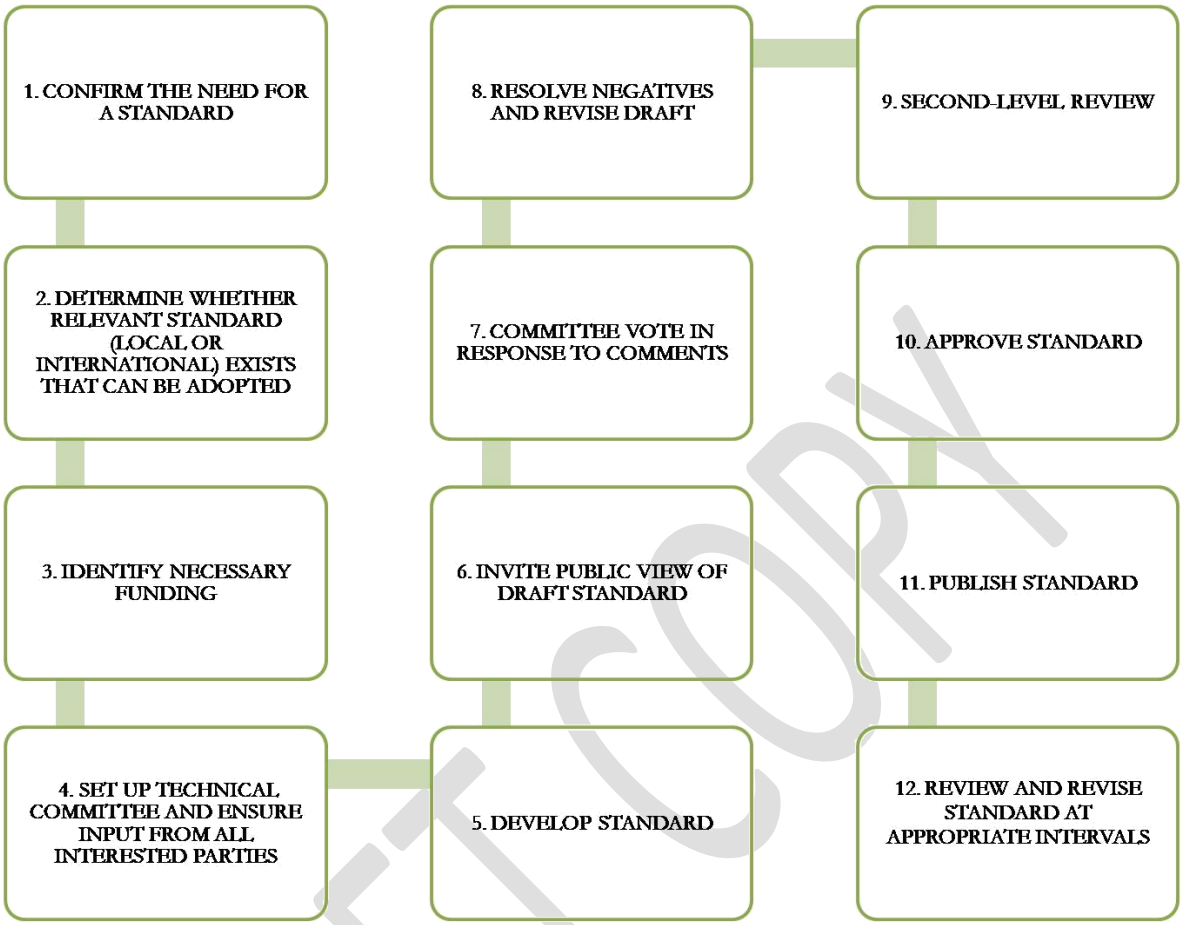


Fig: Typical process for standards development

9.5 Conformity assessment with standards

There are four common industrial methods for assessing conformity to a standard.

1. A product's conformity to standards is commonly assessed by **direct testing**.
2. A process can be assessed by audit. Certification organizations or regulatory authorities attest that products or processes conform to a standard by authorizing the display of their certification mark.
3. The conformity to management standard by an organization is known as management systems registration. Formally established audit procedures are followed by certified auditors who are supported by technical experts of the domain under audit. Management System Registration bodies (Registrars) issue registration certificates to companies that

meet a management standard such as ISO9000, or to medical device manufacturers that meet the ISO13485/ISO9001 standards.

4. Accreditation is used by an authoritative body to give formal recognition that an organization or a person is competent to carry out a specific task.

9.6 National and international standards systems

A country may have many voluntary standards bodies. However, normally there is one official national organization that coordinates and accredits the standards development bodies in the country. This official national organization would have the authority to endorse a document as a national standard in accordance with official criteria, and it also represents the country in the various international standards organizations. In the United States, the American National Standards Institute (ANSI), a private, non-profit organization, is an official national organization. In Canada, it is the Standards Council of Canada (SCC), a crown (government) corporation. In Europe there is a committee composed of CEN (Comité Européen de Normalisation), CENELEC (the European Committee for Electrotechnical Standardization) and ETSI (the European Telecommunication Standards Institute) that supercedes the various European national standards bodies that were in place previously.

For developing countries, reference to a standards system not only helps medical device administration, it is also important for other industrial and economic developments. International development agencies increasingly realize that a standardized infrastructure is a basic requirement for the success of economic policies that will improve productivity, market competitiveness and export capability.

The three major international standardization organizations are the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and the International Telecommunication Union (ITU). Generally, ITU covers telecommunications, IEC covers electrical and electronic engineering, and ISO covers the remainder. For information technology, risk management, quality systems and many other areas, joint ISO/IEC technical committees manage standardization.

Other organizations also produce documents on international standardization. Their documents are usually adopted by ISO/IEC/ITU as international standards if they have been developed in accordance with international consensus criteria. Any grouping of five member countries can also propose a standard to be considered by ISO for adoption as an international standard.

Identification of standards

Standards are generally designated by an alphabetical prefix and a number. The letters (e.g. ISO, IEC, ANSI, CAN, EN, DIN) indicate the body that has approved them, while the numbers identify the specific standard and the year in which it was finalized. The standard reference code often gives an indication of adoption where standards are equivalent. For example:

1. CAN/CSA-Z386-94 means a standard developed in 1994 by the Canadian Standards Association (CSA, one of four accredited Canadian standards development organizations) and designated by the Standards Council of Canada (SCC) as a Canadian national standard.
2. ANSI/AAMI/ISO 15223:2000 means the international standard ISO 15223 (established in 2000) adopted by the Association for the Advancement of Medical Instrumentations in the United States, which in turn is designated by the American National Standards Institute (ANSI) as an American national standard.
3. UNI EN ISO 9001 indicates an Italian national standard (UNI) which is an adoption of a European standard (EN), which is itself an adoption of the International Standard ISO9001.

9.7 Current trends in the use of standards in medical device regulations

Although a standard can be set and mandated by an authority, the current trend is for the adoption of voluntary standards established by consensus from all interested parties (the stakeholders). The use of voluntary standards originated from the realization that while regulations generally address the essential safety and performance principles, manufacturers and users still need to know detailed specifications pertaining to specific products. The provision of such specifications and detailed requirements for the multitude of devices presents an enormous task for regulatory authorities. Fortunately, the wealth of voluntary standards already existing or

being developed provide such precise specifications. The use of voluntary/consensus standards has many advantages including the following:

1. They are normally developed by experts with access to the vast resources available in the professional and industrial communities.
2. By taking advantage of such existing resources, the government can overcome its own limited resources for providing product specific technical requirements and characteristics.
3. Conformity to standards can also be assessed by an accredited third party (such as a notified body in Europe), which is a well-established industrial practice around the world.
4. The use of international standards facilitates harmonized regulatory processes and world trade, and thus improves global access to new technology.
5. As technology advances, it is much easier to update standards than to change regulations. Timely development and periodic revision by expert groups make medical device standards effective and efficient tools for supporting health care.
6. Manufacturers have the flexibility to choose appropriate standards or other means to demonstrate compliance with regulatory requirements.

Regulatory authorities can recognize a standard, fully or partially, provided they clearly specify and publicize their intent. Several standards can also be recognized as a group to satisfy the requirements for a particular device. In some countries, the publication of government-recognized standards mandates product compliance.

Medical devices intended for global use should follow international standards. For example, the ISO Technical Report (ISO 16142:2000) lists a number of significant international standards that may be suitable for demonstrating compliance with certain features of the essential principles of safety and performance of medical devices.

The GHTF has issued the following recommendations regarding the recognition and use of standards:

International standards are a building block for harmonized regulatory processes to assure the safety, quality and performance of medical devices. To achieve this purpose, the following principles are recommended:

- Regulatory Authorities and industry should encourage and support the development of international standards for medical devices to demonstrate compliance with "the Essential Principles of Safety and Performance of Medical Devices" (GHTF document SG1 NO20R5 referred to hereafter as the Essential Principles).
- Regulatory Authorities developing new medical device regulations should encourage the use of international standards.
- Regulatory Authorities should provide a mechanism for recognizing international standards to provide manufacturers with a method of demonstrating compliance with the Essential Principles.
- When an international standard is not applied or not applied in full, this is acceptable if an appropriate level of compliance with the Essential Principles can be demonstrated.
- While it may be preferable for harmonization purposes to use international standards it may be appropriate for Regulatory Authorities to accept the use of national/regional standards or industry standards as a means of demonstrating compliance.
- Standards Bodies developing or revising standards for use with medical devices should consider the suitability of such standards for demonstrating compliance with the Essential Principles and to identify which of the Essential Principles they satisfy.
- The use of standards should preferably reflect current, broadly applicable technology while not discouraging the use of new technologies.
- Standards may represent the current state of the art in a technological field. However, not all devices, or elements of device safety and/or performance may be addressed by recognized standards, especially for new types of devices and emerging technologies

9.8 Standard of Notified Medical Devices

(1) The medical device shall conform to the standards laid down by the Bureau of Indian Standards (BIS) established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time.

(2) Where no relevant standard of any medical device has been laid down under sub rule (1), such device shall conform to the standard laid down by the International Organization for Standardisation (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeial standards.

(3) In case of the standards which have not been specified under sub rule (1) and sub rule (2), the device shall conform to the validated manufacturer's standards.

List of standards of notified medical device available in Bureau of Indian Standards:

1. Disposable Hypodermic Syringes

Indian Standards:

1. IS 10258:2002 / ISO 7886-1:1993
   Sterile hypodermic Syringes for single use

2. IS 10258 (Part 3):2010/ISO 7886-3:2005
   Sterile hypodermic Syringes for single Use: Part 3 Auto- Disable syringe for Fixed-Dose Immunization)

3. IS 12050:1986
   Sterile hypodermic syringes with needle attached for single use

4. IS 12227: 2002 / ISO 8537:1991
   Sterile single use Syringes, with or without needle, for insulin

2. Disposable Hypodermic Needles

Indian Standards:

5. IS 10654: 2002 / ISO 7864: 1993
   Sterile Hypodermic Needles for single use

6. IS 16004:2013/ISO 6009: 1992
Hypodermic needles for single use colour coding for identification

3 Disposable Perfusion Sets

Indian Standards:

7. IS 9824 (Part 1): 1996
Transfusion equipment for medical use: Part 1 Glass transfusion bottle, closures and caps (*first revision*)

8. IS 9824 (Part2):1995
Transfusion equipment for medical use: Part 2 Blood-taking set for single use (first revision)

9. IS 9824(Part 3):1996
ISO 1135-4:1987
Transfusion equipment for medical use: Part 3 Transfusion sets for single use (*first revision*)

4. Cardiac Stents

Indian Standards:

10. IS/ISO 25539-2:2012
Cardiovascular implants -- Endovascular devices: Part 2 Vascular stents

5. Drug Eluting Stents

Indian Standards:

11. IS/ISO 25539-2:2012
Cardiovascular implants -- Endovascular devices: Part 2 Vascular stents

6. Catheters

Indian Standards:

12. IS 9649:1980
Specification for Introducer, Catheter, Urethral

13. IS 5338:1969
Catheter, Eustachian

14. IS 6960:1973
Catheters, metal, female

15. IS /ISO 8836: 2014

Suction Catheters for use in Respiratory Tract

16. IS/ ISO 10555-1:1995
Sterile, single-use intravascular catheters: Part 1 General requirements

17. IS/ISO 10555-2:1996
Sterile, single-use intravascular catheters: Part 2 Angiographic catheters

18. IS/ISO 10555-3:1996
Sterile, single-use intravascular catheters: Part 3 Central venous catheters

19. IS/ISO 10555-4:1996
Sterile, single-use intravascular catheters: Part 4 Balloon dilatation catheters

20. IS/ISO 10555-5:1996
Sterile, single-use intravascular catheters: Part 5 Over-needle peripheral catheters

7. Heart Valves

Indian Standards:

21. IS/ISO 5840:2005
Cardiovascular Implants - Cardiac Valve - Prostheses – Specification

22. IS 11566:1986
Valve retractors

8. Scalp Vein Set

Indian Standards:

23. IS 16097:2013
(Sterile single use Scalp Vein (Winged Needle) Infusion set

9. Orthopaedic Implants

Indian Standards:

24. IS 5347(Part 1):1986
Requirements for orthopaedic implants: Part 1 General requirements *(second revision)*

25. IS 5347(Part 2):1993 / ISO 5832/1-1987
Requirements for orthopaedic Implants: Part 2 Wrought stainless steel *(first revision)*

26. IS 5347(Part 5):2000 / ISO 5832/4:1996
Requirements for orthopaedic implants: Part 5 Cobalt – chromium - molybdenum casting

alloy *(first revision)*

27. IS 5347(Part 7):2002 / ISO 5832/6-1978
    Requirements for orthopaedic implants: Part 7 Wrought cobalt - nickel chromium - molybdenum alloy *(first revision)*

28. IS 5347(Part 8):1997 / ISO 5832/7-1994
    Requirements for orthopaedic implants: Part 8 Forgeable and cold-formed – cobalt – chromium – nickel – molybdenum - iron alloy*(first revision)*

10. Orthopaedic Implants (Concluded)

Indian Standards:

29. IS 5347(Part 15):1997/ ISO 5832-11:1994
    Requirements for orthopaedic implants: Part 15 Wrought titanium 6 - aluminium 7- niobium alloy)

30. IS 5347(Part 16):2002 / ISO 13781:1997
    Requirements for orthopaedic implants: Part 16 Poly (L- Lactide) resins and fabricated forms for surgical implants - In vitro degradation testing)

31. IS 5347(Part 17):2002 / ISO 13782:1996
    Requirements for Orthopaedic Implants: Part 17 Metallic materials - Unalloyed tantalum for surgical implant applications)

32. IS 5347(Part 18):2002 / ISO 13356:1997
    Requirements for orthopaedic implants: Part 18 Ceramic materials based on yttria-stabilized tetragonal zirconia (Y- TZP)

33. IS 10235(Part 2):1982
    Glossary of terms in orthopaedics: Part 2 Mechanics and materials for implants

34. IS 11088:1984
    Guide for retrieval and analysis of metallic orthopaedic implants

35. IS 14228:1995/ ISO 8827:1988
    Implants for surgery - Staples with parallel legs for orthopaedic use - General requirements

11. Internal Prosthetic Replacements

Indian Standards:

36. IS 6802:1986
    Prosthetic hip joint *(first revision)*

37. IS 7373:2003
    Hip disarticulation joint unit for lower limb prosthetic fitments (*second revision*)

12. Skin Ligatures, Sutures and Staplers

Indian Standards:

38. IS 9165(Part 1):1992
    Surgical instruments - Needles, suture: Part 1 Specification (*first revision*)

39. IS 9165(Part 2):1992
    Surgical instruments - Needles, suture: Part 2 Eyed needles - Sizes, shapes and dimensions

40. IS 13127:1991
    Surgical Instruments - Suture Clip Applying Forceps, Wachenfeld Type - Shape, Dimensions and Mass

41. IS 5678:1970
    Specification for Forceps, eye, conjectival, suture (Moorfield's pattern)

13. Condoms

Indian Standards:

42. IS/ISO 4074:2002 (Natural latex rubber condoms - Requirements and test methods

43. IS/ISO 23409:2011(Male condoms- Requirements and test methods for condoms made from synthetic materials)

44. IS/ISO 16037:2002
    Rubber condoms for clinical trials - Measurement of physical properties

14. Tubal Rings

Indian Standards:

45. IS 13009:2000 (Contraceptive devices - Tubal ring - Specification *(first revision)*

15. Surgical Dressings

Indian Standards:

46. IS 4513:1968
    Specification for Scissors, Surgical Dressing and Stitch

47. IS 11163:1985
    First-aid dressings

48. IS 14944:2001
    Surgical dressings - Methods of test

16. Blood / Blood Component Bags

Indian Standards:

49. IS 15102:2002 / ISO 3826: 1993
    Plastics Collapsible Containers for Human Blood and Blood Components

Process standards:

IS/ISO 13485:2016

Medical Devices-Quality Management System-Requirements for Regulatory Purposes

ISO 14971:2007

Medical Device-Application of risk management to medical device

ISO 14155:2011

Clinical Investigation of Medical devices for human subjects

ISO 25424:2009

Sterilization of medical devices-Low temperature steam and formaldehyde-requirements for development, validation and routine control of a sterilization process for medical device

ISO 15223-1:2016

Medical devices-symbols to be used with medical device labels, labelling and information to be supplied-part 1: General requirements

ISO 14160:2011

Sterilization of health care products -- Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives -- Requirements for characterization, development, validation and routine control of a sterilization process for medical devices

ISO 14937:2009

Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

ISO 20857:2010

Sterilization of health care products -- Dry heat -- Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 11135:2014

Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of sterilization process for medical devices

ISO 11137-1:2006

Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

ISO 11737-2:2009

Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

ISO 17665-1:2006

Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 17664:2017

Processing of health care products -- Information to be provided by the medical device manufacturer for the processing of medical devices

ISO 18113-1:2009

In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 1: Terms, definitions and general requirements

ISO 23640:2011

In vitro diagnostic medical devices -- Evaluation of stability of in vitro diagnostic reagents

ISO 10993-1:2009

Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

ISO 10993-2:2006

Biological evaluation of medical devices -- Part 2: Animal welfare requirements

ISO 10993-3:2014

Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

ISO 10993-4:2017

Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood

ISO 10993-5:2009

Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity

ISO 10993-6:2016

Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation

ISO 10993-7:2008

Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals

ISO 10993-9:2009

Biological evaluation of medical devices -- Part 9: Framework for identification and quantification of potential degradation products

ISO 10993-10:2010

Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

ISO 10993-11:2017

Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity

ISO 10993-12:2012

Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials

ISO 10993-13:2010

Biological evaluation of medical devices -- Part 13: Identification and quantification of degradation products from polymeric medical devices

ISO 10993-14:2001

Biological evaluation of medical devices -- Part 14: Identification and quantification of degradation products from ceramics

ISO 10993-15:2000

Biological evaluation of medical devices -- Part 15: Identification and quantification of degradation products from metals and alloys

ISO 10993-16:2017

Biological evaluation of medical devices -- Part 16: Toxicokinetic study design for degradation products and leachables

ISO 10993-17:2002

Biological evaluation of medical devices -- Part 17: Establishment of allowable limits for leachable substances

ISO 10993-18:2005

Biological evaluation of medical devices -- Part 18: Chemical characterization of materials

ISO/TS 10993-20:2006

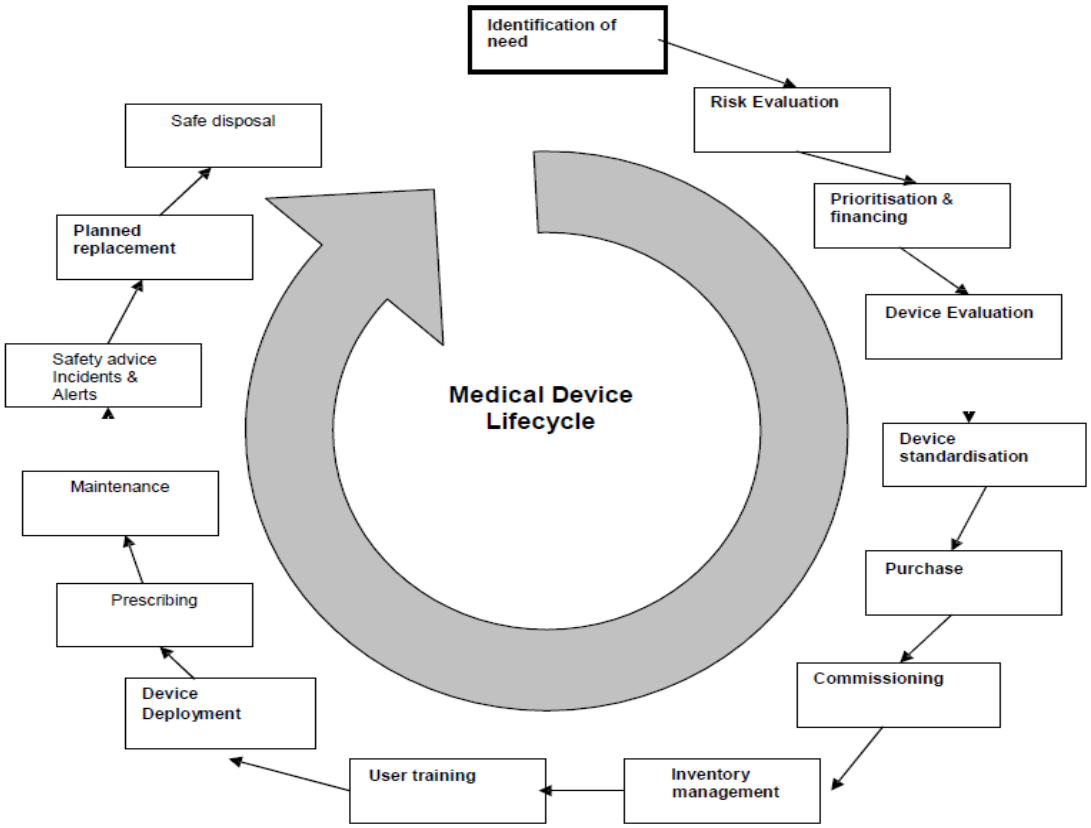
Biological evaluation of medical devices -- Part 20: Principles and methods for immunotoxicology testing of medical devices

ISO/TR 10993-22:2017

Biological evaluation of medical devices -- Part 22: Guidance on nanomaterials

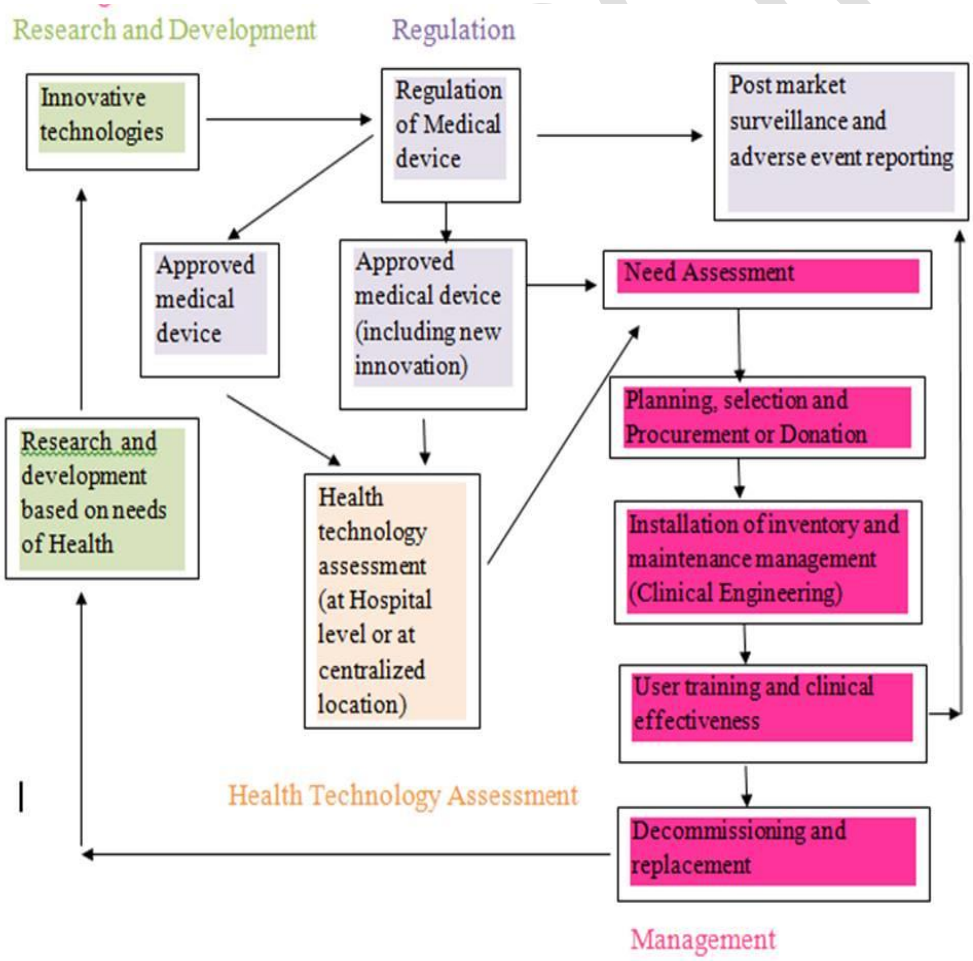
Life cycle of Medical device and Key stakeholders:

Life of medical devices mostly starts with researchers, identifying the need for development of medical device for delivering the Diagnostic or Therapeutic or Assistive or Preventive care. From the initial design phase, plan for identification of the potential risk associated with the medical devices and plan for mitigating the same is developed. Additionally, identifying appropriate nomenclature and device evaluation process in terms of clinical trials is conducted to validate the functions of medical devices. Further devices are compared for existing medical devices standards (ISO/IEC etc) and verifying the compliance with same is conducted. On successful completion of all the above process, it's submitted to approval from regulator of medical device or other government bodies (in absence of medical devices regulator in the country intended for manufacture or sell the medical device). In certain countries there are multiple laws on medical devices, on compiling all the next major phase in the life of medical devices starts.



Procurement of medical devices depending on the nature occurs mostly at retail store (for personal care or home care devices) or hospital/ clinical establishment. With wide range of technology available in market it has become difficult to choose the appropriate devices. Health technology assessment is a new approach, mainly used by public health facility or government organizations, to enable responsible procurer to choose the best medical devices delivering with maximum value for investment. Procurement is generally followed by quality inspection and commissioning of the medical device. Further necessary steps are followed to add devices to inventory management system of organization.

1.Research and Development 2.Regulation 3. Health Technology Assessment 4.Management



End users/Healthcare professional of medical devices and clinical engineers (entrusted with maintenance at user level) are trained by medical device manufacturer or its representative to use the devices as per user instruction given by Manufacturer. Training is followed by deployment of medical devices or prescribing of devices is initiated.

Periodic and corrective maintenance process is an ongoing process throughout the life of medical devices till the decommissioning of medical devices. Similarly, along with maintenance another key activity is the identification of incidents or safety issues or adverse events associated with medical devices. These process of identification through post market surveillance, add to the improvement of medical devices and early intervention or implementation of corrective measure to reduce the repeatability of adverse events.

Total life cycle of medical devices is usually defined by the manufacturer at the time of production. Hence the phase is planned replacement of medical devices with the next iteration or another technology. This phase is also referred as obsolete replacement or condemnation. Certain equipments like X-ray, Nuclear medicine devices like PET are governed in most of the countries by rules or regulation on decommissioning of atomic energy devices. In India, Atomic energy regulatory board (AERB) sets the guideline and rules on these medical devices. Other category of medical device are advised to decommission or disposed after use, complying to Biomedical Waste Management rules or E waste management rules or Central/State pollution control board (Statutory board).

I. Nomenclature of Medical devices.

The nomenclature of medical devices is a coding system used to generically identify medical devices and related health products. Having a nomenclature system in place for medical devices facilitates their management and regulation by standardizing terms that enable communication despite linguistic and other barriers. Several naming systems for medical devices exist and each is used by a different group of professionals depending on the needs of that particular group, needs such as maintenance, procurement, accounting, stock keeping, regulatory affairs, adverse medical device event reporting, and customs operations. ISO 15225:2016 specifies rules and

guidelines for a medical device nomenclature data structure, in order to facilitate cooperation and exchange of data used by regulatory bodies on an international level between interested parties, e.g. regulatory authorities, manufacturers, suppliers, healthcare providers and end users.ISO 15225:2016 includes guidelines for a minimum data set and its structure. These guidelines are provided for system designers setting up databases that utilize the nomenclature system described herein. The requirements contained in this International Standard are applicable to the development and maintenance of an international nomenclature for medical device identification.

Further nomenclature systems of interest for medical device identification include, for example:
• The International Statistical Classification of Diseases and Related Health Problems (ICD). ICD-10 is the tenth revision of a WHO developed medical classification list for diseases, disorders, health symptoms, and injuries. It serves to accurately code medical diagnoses and is employed by all member states, in for example, epidemiology, health management and clinical settings.
• The Unique Device Identification (UDI) system that is being developed by the U.S. Food and Drug Administration (FDA) to label medical devices through their distribution and use. The related Global UDI Database will be publically accessible for download and use.
• The United Nations Standard Products and Services Code (UNSPSC) that is an open, global, multi-sector classification system divided in five hierarchical levels. It was developed by the United Nations Development Programme (UNDP) and Dun & Bradstreet Corporation (D&B) in 1998 and is managed by GS1 US, a not-for profit organization, since 2003.

The above organizations develop or use medical device nomenclature for their core function, but there is two organizations exclusively or primarily work on developing nomenclature for medical devices.

(i) The Global Medical Devices Nomenclature System (GMDN) was developed by the European Committee for Standardization (CEN) and medical device experts from around the world (manufacturers, healthcare authorities and regulators) based on the international standard ISO 15225. The GMDN is a poly-hierarchical system. Product identification is done by unique

numerical five-digit numbers that are associated with a term (medical device name), a definition that includes the intended use(s) and the device category (based on device application, technology, or other common characteristics). Identification of all specific medical devices having substantially similar generic features is possible through cross-referencing.

(ii) Universal Medical Device Nomenclature System (UMDNS) is a standard, free of charge; monthly updated, international nomenclature and computer coding system to help you better manage medical devices. UMDNS is the worldwide nomenclature that has been officially adopted by many nations. UMDNS facilitates identifying, processing, filing, storing, retrieving, transferring, and communicating data about medical devices. The nomenclature is used in applications ranging from hospital inventory and work-order controls to national agency medical device regulatory systems and from e-commerce and procurement to medical device databases.

An example of GMDN code and UMDN code:

GMDN Term Name: Scalpel, single-use
GMDN Code: 47569

GMDN Definition: A sterile, hand-held, manual surgical instrument constructed as a one-piece handle and scalpel blade (not an exchangeable component) used by the operator to manually cut or dissect tissue. The blade is typically made of high-grade stainless steel alloy or carbon steel and the handle is often made of plastic. This is a single-use device.

UMDN Term: Knives, Surgical, Multipurpose, Scalpel
UMDN code: 12252

UNDN Definition: Multipurpose small surgical knives designed to cut or dissect tissue. These scalpels may consist of manual, handheld knives with a straight handle and an integral blade with a sharp convex edge. They are available as reusable or single-use instruments. Scalpels may also consist of a combination of a reusable handle and a detachable single-use or reusable blade placed at the distal end. Multipurpose scalpels are used in general, plastic, and in a variety of

other types of surgical procedures. Dedicated scalpels intended for microsurgical procedures are also available.

II. Medical devices Standards

Conformity with voluntary standards is a means by which the manufacturer may demonstrate that a medical device conforms to one or more of the Essential Principles of safety and performance, consistently throughout its life cycle.

Medical device standards can largely be grouped into three categories:
■ Basic standards (also known as horizontal standards), which cover fundamental concepts, principles and requirements applicable to a wide range of products and/or processes, e.g. QMS (ISO 13485), risk management system (ISO 14971), clinical investigation (ISO 14155);

Example in detail: ISO 13485:2016 (Medical devices - Quality management systems) specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). ISO 13485:2016 can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations. Requirements of ISO 13485:2016 are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. The processes required by ISO 13485:2016 that are applicable to the organization, but are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system by monitoring, maintaining, and controlling the processes.

ISO 14971:2007 specifies a process for a manufacturer to identify the hazards associated with medical devices, including in vitro diagnostic (IVD) medical devices, to estimate and evaluate

the associated risks, to control these risks, and to monitor the effectiveness of the controls. The requirements of ISO 14971:2007 are applicable to all stages of the life-cycle of a medical device.

ISO 14155:2011 addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes. It specifies general requirements intended to protect the rights, safety and well-being of human subjects, ensure the scientific conduct of the clinical investigation and the credibility of the results, define the responsibilities of the sponsor and principal investigator, and assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices. ISO 14155:2011 does not apply to *in vitro* diagnostic medical devices.

■ Group standards (also known as semi-horizontal standards), which cover aspects applicable to families of similar products or processes with reference to basic standards, e.g. sterility (ISO 14937), electrical safety (IEC 60601-1), biocompatibility (ISO 10993);

Example in detail: IEC 60601-1:2005 contains requirements concerning basic safety and essential performance that are generally applicable to medical electrical equipment. For certain types of medical electrical equipment, these requirements are either supplemented or modified by the special requirements of a collateral or particular standard.

ISO 10993-1:2009 describes the general principles governing- the biological evaluation of medical devices within a risk management process, the general categorization of devices based on the nature and duration of their contact with the body, the evaluation of existing relevant data from all sources, the identification of gaps in the available data set on the basis of a risk analysis, the identification of additional data sets necessary to analyze the biological safety of the medical device and the assessment of the biological safety of the medical device.

ISO 14937:2009 specifies general requirements for the characterization of a sterilizing agent and for the development, validation and routine monitoring and control of a sterilization process for medical devices. It applies to sterilization processes in which microorganisms are inactivated by

physical and/or chemical means and is intended to be applied by process developers, manufacturers of sterilization equipment, manufacturers of medical devices to be sterilized, and organizations responsible for sterilizing medical devices. This standard is applicable to only devices which are intended to be sterile while sale/pre-use.

■ Product standards (also known as vertical standards), which cover safety and performance aspects of specific products or processes, e.g. standards for infusion pumps (IEC 60601-2-24), X-ray machines (IEC 60601-2-54), blood glucose meters for self-testing (ISO: 15197) and for IVDs.

Example in detail: IEC 60601-2-24:2012 applies to the basic safety and essential performance of infusion pumps and volumetric infusion controllers. This standard applies to administration sets to the extent as their characteristics influence the basic safety or essential performance of infusion pumps and volumetric infusion controllers. However this standard does not specify requirements or tests for other aspects of administration sets. This particular standard specifies the requirements for enteral nutrition pumps, infusion pumps, infusion pumps for ambulatory use, syringe or container pumps, volumetric infusion controllers and volumetric infusion pumps. However, particular standard does not apply to the following: devices specifically intended for diagnostic or similar use; devices for extracorporeal circulation of blood; implantable devices; equipment specifically intended for diagnostic use within urodynamics; equipment specifically intended for diagnostic use within male impotence testing; and devices covered by ISO 28620.

IEC 60601-2-54:2009 applies to the basic safety and essential performance of medical electrical equipment and medical electrical systems intended to be used for projection radiography and radioscopy. The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of Medical equipment for radiography and radioscopy. Requirements for additional provisions for Medical equipment for interventional applications are covered by IEC 60601-2-43. IEC 60601-2-54:2009 is about type testing of X-ray systems. For the type test of a given product only one particular standard applies.

ISO 15197:2013 specifies requirements for *in vitro* glucose monitoring systems that measure glucose concentrations in capillary blood samples, for specific design verification procedures and for the validation of performance by the intended users. These systems are intended for self-measurement by lay persons for management of diabetes mellitus.ISO 15197:2013 is applicable to manufacturers of such systems and those other organizations (e.g. regulatory authorities and conformity assessment bodies) having the responsibility for assessing the performance of these systems.

At the expanded level, the regulatory authority may wish to establish a procedure to identify national versions of international standards that it accepts as providing presumption of compliance to specific Essential Principles, i.e. "recognized standards". Preference for recognition should be given to international standards, e.g. those of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), regional standards and the national versions of international standards.

It is also important that national standards correspond to the current version of international standards. As international standards are periodically revised, national standards will have to be revised accordingly and the authority should establish a transition period for manufacturers to adopt the new versions. To maintain the necessary flexibility in utilizing standards, it is better to adopt a system of recognizing standards through guidance documents or guidelines than placing the standards into legislation; they can then be updated to stay current and can be revised much faster than legislation can be updated.

II. A Common testing's conducted voluntarily or by instruction of National Regulator on Medical devices (CDSCO) by Manufacturer against basic standards (Horizontal standards) and group standards (Semi Horizontal standards) associated with Medical devices including In-vitro diagnostic devices.

(a) Electromagnetic interference and Electromagnetic compatibility Testing: The horizontal standards that are applicable to medical devices (including IVD), against which testing are conducted voluntarily by manufacture or by instruction through act and rules laid by Government of India from time to time. Wide range of Medical devices available in Indian

Medical Devices market is having electronic components or biomaterials or combination of both. Hence EMI/EMC or bio compatibility is commonly tested. For most IVD, general ISO/IEC standards are considered applicable against which compliance testing are conducted voluntarily by manufacturer in addition to specific standards prescribed by National Medical devices regulator (CDSCO).

It is highly important that the operation of Medical Devices must not degrade their own performance or the output of other systems. Electromagnetic interference and Electromagnetic compatibility (EMI/EMC) test labs, therefore, ensure that the medical devices are protected against external effects (lightning, electromagnetic pulse, electrostatic discharge and man-made Radio frequency transmissions) and internal effects (electronic noise emissions, self-generated RF transmissions from antennas and cross-coupling of electrical currents). This would guarantee self-compatibility within the system (internal environment), with other systems as well as the external environment to provide required performance. An Electromagnetic Interference (EMI) may be defined as any degradation in the performance of an equipment (device/system/sub-system) resulting in malfunctioning of the equipment due to quality parameters of incoming energy. Interference occurs if the received energy causes malfunctioning of the receptor. There are several interference control techniques that could be applied to reduced or eliminate interference at source, some of them are :

a) Shielding: In order to reduce the coupling of radiated electromagnetic energy into the equipment, Metal barriers are used.

b) Proper grounding: Depending upon the frequency of operation, single point, multi point or Hybrid grounding should be done.

c) PCB layout: The early stage design must be modified to a proper PCB design considering the effects of interference.

d) EMI filtering: The interference on the power, signal and control lines would suppress via EMI filtering.

Electromagnetic Compatibility (EMC) is a near perfect state in which a receptor (system / device

/ subsystem) functions satisfactorily in common electromagnetic environment, without introducing intolerable electromagnetic disturbance to any other devices/ equipment/system in that environment. The goal of Electromagnetic compatibility is correct operation, in electromagnetic environment of different equipment which uses electromagnetic phenomena, and the avoidance of any interference effects during the course of the co-existence. Electromagnetic compatibility is achieved by addressing both emission and susceptibility issues, i.e., quieting the sources of interference and hardening the potential victims.

Typical parameters in EMI/EMC testing of electronic/electrical medical equipments are: Conducted Emission Test, Radiated Emission Test, Harmonic Current Emission test, Voltage Fluctuation & Flicker test, RF Radiated Susceptibility Test, Electrostatic Discharge immunity test, Electrical Fast Transient (EFT)/ Burst Immunity test, High Energy/ Telecom Surge Immunity test, Conducted RF Susceptibility Test, Power Frequency, Magnetic Field Immunity Test, Pulse Magnetic field immunity test, Voltage dips, Short Interruption & Voltage Variations, Immunity test Ring Wave/ Damped. Oscillatory Wave Immunity test, DC Voltage dips, Short Interruption & Voltage Variations Immunity test.

The tests are usually conducted against ISO standards like ISO/IEC 61000, 61326 etc in laboratory following ISO ISO/IEC 17025 or specified by National regulator on Medical devices (CDSCO).

(b) Biocompatibility testing: Biomaterials can be derived either from nature or synthesized in the laboratory using a variety of chemical approaches utilizing metallic components, polymers, ceramics or composite materials. They are often used and/or adopted for a medical application, and thus performs, augments, or replaces a natural function. Such functions may be benign, like being used for a heart valve, or may be bioactive with a more interactive functionality such as coated hip implants. Biomaterials are also used every day in dental applications, surgery, and drug delivery. Biocompatibility, by definition, a measurement of how compatible a device is with a biological system. The purpose of performing biocompatibility testing is to determine the fitness of a device for human use, and to see whether use of the device can have any potentially harmful physiological effects. Typically, material characterization and analysis of a device's components are conducted prior to any biological testing.

Biocompatibility testing involves toxicology (Cyto-compatibility, Tissue compatibility, Hemo-compatibility, Histopathology etc), biomaterial associated infection (Sterility evaluation etc), mechanical and performance testing (Accelerated Aging, Package validation etc). The tests are usually conducted against ISO standards like ISO 10993 in laboratory following ISO ISO/IEC 17025 or specified by National regulator on Medical devices.

(c) Horizontal standards on IVD: General or basic horizontal standards against which testing of IVD is conducted voluntarily or on instruction of National regulator on Medical devices (CDSCO). Example of some below:

ISO 18113-1:2009-In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements, Part 2: In vitro diagnostic reagents for professional use, Part 3: In vitro diagnostic instruments for professional use, Part 4&5: In vitro diagnostic reagents for self-testing.

ISO 17511 specifies how to assure the metrological traceability of values assigned to calibrators and control materials intended to establish or verify trueness of measurement. The calibrators and control materials are those provided by the manufacturers as part of, or to be used together with, in vitro diagnostic medical devices. External quality assessment (survey) samples, with proven commutability, whose values have been assigned by means of internationally agreed reference measurement systems or internationally agreed conventional reference measurement systems fall within the scope of ISO 17511. ISO 17511 is not applicable to control materials that do not have an assigned value and are used only for assessing the precision of a measurement procedure, either its repeatability or reproducibility (precision control materials); control materials intended for intra-laboratory quality control purposes and supplied with intervals of suggested acceptable values, each interval obtained by interlaboratory consensus with respect to one specified measurement procedure, and with limiting values that are not metrologically traceable; correlation between results of two measurement procedures at the same metrological level, purporting to measure the same quantity, because such "horizontal" correlation does not provide metrological traceability; calibration derived from correlation between the results of two measurement procedures at different metrological levels, but with quantities having analytes of different characteristics; metrological traceability of routine results to the product calibrator and

their relations to any medical discrimination limit; and properties involving nominal scales, i.e. where no magnitude is involved (e.g. identification of blood cells).

ISO 15193, In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for content and presentation of reference measurement procedures. ISO 15194, In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation. ISO 15198:2004, Clinical laboratory medicine — In vitro diagnostic medical devices — Validation of user quality control procedures by the manufacturer. ISO 18153, In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials. IEC 62366:2015 Medical devices—Part 1: Application of usability engineering to medical devices.

III. Technical Specification on Medical devices:

Technical specification enable key transaction, from key stakeholder (Manufacture) to another key stakeholder (Hospital or Personal use device medical device). Technical specifications are generally developed as per the need and availability of associated technology or clinical service intended to deliver. In India, Ministry of Health and Family Welfare had released technical specification of approximately 160 medical devices, commonly used till the level of secondary care institutions. This enables uniform availability of technology across country while procuring under National Health Mission and support State/UT on drafting technical specification. WHO is doing similar exercise to aid countries across the globe in procuring medical devices, approximately 61 specifications are published so far. In India Ministry of Health and Family Welfare with support of its Technical support organization National Health Systems Center, WHO collaborating center for priority Medical Devices and Health Technology Policy is planning to expand technical specification to another 400 medical devices commonly used till secondary care public health facilities.

India has adopted the same template used by WHO for drafting the technical specification as the specification enable to capture key areas that were left out in conventional specifications drafted

by autonomous or state public health facilities in India. Some of the key features are as below:

1. Name and coding
2. General section indicating clinical purpose, department using device etc.
3. Technical section consisting of Technical characteristic of device, user interface, software etc.
4.Physical Characteristics depicting dimensions, configuration, noise, mobility etc.
5 Energy source signifying Battery, tolerance, power consumption, protection etc.
6. Accessories, spare part, consumables associated with device.
7. Environmental and departmental conditions like disinfection, sterility, temperature etc.
8. Standard and safety - indicating regulatory, certificates, performance and safety standards.
9. Training and installations- Pre-installation, sign off requirements/checks, training etc.
10. Warranty and maintenance- service contract, warranty duration etc.
11. Documentation to be supplied along device like operating manuals, service manual etc.
12. Notes section indicating warning signs, service support contact information's etc.

IV. Other Acts /Policy/Government organizations directly involved with Medical devices:

Medical Devices Industry is a vibrant and inter-disciplinary in nature, hence various government departments or organizations or Act and Rules govern medical devices directly or indirectly. General laws or government organizations involved with medical devices frequently are described below. Apart from these central government initiatives, various state governments are also actively supporting various schemes or organizations to nurture the field of medical devices.

IVa. Key Act or Rules in India other than Drugs and Cosmetics act in the life cycle of medical device.

Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act, 1994: The sale of ultrasound machines/imaging machines are governed as follows-

(1) No organization including a commercial organization or a person, including manufacture, importer, dealer or supplier of ultrasound machines/imaging machines or any other equipment, capable of detecting sex of foetus, shall sell distribute, supply, rent, allow or authorize the use of any such machine or equipment in any manner, whether on payment or otherwise, to any Genetic

Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person unless such Centre, Laboratory, Clinic, body or person is registered under the Act.

(2) the provider of such machine/equipment to any person/body registered under the Act shall send to the concerned State/UT Appropriate Authority and to the Central Government, once in three months a list of those to whom the Machine/equipment has been provided.
(3) Any organization or person, including manufacturer, importer, dealer or suppler of ultrasound machines/imaging machines or any other equipment capable of detecting sex of foetus selling, distributing, supplying or authorizing, in any manner, the use of any such machine or equipment to any Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person registered under the Act shall take an affidavit from the Genetic Counselling Centre, Genetic Laboratory, Genetic Clinic, Ultrasound Clinic, Imaging Centre or any other body or person purchasing or getting authorization for using such machine/equipment that the machine/equipment that the machine/equipment shall not be used for detection of sex of foetus or selection of sex before or after conception.

The ultrasound machines/imaging machines are regulated as follows–
(1) The use of portable ultrasound machine or any other portable ultrasound machine or any other portable machine or device which has the potential for selection of sex before conception or detection of sex during pregnancy shall be permitted only in the conditions, namely
(a) the portable machine being used, within the premises it is registered, for providing services to the indoor patients;

(b) as part of a mobile medical unit, offering a bouquet of other health and medical services. Explanation- For the purpose of this sub-rule, the expression “other health and medical services” means the host of services provided by the mobile medical unit which may include the following, namely:-

(i) Curative
(a) Referral of complicated cases;

(b) Early detection of TB, Malaria, Leprosy, Kala-Azar and other locally endemic communicable diseases and non-communicable diseases such as hypertension diabetes cataract cases, etc.;
(c) Minor surgical procedures and suturing;
(d) Specialist services such as O and G Specialist, Paediatrician and Physician.

(ii) Reproductive and child Health Services.
(a) Ante natal checkup and related services;
(b) Referral or complicated pregnancies;
(c) Promotion of institutional deliveries;
(d) Post-natal checkup;
(e) Immunization clinics;
(f) Treatment of common childhood illness;
(h) Adolescents care such as lifestyle education, counsellling, treatment of minor ailments.

(iii) Family planning services
(a) Counselling for spacing and permanent method;
(b) Distribution of contraceptives.

(iv) Diagnostic
(a) Investigation facilitates like hemoglobin, urine examination;
(b) Clinical detection of leprosy tuberculosis or endemic diseases;
(c) Screening of cancer, etc

(v) Specialized facilities and services
(a) X-ray; (b) ECG; (c) Ultrasound test.

(vi) Emergency services and care in times of disaster or epidemic or public health emergency or accident, etc.

Biomedical Waste management rules 2016: Most of the consumables of medical devices/reagents associated with medical device/single-use IVD is to be disposed after use as per

direction of Ministry of Environment & Forests through Bio-medical Waste Management (BMW) Rules, 2016. The BME rules 2016 which will bring in a wider and more comprehensive regime for bio waste management. Under the new regime, the coverage has increased and also provides for pre-treatment of lab waste, blood samples, etc. It mandates bar code system for proper control.

Atomic Energy Regulatory Board, Atomic Energy Safe Disposal of Radioactive Waste Rules, 1987 Radiation Protection Rules, 1962: All the medical devices with radiations sources are regulated (sale/commissioning/decommissioning/license for operation) by AERB. The rules govern the management of spent radioactive sources and radioactive waste arising from the use of radionuclide's in medicine including decommissioning of such facilities. Common medical devices associated with radiations and regulated by AERB as follows- CT scan, PET Scan, SPECT scan, X ray, C arm, O arm, Mammography unit, LINAC, Cobalt therapy, Brachy therapy equipment etc.

Radionuclides, in the form of sealed and unsealed sources, are extensively used in medicine. Such applications could result in generation of significant quantities of solid and liquid wastes and occasionally gaseous wastes. Much of the solid waste consists of contaminated items, such as paper, plastics, glassware, equipment and other biological waste.

Liquid radioactive wastes comprise of aqueous and organic streams, such as patients' urine (primarily in thyroid cancer therapy) and effluents from decontamination processes. In many applications of radionuclides, the radioactive waste generated may comprise of short-lived radionuclides, which may be managed by providing storage for decay.

E-waste (Management) Amendment Rules, 2018 & Batteries (Management and Handling) Rules, 2001: Integration of medical devices with electronics has exponential raised over the last couple of decades. Hence the waste associated with medical devices that are electronic or battery components in nature are to be disposed as per Government has amended the E-waste (Management) Rules 2016 & Batteries (Management and Handling) Rules. This would facilitate and effectively implement the environmentally sound management of e-waste in India. The

objective is to channelize the E-waste generated in the country towards authorized dismantlers and recyclers in order to formalize the e-waste recycling sector.

IV.b Act/Rules on preparation of Standards including Medical devices:

BIS is the National Standard Body of India established under the BIS Act 1986 for the harmonious development of the activities of standardization, marking and quality certification of goods and for matters connected therewith or incidental thereto. The Act of 1986 is revised to BIS act 2016, establishing the Bureau of Indian Standards (BIS) under Ministry for Consumer Affairs, Food and Public Distribution as the National Standards Body of India.

Currently following Medical Devices are under mandatory product certification:

Medical Equipment			
1.	IS 3055 (Part 1)	Clinical thermometers :Part1 Solid stem type	Clinical Thermometers (Quality Control), 2001 GSR No. 843(E) dated 9 Nov. 2001
2.	IS 3055 (Part 2)	Clinical thermometers :Part 2 Enclosed scale type	
3.	IS 7620 (Part 1)	Diagnostic Medical X-Ray Equipment	Diagnostic Medical X- Ray Equipment AERB/443/39 MDX/3509/94,Oct. 94

There are 14 division council in BIS, Medical equipment and Hospital planning department prepares standards under following technical committee:

(a) Surgical Instruments (b) Orthopaedic Instruments, Implants And Accessories (c) Obstetric And Gynaecological Instruments And Appliances (d) Ear, Nose And Throat Surgery Instruments (e) Ophthalmic Instruments And Appliances (f)Thoracic And Cardiovascular Surgery Instruments (g) Neurosurgery Instruments Implants And Accessories (h) Dentistry (i)Artificial Limbs, Rehabilitation Appliances and Equipment for the Disabled (j) Medical Laboratory Instruments (k) Anaesthetic, Resuscitation And Allied Equipment (l) Hospital Equipment and Surgical Disposal (m)Veterinary Hospital Planning And Surgical Intruments (n) Hospital Planning (o) Eletromedical Dignostic Imaging and Radiotherapy equipment (p) Health Informatics (q) Immuno-biological Diagnostic Kits (r) Medical Biotechnology And Nanotechnology (s) Hospital Bio Medical Waste Management And Infection Control.

IV.c Support in Research and Development of Medical Device.

Department of Biotechnology: Innovation is the key to address the unmet clinical needs. The demand for medical devices and implants is growing rapidly globally as well as in India. Innovation in medical technologies for developing solutions for local problems is the need of the hour. In the country like India, we need solutions that are affordable, simple, robust, reliable and flexible enough to work in small towns, clinics and government health centres. Realising the need to foster and promote development of indigenous affordable medical technologies, DBT has taken initiatives to implement med-tech innovation biodesign programmes and building capacity for innovative research, prototyping, validation and testing of medical technologies.

Medical Technology Assessment Board under Department of Health Research: The Government of India is committed to extend healthcare services to its 1.25 billion population as part of India's Universal Health Coverage (UHC) agenda. The Medical Technology Assessment Board (MTAB) to be set as a part of Department of Health Research, Ministry of Health and Family Welfare aims to reduce the cost and variations in patient care, expenditure on medical equipment in directly affecting the cost of patient care, overall cost of medical treatment, reduction in out of

pocket expenditure of patients and streamline the medical reimbursement procedures for effective implementation of the Universal Coverage Programme.

Department of Science and Technology: Biomedical Device and Technology Development program is initiated during 2016. Department was earlier supporting development of instruments for Medical and Healthcare applications through Instrumentation Development Programme. BDTD has been evolved considering the concern of medical device industry for R&D to develop new innovative products as per global standards. The mandate of BDTD is to evolve and support projects for design & development of devices for:

a. Early-Stage Prototype Development: (The integration and testing of basic components in a laboratory environment).

b. Late-Stage Prototype Development (Fabrication of compact prototype for testing and validation)

c. Pilot Scale Testing and validation: (Upon completion of the technology's design, fabrication final testing with limited number of prototypes) with mandatory manufacturer industry participation.

The focus of DST-BDTD will be on development of devices and related technologies. The targeted categories include screening, diagnostic, surgical and life support equipments for clinical applications in healthcare sector.

Biotechnology Industry Research Assistance Council & Department of Electronics and Information Technology: BIRAC flagship schemes are to make significant investments in the medical devices sector and hence promoting the R&D of medical devices. BIRAC has supported more than 100 industries of Medical Fraternity and is supporting many ideas of young individual researchers, SME and large companies. Department of Electronics and Information Technology (DeitY) Industry launched Innovation Programme on Medical Electronics with an aim to promote and foster cutting edge technologies in the field of Medical Electronics. These include supporting the entire value chain of Electronics R&D activities in the country ranging from the basic components to sophisticated product development.

Department of Electronics and Information Technology: Electronics has all along made valuable contribution in the field of medicine. The quality and availability of health care are becoming increasingly dependent on radically new diagnostic, monitoring, and prosthetic instruments provided by electronics some examples being from a simple thermometer, blood pressure measurement instrument, stethoscope to the high end MRI machine. Medical Electronics is a specialized discipline which integrates engineering with biomedical sciences and clinical practice. The miniaturization of electronics devices and integration technologies is leading to development of new electronic medical devices for measurement of physiological variables for use in diagnostics, therapy and monitoring to improve the well-being of the population. Thus, the impact of electronics on health care is now a widely accepted fact. Health care may indeed present the most promising opportunity to improve the quality of life in our society through electronics. In the coming years, there will be greater demand for medical electronics in the country with the Government programmes like National Rural Health Mission which aims to provide technology at grassroots level.

Presently, the penetration of medical devices in India is very low, therefore, under the Medical Electronics and Health Informatics Programme, the government encourages the businesses, R&D institutions and academia to use innovation and new technology to develop new systems as well as to bring down costs of technology and make it more accessible.

IV d. Human Resource Development for Medical devices Industry

Human resource is a key ingredient for any industry; Medical device industry's need for trained manpower is aided by All India Council of Technical Education under Ministry of Human Resource Development and Ministry of Skill Development. AICTE across the country have approved 89 colleges to provide graduation and post-graduation in biomedical engineering, creating trained manpower approximately 4000 students every year. Medical device industry requires lot multidisciplinary expertise from various engineering, management, clinical field etc. In addition to MHRD, Skill development ministry pushes various skill enhancement programs supporting medical devices industry under Health Skill sector council, Electronics Skill sector council, Management and Entrepreneurship Skill sector council etc. Addition to this various

Institute are set up under Parliamentary act or by Ministry to ensure availability of HR for Industry.

IV.e Medical device Industry Promotion Initiatives

Department of Industrial Policy & Promotion: DIPP under Ministry of commerce has given key priority in Foreign Direct Investment (FDI) policy for Medical Devices. FDI policy aim to be a major driver of economic growth and a source of non-debt finance for the economic development. Government has put in place an investor friendly policy on FDI, under which FDI up to 100%, is permitted on the automatic route in most sectors/ activities. FDI policy defines medical devices harmonizing with the global definition, to enable production of medical devices in country without hammering the existing local manufacturers.

Department of Pharmaceutical: Medical Devices Industry issues relating to promotion, production and manufacture; excluding those specifically allotted to other departments is dealt by the DoP. Department of Pharmaceutical have actively supported in drafting uniform marketing practices in medical devices, preference in public procurement, cluster development scheme to boost production of medical devices and various annual meet like medical expo to proactively interact with medical device industry.

Department of Commerce & Quality council of India: Owing to high growth potential of Medical Devices in terms of domestic manufacturing and global exports, the Medical Devices, Surgical Equipments and Pharmaceutical Machineries has emerged as the 'Sunrise Sector' of India.

Government has announced that it would open three medical devices parks. The 200 acre park is being established in Vishakhapatnam, by Government of Andhra Pradesh. Similarly, the Maharashtra Government is considering a 200 acre park in Mihan, Nagpur, Maharashtra. EEPC INDIA under the directions of Ministry of Commerce & Industry, Government of India was assigned as the nodal agency to boost export of medical device and pharma machinery sector.

QCI an autonomous body, set up by Government of India, to establish & operate National accreditation structure and promote quality. It has launched voluntary scheme 'ICMED' or Indian Certification of Medical Devices to bring international respect to medical devices which

are made in India. It aims to bring down the substantial time and cost-run to obtain globally accepted quality certification for Indian companies and eliminate the malpractices of sub-standard or fraudulent certification or quality audits.

The Scheme has been launched with two levels of certification:-

- ICMED 9000 certification which is ISO 9001 plus additional requirements
- ICMED 13485 which is ISO 13485 plus additional requirements

11. Post market vigilance and safety requirements

Ministry of Health and Family Welfare, Government of India, has approved the commencement of "Materiovigilance Programme of India (MvPI)" vide approval dated 10/2/2015 with Indian Pharmacopoeia Commission, Ghaziabad as The National Coordinating Centre, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Department of Science and Technology, Thiruvananthapuram, functioning as a National Collaborating Centre and National Health System Resource Centre (NHSRC), New Delhi as be the Technical Support and Resource Centre.

Presently, MvPI is having 10 dedicated functional Medical Device Adverse Event Monitoring Centers (MDMCs) all over the country. All the Adverse Drugs Reaction Monitoring Centres (AMCs) under Pharmacovigilance Programme of India (PvPI) have also been entrusted to report adverse events due to the use of medical devices. In order to ensure effective culture of AEs reporting from MDMCs, AMCs and individual, clinician, biomedical engineers, clinical engineers, hospital technology manager, pharmacists, nurses, technicians, MvPI has introduced various tools for AE reporting to develop India-specific data for making regulatory decisions by the CDSCO. For more details, Please refer to **Guidance Document for MvPI (version 1.0)** which is available on www.ipc.gov.in

Scope of MvPI is to:

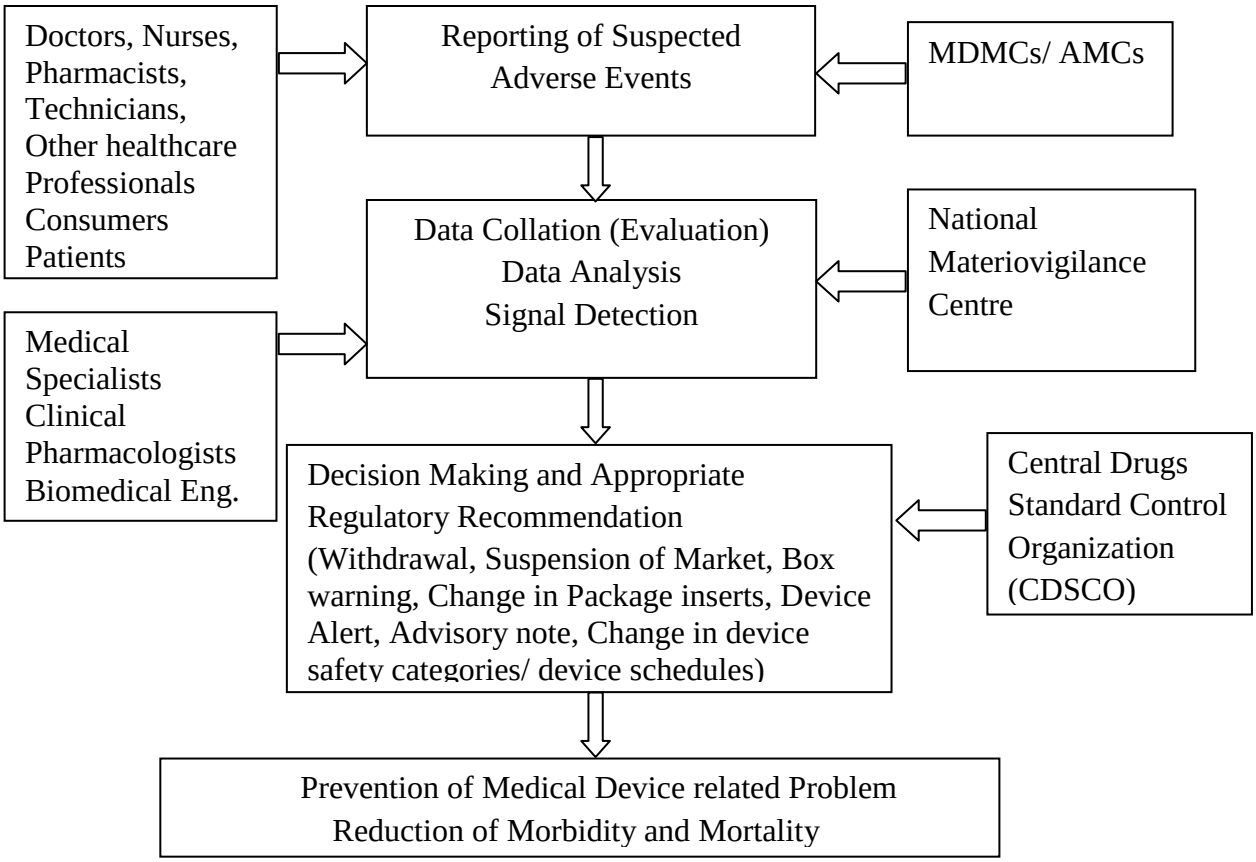
- Create a nation-wide system for patient safety monitoring.
- Analyse the benefit-risk ratio of medical devices.
- Generate evidence-based information on safety of medical devices.
- Support CDSCO in the decision-making process on use of medical devices.
- Communicate the safety information on use of medical devices to various stakeholders to minimise the risk.
- Emerge as a national centre of excellence for Materiovigilance activities.
- Collaborate with other healthcare organisations for exchange of information and data management.

Launch of Materiovigilance Programme of India (MvPI)

The Materiovigilance Programme of India (MvPI) to monitor the safety of medical devices in the country was formally launched on 06th July, 2015 at IPC, Ghaziabad by The Drugs Controller General (India).

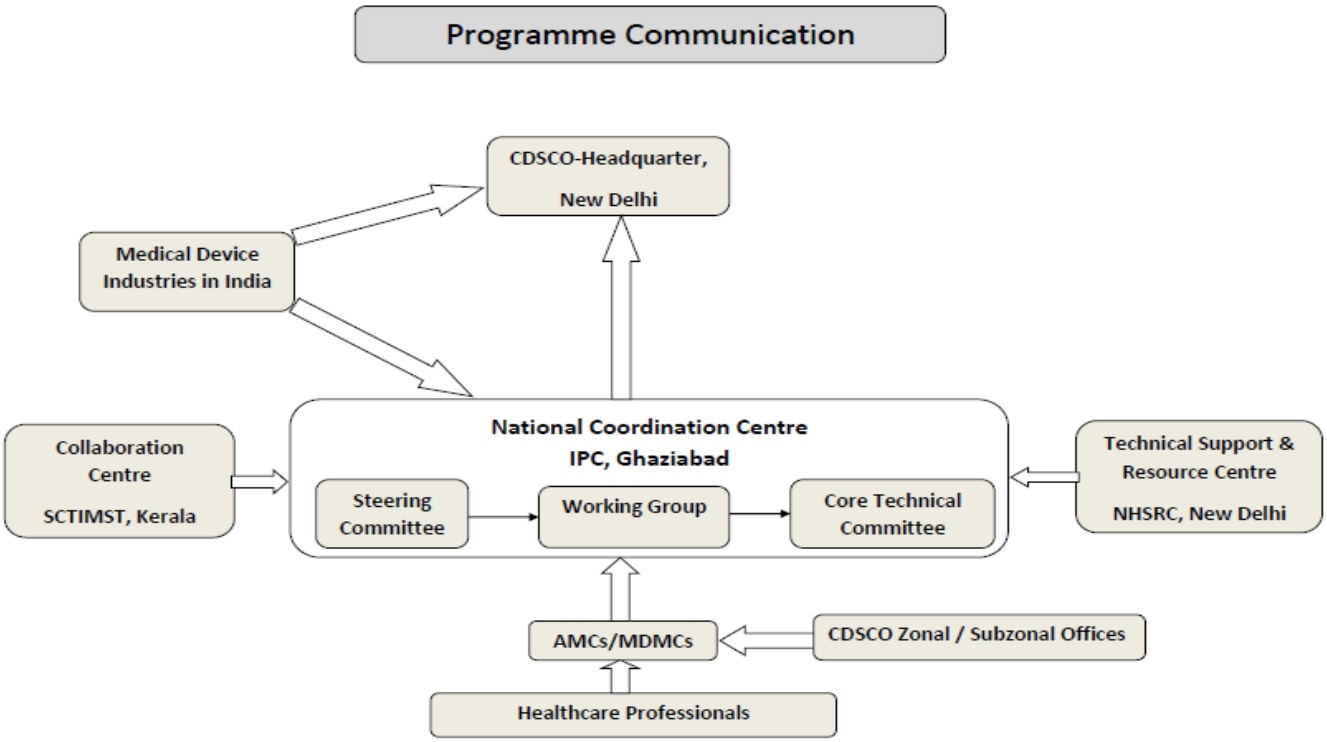
Data Flow

Once the Medical Institute is enrolled as an AMC/MDMC, the AMC starts sending Medical Device Adverse Event (MDAE) Reports to NCC-MvPI. These reports are then assessed at NCC-MvPI for quality of data and if found valid, they are further processed/ evaluated and put up to the core technical committee (CTC) for any recommendation to the national regulatory authority. But if the data is not complete or valid, then the reports are reverted to their concerned AMCs/MDMCs with the query or necessary comments, so that the respective report can be corrected or completed and sent to NCC again for evaluation. The recommendation of the CTC is forwarded to the CDSCO for further discussion and regulatory action, if any.



MvPI Communications

Effective communication channels are the key to successful functioning of MvPI. The following chart depicts the movement of information between the key stakeholders and ensures the continuous transfer of data, information, and knowledge.



Who can Report?

Under MvPI, Clinicians, Biomedical Engineers, Clinical Engineers, Hospital Technology Managers, Pharmacists, Nurses, Technicians can report medical device adverse events. Medical Device Manufacturers/CDSCO notified Medical Device Manufacturers/ Medical Device Importer-Trader can also report adverse events specific to their products to National Coordination Centre , i.e., NCC-MvPI, IPC, Ghaziabad.

Why to Report?

Medical devices have been associated with several adverse effects and at times become fatal to the patients. As a stakeholder it is their responsibility to report adverse events associated with use of Medical Devices and safeguard the health of public.

What to Report?

In order to foster the habit of reporting MvPI encourages reporting of all types of adverse events related to medical devices- irrespective of the fact whether they are known or unknown, serious and non-serious, frequent or rare. Although Materiovigilance is primarily concerned with adverse events associated with medical devices used in India.

How and Whom to Report?

The 'Medical Device Adverse Event (MDAE) reporting form' which is available at www.ipc.gov.in may be used to report any adverse event due to the use of medical devices. Medical Device Adverse Event Monitoring Centres (MDMCs) /Adverse Drugs Reaction Monitoring Centres (AMCs)/ Healthcare professionals after filling the MDAE form, can submit the scanned copy to the National Coordination Centre via e-mail mvpi.ipcindia@gmail.com

NCC-PvPI helpline 1800-180-3024 (Toll free) also provides assistance in medical device adverse event reporting.




MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

Materiovigilance Program of India (MvPI)

Type of report (Tick) : Initial( ) Follow up( )	Report No:
A.PATIENT DETAILS (Fill appropriate details only)	
1. Patient Hospital ID……	3. Age at time of Event or Date of Birth……
2. Patient Initials……	4 .Sex: M( ) F( ) Other( )
	5 .Weight (Kg)……
B.Event Description	

B1.Prima facie reason for the event (Tick all applicable)	a) Electrical ( ) b) Electronics ( ) c) Mechanical ( ) d) Biocompatibility e) Clinical application error ( ) f) Other ( )……

2a. Seriousness of event (Tick appropriate)	
a) Death (dd/mm/yyyy) ( ) ……/……/…… b) Congenital-anomaly ( ) c) Life threatening ( ) d) Required intervention to prevent death or impairment of body function ( ) e) Hospitalization/Prolonged impairment/damage ( ) f) Disability ( ) g) Other (Please specify)……	**2.b Near Miss Event (Tick Relevant)** Yes( ) No( )
3a. Date on which hospital or manufacturer became aware of event (dd/mm/yyyy) ……/……/……	**3b. Date of event** - (dd/mm/yyyy) ……/……/……

4. Location of event - OPD ( ) IPD ( ) Other (please specify)……..

5.Device Category: (Tick all applicable)
5.a) Therapeutic ( ) Diagnostic ( ) Both ( )
5.b) Implantable device ( ) Non- Implantable Device ( )
5.c) Single use device ( ) Reusable device ( ) Reuse of manufacture marked single use device ( )

6. Date (For Medical device subject to preventive maintenance and calibration as per manufacturer instructions)

Last preventive maintenance dd/mm/yyyy)	Last calibration (dd/mm/yyyy)

7. Location of device after the incident
a) Place of use ( )
b) Place of reporter ( )
c) Place of Manufacture/vendor ( )
d) With Patient or end user ( )
e) Discard as waste ( )

8. Is device in use after incident Yes ( ) No( )

9 (A) Is same model device available in organization? Yes ( ) No ( ) If yes, Quantity……
(B) Organization- Healthcare facility ( ) Manufacturer ( )

C. MEDICAL DEVICE(S)DETAIL

Generic name of medical device(UMDN/ GMDN code) (1)	Name of manufacturer (2)	Brand name (3)	Model No. (4)	Serial No. (5)	Batch/lot No. (6)	Catalogue No.(for Instrument Only (7)	Date of Installation/ Implantation/ Explanation (8)	List of Accessories (9)

10. Actions taken immediately after incident	**11. A** Whether other medical devices were being used at same time with above device for therapeutic or diagnostic service? If yes, please……. **11 B.** Any history of adverse event(s) from device with same serial/model/catalogue number. If yes please specify……

D.REGULATORY DETAILS CENTRE			E.REPORTER DETAILS of MvPI
i) Manufacture name: ii)Regulator in Country of origin (if any): iii)Regulatory status and regulator name In country other than the regulator in the country origin (if any):	Entity legally representing Notified body name and full address (if applicable):	Notified body name i)In country of manufacturing: (ii) In India	Name and professional address (Hospital /Medical device manufacturer address)..... ..... E-Mail..... Pin..... Tel.no. (with STD code)..... Designation..... Signature..... Date of report (dd/mm/yyyy).....

F. Causality Assessments Details

F.1 Causality Assessments Details Completed ( ) In Progress ( ) Awaited ( )

Additional information (Minutes of clinical establishment on medical device adverse event reporting committee, Photos/Videos of incidents, base line study ,root cause analysis , failure mode effect analysis or any other supporting documents) :

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest exten Programme staff is not expectedto and willnot disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the adverse event.

National Collaboration centre- Materiovigilance Programme of India

1) **Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST)** under the Department of Science & Technology, Government of India. Biomedical Technology Wing, Poojappura, Thrivananthapuram 695012, Kerala.
Phone: 91- 471 – 2340411, Fax: 91- 471 -2341814 Email: head-bmtw@sctimst.ac.in.

National Coordination Centre- Materiovigilance Programme of India

2) **Indian Pharmacopoeia Commission (IPC),** Ministry of Health and Family Welfare, Government of India, Sector- 23, Rajnagar, Ghaziabad-201002, Tel.: 0120-2783400, 2783401, and 2783392, FAX: 0120-2783311, Email. ipclab@vsnl.net, pvpi.ipcindia@gmail.com, mvpi.ipcindia@gmail.com.

Technical support and Resource Centre- Materiovigilance Programme of India.

3) **National Health System Resource Centre (NHSRC)**, NIHFW campus, Baba Gangnath marg, Munirka, New Delhi-110067, Phones: 011 26108982 / 83 / 84 / 92 /93, Fax: 011-26108994 Email: nhsrc.india@gmail.com

Where to report?
Duly filled Medical Device Adverse Event Reporting Form can be send to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector-23, Rajnagar, Ghaziabad-20002, Tel-0120-2783400, 2783401 and 2783392, FAX:0120-2783311 or email to mvpi.ipcindia@gmail.com Or Call on Helpline no. 1800 180 3024 to report Adverse event.

Event description Details of adverse event including description of device (deficiency or malfunction), clarification of hazards associated with device and the associated risk of patient, user or person any possible risk to patient associated with previous use.

Additional Information: Other relevant information related to treatment should be provided and Instruction how to fill form is provided in guidance document.

FREQUENTLY ASKED QUESTIONS

Ques: Whether In-Vitro Diagnostic kits/reagents are regulated in India?

Ans: Yes, all In -Vitro Diagnostic kits/reagents are regulated in India under the provisions of the Medical Device Rules, 2017.

Ques: Where can we get a copy of the Medical Device Rules, 2017?

Ans: The copy of the Medical Device Rules 2017 is available in the CDSCO Website under the link: http://www.cdsco.nic.in/writereaddata/Medical%20Device%20Rule%20gsr78E.pdf

Ques: Name and address of the Regulatory Authority that governs the regulations of Import of IVD kits/reagents in India?

Ans: The Drugs Controller General (India), Central Drugs Standard Control Organization (CDSCO), *Directorate General of Health Services* , Ministry of Health and Family Welfare, Government of India , FDA Bhavan, ITO, Kotla Road, New Delhi -110002
Phone: 91-11-23236965 / 23236975,
Fax: 91-11-23236973,
E-mail:- dci@nic.in.

Ques: What are the activities regulated by the CLA & SLA with respect to In Vitro diagnostic in India?

Ans:

Central Licensing Authority	State Licensing Authorities
Enforcement of rules in matters related to: • Import of all Classes of IVDs. • Manufacture of Class C and Class D IVDs. • Clinical performance evaluation and approval of new in vitro diagnostic. • Registration of Notified Bodies. • Registration of Laboratories for carrying out test or evaluation. • Test licences for manufacture or import of all classes of IVDs	Enforcement of rules in matters related to: • manufacture for sale or distribution of Class A or Class B IVD • Sale, stock, exhibit or offer for sale or distribution of IVDs of all classes.

Ques: Which division of CDSCO is responsible for review of IVD kits/reagents?

Ans: Medical Devices & Diagnostics Division, Central Drugs Standard Control Organization (CDSCO), *Directorate General of Health Services*, Ministry of Health and Family Welfare, Government of India FDA Bhavan, ITO, Kotla Road, New Delhi -110002.

Ques: What is an In-Vitro Diagnostic (IVD)?

Ans: IVDs are substances intended to be used outside human or animal bodies for the diagnosis of any disease or disorder in human beings or animals covered under sub-clause (i) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 and IVDs that are notified, from time to time, as a device under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940.

Ques: What is an In-Vivo Diagnostics?

Ans: When Diagnosis of disease and disorders are carried out in the body of living human or animal that is done in-vivo as opposed to in a laboratory method that does not use the living organism as the host of the test. In vivo is the opposite of in vitro.
These materials are chemical, biological, or radioactive substances used in diagnosing or monitoring the state of human or veterinary health by identifying and measuring normal or abnormal constituents of body fluids or tissues.
For example: Angio-urographic diagnostic agents, Barium diagnostic agents, Cold kits for labeling with technetium, Contrast media diagnostic products (e.g., iodine and barium)

Ques: Whether MDR 2017 is also applicable for in vivo diagnostic products?

Ans: Since in-Vivo Diagnostics are interventional and put into systemic circulation in living bodies, all principles and norms applicable for regulations of chemical, biological and radiological drugs shall also be applicable in such products.

Ques: How are IVDs classified in India under Medical Device Rules, 2017?

Ans: IVDs are classified under Chapter II, Rule 4, Sub-rule (2) of Medical Device Rules 2017 on the basis of parameters specified in Part II of the First Schedule, in the following classes, namely:—
(i) low risk - Class A;
(ii) low moderate risk- Class B;
(iii) moderate high risk- Class C;
(iv) high risk- Class D.

Ques: Who will have the responsibility of doing Classification of IVD as per Class A/B/C/D?

Ans: Reference Rule 4 (3), This rule specifies that Central Licensing Authority shall classify the Medical Devices.

Ques: Whether on market approved products, in India have to be newly registered as per Medical Device Rules 2017, when the existing license gets expired?

Ans: Yes, IVD products which are currently registered in India have to be registered according to the provisions of Medical Device Rules 2017.

Ques: Are instruments, equipment and software used with IVDs covered in the scope of medical device rules 2017?

Ans: No. Instruments, equipment and software used with IVDs are not be covered in Medical Device Rules 2017.

Ques: Which IVD kits/reagents fall under the category of Class A, Class B, Class C, Class D products?

Ans: Please refer to the classification list issued by CLA available at CDSCO website.

Ques: Whether the wholesale license issued under the Drugs and Cosmetics Rules, 1945 will be valid as per the Medical Device Rules 2017.

Ans: Yes.

Ques: Whether any product, intended for use in determining the presence of host cell protein contamination, in products manufactured by expression in the CHO cell line and other technology for Research and manufacturing use only and is not intended for diagnostic use in humans or animals, are being regulated under the provision of Medical Device Rules 2017?

Ans: No.

Ques: Whether any product used in determining the presence of histamine, substances, Microbial detection in food & food products, animal feeds, liquor (wine, beer), environmental samples like water & Soil etc. and is not intended for diagnostic use in humans or animals, are being regulated under the provision of Medical Device Rules 2017?

Ans: No.

Ques: Will products such as RUO – Research Use Only, Q.C. material for accreditation, panel for Q.C testing & product used for food, water, sterility testing used by various industry for Q.C etc., and is not intended to be used in human or animals for diagnosis of any disease or disorder, be regulated under MDR, 2017 ?

Ans: No.

Ques: Will products such as microbiological culture media, stains indicators and reagents used for food and water testing and is not intended to be used in human or animals for diagnosis of any disease or disorder be regulated under MDR, 2017?

Ans: No.

Ques: Whether Empty Specimens collection tubes without needle used for the collection of Blood, Urine, Stool, Sputum, Semen, etc., for purpose of specimens collection are being regulated under the provision of IVD MD Medical device Rules, 2017?

Ans: No.

Ques: Whether IVDs for HBsAg, HIV and HCV approved to manufacture or import by the CLA or SLA, as the case may be, permitted to use for both the purposes; for blood screening and diagnostic.

Ans: Yes. In-vitro Diagnostic devices for HBsAg, HIV and HCV manufactured/imported under valid license issued by the CLA or SLA, may also be used in Blood Bank, as the criteria like Sensitivity (%) and Specificity (%) for evaluation of the HBsAg, HIV and HCV diagnostic kits for the Transfusion purpose (Blood Banks) and Diagnostic purpose are same, Provided the manufacturer claims in the product labels or in the IFU that the product is intended both the purposes; for blood screening and diagnostic.

Ques: Whether all Serodiagnostic test kits are prohibited?

Ans: No**;** only ―Serodiagnostic test kits for diagnosis of tuberculosis‖ are prohibited to Import, Manufacture, Sale, Distribution and Use in the country under Section 10A and Section 26A of the IVD MDs and Cosmetics Act, 1940 Gazette notification(s) GSR432(E) & GSR433(E) dated June 7, 2012.

Ques: What are considered to be the major changes in Post approval of IVD?

Ans: Reference Sixth Schedule: Changes in labels, manufacturing process, equipment or testing and primary packaging material have been included in the list of major changes which needs prior approval from the competent authority.

Ques: Can Third party/Authorized Consultant ask the status of the application?

Ans: No, The Regular employee, authorized by the competent person of the applicant company may only ask the status of their application.

Ques: Who is authorized to make a Technical Presentation, on behalf of applicant, when asked by the CDSCO?

Ans: Only Subject Expert or Technical Person of the company who is equally competent to make technical presentation.

Ques: How should the documents be notarized?

Ans: The notary should ensure that documents are properly authenticated by either signing the total document set together in a set or each pages in case of a standalone certificate (Declaration from notary).

Ques: What is the time limit for submission of query response?

Ans: As per CDSCO notice dated 13th July 2016, an application can be disposed off on the basis of merit unless extension is sought within 45 days of raising the query. In case query response couldn't be submitted by the applicant due to some reasonable issue, the applicant shall ask for the extension within 45 days of receiving query.

Ques: Where can I submit my enquiries related to Import and Manufacture of IVDs?

Ans: All enquiries regarding the submission and approvals can be sent to the Drugs Controller General India (dci@nb.nic.in) - CDSCO, FDA Bhawan, ITO, Kotla Road, New Delhi - 110002.
Phone: 91-11-23236965/23236975.
Fax: 91-11-23236973.

Ques: What is the method for getting refund of challan amount if any manufacturer does not want to register the product or withdraw their application?

Ans: Need industry inputs for drafting this answer.

Ques: Will post-approval change notification approval require submission of fee?

Ans: No

Ques: Which will be the Medical Device Testing Laboratory for IVD Medical devices?

Ans: National Institute of Biologicals, Sec-62 Institutional Area, Noida-201 309 or as notified from time to time.

Ques: What will be time-period for approval by CLA for implementation of a Major change?

Ans: 60 days. In case CLA do not indicate approval or rejection within sixty days, such change shall be deemed to have been approved by the licensee.

Ques: What will be time-period for approval by CLA for implementation of a Minor change?

Ans: Implementation of minor change do not need prior approval provided licensee inform CLA within a period of thirty days after the change takes place or becomes effective.

Ques: What are the requirements for import of Class-A/B/C/D In-Vitro Diagnostic Medical device in India?

Ans: For the import of Class A, B, C & D IVDs, applicant have to submit the documents as per Fourth schedule Part I, Part II and Part III (Appendix I & III, only), along with fee as per second schedule. Guidance document on import of IVDs is available on CDSCO website.

Ques: Who can apply for grant of licence to import IVD kits and reagents in to India?

Ans: An authorised agent holding licence to manufacture or wholesale licence under issued under MDR, 2017, may submit an application for grant of import licence for IVD to the Central Licensing Authority.

Ques: Whether multiple Indian agents are allowed to apply for import licence for same product having same manufacture?

Ans: Yes. All the applicants shall need to submit separate application under MDR, 2017.

Ques: Whether manufacturing site of IVD will be inspected before grant of Manufacturing License.

Ans: For Indigenous manufacturers of IVDs:
(i) For Class A IVDs, no audit of the manufacturing site shall be necessary prior to grant of licence or loan licence to manufacture for sale or for distribution of Class A IVDs; and

(ii) For Class B, Class C and Class D IVDs, before grant of the manufacturing licence the audit/inspection of the manufacturing site shall be carried out.

Ques: Whether overseas manufacturing site of IVD will be inspected before grant of import License?

Ans: No. However, if the Central Licensing Authority, believes, as it think fit, may carry out an inspection of the overseas manufacturing site before grant of import licence.

Ques: In case CLA changes the risk based Classification of any product, after approval under the medical device rules 2017, then the license issued under new Rules will continue to be valid for what period? What will be the transition time period given to the industry to adjust according to the new classification?

Ans: In case CLA changes the classification of any IVD product (eg. from Class B to C), the earlier license shall continue to be valid till the final decision taken on the application by the CLA or SLA, as the case may be. Adequate transition time from the date of such notification will be given to industry to prepare documents according to the new classification.

Ques: In case of such a change in classification, whether applicant needs to do fresh application or only additional documents and fees will be required to be submitted?

Ans: Only additional documents along with the fees (only in case of change from A to C/D or B to C/D) shall be submitted by the applicant to the CLA or SLA, as the case may be.

Ques: Whether essential principles for safety and performance of IVDs shall be applicable for both importer and indigenous manufacturers?

Ans: Yes.

Ques: Since the nature of the class A products is intended to be used in conjunction with the IVD products (example: washing solutions, buffers etc) no separate EP checklist is generated during the design and development. Can a manufacturer's declaration suffice?

Ans: Only relevant provisions of the essential principles for safety and performance of IVDs shall need to be complied with the manufacturers, with the justification that why other provisions are not applicable.

Ques: What is the validity of Import License or licence to manufacture for IVD issued under MDR, 2017?

Ans: Import License or licence to manufacture for IVD issued under MDR, 2017 shall continue to be perpetually valid till suspension or cancellation, provided that the licencee shall pay a Licence Retention fee in every five years under the provisions of MDR, 2017.

Ques: How to register additional Class-A/B/C/D IVD Medical Device in the already approved/valid Import License (MD-15)?

Ans: Licence for additional medical device manufactured at the same manufacturing site and having same legal manufacturer shall be made by the same authorised agent accompanied with only additional product Registration fee as specified in the Second Schedule and respective documents as specified in the Fourth Schedule (See Rule-36 sub-rule 4).

Ques: How much fees required to be paid along with the application for grant of import licence for IVDs.

Ans: For each distinct Class-A, Class B, Class C ad Class D IVDs:

Category	Product Fees (USD)	manufacturing site (USD)
Class-A	10	1000
Class-B	10	1000
Class-C	500	3000
Class-D	500	3000

Ques: How much fees required to be paid along with the application for grant of licence to manufacture of IVDs?

Ans: For each distinct Class-A, Class B, Class C ad Class D IVDs:

Category	Product Fees (INR)	Manufacturing site (INR)
Class-A	500	5000
Class-B	500	5000
Class-C	1000	50000
Class-D	1000	50000

Ques: How to endorse/Add additional IVD kits in the approved/valid Import License of the same manufacturing site?

Ans: The applicant shall endorse/add additional product under a valid import license in MD-15, provided the legal and actual manufacturer are same, by submitting the additional product Registration fee (as per second schedule) and documents mentioned in Fourth schedule (Part I, Part II and Part III (Appendix I & Appendix III, only)) of medical device Rules 2017.

Ques: Whether IVD kits/reagents, having valid Import License, can be imported from any notified ports of India?

Ans: Yes

Ques: Whether authorised agent holding valid Import licence is required to stock for any state in the India?

Ans: No. Single license may be issued, in respect of the import of more than one IVD Medical device or a group/class of IVD medical device manufactured by the same legal and actual manufacturer to the Importer through which importer can import the products through any notified port under **Medical Device Rules, 2017.**

Ques: Is it mandatory for IVD medical devices to be imported into India initially only at the warehouse address that is listed on the medical device import licence?

Ans: No, IVD Medical Devices, having valid Import Licence, can be imported from any notified ports of India and stored and distributed from any registered warehouse. It is not mandatory to initially stock in the warehouse address that is listed in the import license.

Ques: Whether IVD medical device imported under valid import license can stock in any other wholesale license premises other than stated in the Import License?

Ans: Yes.

Ques: What is all the In-Vitro diagnostic Kits/Reagents need NOC from the other departments for import?

Ans:
a. NOC from department of Animal Husbandry, Dairying and Fisheries (DADF), Government of India, Krishi Bhavan, New Delhi in respect of products intended for veterinary purpose
b. NOC from DG, ICMR, New Delhi OR NABL Accredited Lab or govt. recognized Agency.
c. NOC from Bhabha Atomic Research Centre (BARC), Mumbai, in case Radio Immuno Assay IVD Kits.

Ques: Whether the applicant has to mention intended use of the proposed product in the product list or Form No. MD-14 during the submission of the applications?

Ans: Yes; applicant has to mention the specific intended use of the proposed product in the product list matching with the Intended Use/Purpose/claim statement in product insert/brochure/Instructions for use.

Ques: What is a Central Medical Device Testing Laboratory?

Ans: Central medical devices testing laboratory means a medical devices laboratory established or designated by the Central Government under rule 19 and shall be deemed to be a Central Drug Laboratory established for the purpose of section 6 of the Act.

Ques: How many batches have to be evaluated for the submission of Performance evaluation reports for grant of import license for Class B, class- C & class- D IVDs?

Ans: The applicant shall submit performance evaluation reports (PER) for three independent batches of IVDs, manufactured by using three different lots of key raw materials (e.g. Antigen, antibody).

Ques: When Central Medical Device Testing Labs or Laboratories registered with CLA for carrying out evaluation are unable to conduct the Performance Evaluation, whether PE can be conducted at any other Government Laboratory/hospital of national repute or NABL accredited Labs?

Ans: Yes, provided the reports generated by such Government Laboratory/hospital of national repute or NABL accredited Labs shall meet the specification criteria as per the Guidance Document issued by the CLA.

Ques: Whether approval/Marketing authorization, issued by the competent Authorities in EU, U.K., Australia, Canada, Japan and USA, will be considered for exemption of Clinical Performance Evaluation (CPE) of New IVDs (Class B, Class C & Class D) in India.

Ans: No. Clinical Performance Evaluation has to be conducted in India for approval of new IVDs, irrespective of its regulatory status in these countries.

Ques: Will clinical performance evaluation be required for grant of permission to manufacture or import any new IVD of Class A?

Ans: No. Clinical performance evaluation (CPE) may not be necessary, except in cases, where the CLA, considers it necessary depending on the nature of the IVD.

Ques: What is the criteria for evaluation of Rapid ELISA & CLIA-based (HIV, HBsAg, HCV) Diagnostic kit adopted by NIB, Noida. Whether the same criteria will also be applicable for other medical device testing labs.

Ans:

Analyte	ELISA / CLIA/ ELFA/ ECLIA/ CMIA/MEIA etc.		Rapid Kit	
	Sensitivity	Specificity	Sensitivity	Specificity
Anti-HIV	100%	≥ 98%	100%	≥ 98%
HBsAg	100%	≥ 98%	100%	≥ 98%
HCV	100%	≥ 98%	≥ 99%	≥ 98%

All medical device testing labs shall follow the above specified criteria for Rapid, ELISA & CLIA based HIV, HBsAg & HCV diagnostic kits.

Ques: What is the sample size required to conduct performance evaluation of IVDs of Class B, Class C & Class D in the designated medical device testing labs?

Ans: The sample size shall be statistically significant as per the protocol designed and approved by respective MDTL.

Ques: What are the Minimum criteria for evaluation of IVD Kits/reagents intended for Malaria, TB, Dengue, Chikunguniya, Typhoid, Syphilis and Cancer and other Class B & C IVD kits?

Ans: The IVDs shall comply with the minimum performance criteria (Clinical sensitivity, specificity, repeatability, reproducibility, accuracy, Linearity, Variance etc.) as claimed in the IFU/COA/Product insert issued by the manufacturer.

Ques: What is the structure, content and format for Performance Evaluation Reports?

Ans: Typically a Performance Evaluation Report should mention following details:
Product name, lot/Batch number, Date of Manufacture, date of Expiry, manufacturer's name, importer name, number of samples tested, testing principle (ELISA/Rapid/NAAT etc.), information about reference used, Testing procedure, Specificity, Sensitivity, Positive predictive value, Negative predictive value, Report number, Date of analysis, designation & Signature of analyst and authorized signatory of the laboratory etc.
Performance indicators for example Sensitivity, Specificity, PPN and NPN, Repeatability, Reproducibility and Accuracy criteria should be accepted as applicable for any specific IVD product with rational.

Ques: What is the Test license?

Ans: The Test License(s) are for manufacture or import small quantities of IVDs, for the purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training.

Ques: How much fees for the "Test License" to import for IVD kits/reagents in India?

Ans:

Classification	Fee (USD)
Class-A, class B, Class C & Class D	100

Ques: What is the validity period of "Test License" for IVD kits/reagents in India?

Ans: Test licence shall, unless cancelled earlier, be in force for a period of three years from the date of its issue (refer Rule 41(5) of Medical Device Rules, 2017).

Ques: Could it be possible to mention multiple sites in a "single" test license application for the purpose of Clinical Investigation, Testing, Evaluation, demonstration and training?

Ans: Yes,

Ques: What is a "New IVD"?

Ans: "New IVD" means any medical device as referred to in sub-clause (A) of clause (zb) used for in vitro diagnosis that has not been approved for manufacture for sale or for import by the Central Licensing Authority and is being tested to establish its performance for relevant analyte or other parameter related thereto including details of technology and procedure required.

Ques: What is a predicate device?
Ans: "predicate device" means a device, first time and first of its kind, approved for manufacture for sale or for import by the Central Licensing Authority and has the similar intended use, material of construction, and design characteristics as the device which is proposed for licence in India.

Ques: Whether the products which are already approved to import or manufacture for sale in India shall be considered as a predicate device when the application for the same products is made under the Medical Device rules 2017?

Ans: Yes.

Ques: Whether both legal (If any) and actual manufactures name and address should be stated in the Free Sale Certificate issued by the National Regulatory agency for the purpose of Import of IVDs in India?

Ans: Yes.

Ques: Any changes in name and/or address of Indian agent/Importer or change in constitution after issue of import licence are required to be communicated to the Licensing Authority?

Ans: Yes, Indian authorized agent shall inform such change to CLA in writing within a period of forty five days in the event of any change in the constitution of the overseas manufacturer or authorized agent.

Ques: Any changes in name and/or address of legal and/or actual manufacturer after issue of Import License are required to be communicated to the Licensing Authority?

Ans: Yes, licensee or, authorized agent in India need to take prior approval from licensing authority in case of change in name and/or address of legal and/or actual manufacturer.

Ques: Whether acquisition/merger of one company by another company is considered as change in constitution of the company?

Ans: Change of constitution is defined as:
(i) A firm means change from proprietorship to partnership including Limited Liability Partnership or vice versa;
(ii) a company means-
(A) its conversion from a private to a public company, or from a public to a private company; or
(B) any change in the ownership of shares of more than fifty per cent. of the voting capital in the body corporate or in case of a body corporate not having a share capital, any change in its membership; and where the managing agent, being a body corporate is a subsidiary of another body corporate, includes a change in the constitution of that other body corporate within the meaning of this clause.

Ques: What are the changes that require an applicant to make a fresh import license application?

Ans: Fresh import license application shall be made only in case of change of constitution.

Ques: Is it correct that a major change can be implemented after 60 days in case CDSCO does not respond to the change notification?

Ans: Yes.

Ques: Whether the Importer who is having valid import license but there is some change in the name of importer or address of Importer still can he imports till another license is granted.

Ans: No.

Ques: What is the procedure for expanding/ modifying the currently registered indications?

Ans: Expanding or modifying the indications/intended use are considered as a major change under sixth schedule of Medical Device Rules 2017. This shall require prior approval before the implementation.

Ques: Whether any major change which is notified to the Regulatory Authority but response from CLA is awaited can be imported in India?

Ans: No. In case response/approval is not received within 60 days from the notification submission, the products undergone a major change shall be allowed for import.
Ques: What is the time line to notify CLA for a major post approval changes mentioned in sixth schedule?

Ans: All major changes specified in the sixth schedule of Medical device rules 2017, shall need prior approval from CLA to carry out or, implement the change.

Ques: What are the post approval changes that require as specified in the sixth schedule require prior approval from CLA or SLA?

Ans: For major changes, prior approval is required from CLA or SLA, as the case may be, before implementation and for minor changes the licencee shall notify the CLA or SLA, as the case may be.

Ques: In case the registered manufacturing site (Actual Manufacturer) remain unchanged (Plant master file to be precise), but Legal manufacturer entity changes to a different entity, whether same Plant Master Files shall be acceptable when submitted towards fresh registration?

Ans: Yes; provided the Plant Master File is updated with consequential changes.

Ques: Whether authorised agent can submit single application for grant of import licence for same product manufactured at more than one manufacturing sites.

Ans: Yes, provided that the applicant shall submit separate fee for each of the sites. Any subsequent application by the same authorised agent, after the grant of import licence, for endorsement of additional product or additional manufacturing site may also be made under the provisions of MDR, 2017.

Ques: What are the Labeling requirements for IVD in India?

Ans: Product labels shall comply with the requirements of the Chapter VI of Medical Device Rules, 2017.

Ques: at the time of submitting applications for Import of IVDs, are original labels as per Rule 44 **to be submitted to the CLA?**

Ans: Specimen Original Labels should be submitted as per Chapter-VI of MDR-2017.

Ques: Can the importers of IVDs stickered for India-specific requirements on labels after/post landing in India at customs warehouse/FTWZ or place approved by the Licensing Authority?

Ans: Yes, provided that the India-specific requirements are specified in the Chapter VI of MDR, 2017.

Ques: Whether shelf life of the IVDs can be stated on the label instead of date of manufacture?

Ans: No. Both shelf life or expiry date and date of manufacture shall require on the labels.

Ques: Whether Certificate of Exportability (which reflects that the proposed products may not be freely sold in the country of origin but can be exported), is acceptable as Free Sale Certificate?

Ans: No.

Ques: Will Free Sale Certificate be acceptable for IVDs manufactured and authorized for sale in countries other than Australia, Canada, Japan, European Union, or the United States of America? If no, what are the additional requirements for the same?

Ans: No. Where a Class C and Class D IVD intend to be imported from countries other than Australia, Canada, Japan, European Union, or the United States of America, the import licence may be granted after its safety and effectiveness has been established through clinical performance evaluation in India. And where a Class A and Class B IVD intend to be imported from countries other than Australia, Canada, Japan, European Union, or the United States of America, the import licence may be granted after its safety and performance has been established through published safety and performance data or through clinical investigation in the country of origin and a free sale certificate from the country of origin is furnished.

Ques: Can an importer import a IVDs having residual shelf life less than 60 % for non-Commercial or testing purpose?

Ans: Yes, notification # IMPORT/Misc/2015-DC Dated 1/12/2015 will still be valid for the import of IVDs for testing purpose under a test license under Medical Device Rules 2017. However, the same shall also be applicable for the products imported under a test license for the purpose of demonstration or training.

Ques: If yes, for the above question, whether the same will be communicated by CLA to all the port offices and Medical Device Testing labs?

Ans: Yes, CLA shall inform to all port offices and medical device testing labs on permission of import of IVD products using test license, having residual shelf life less than 40%, 50%, 60%, as compared to total shelf life of the product, with reference to Rule 44 of medical device rules 2017.

Ques: when applying for import license application in MD-14, if three batches are not available with the manufacturer for performance evaluation, whether the applicant can submit the import license application?

Ans: Yes; Import License in Form 14 application can be submitted with one lot report, along-with undertaking of availability of remaining two lots. Import license in Form MD-15 shall be issued by CLA with the condition on submission of performance evaluation reports for remaining 2 lots prior to the sale of the product in Indian market.

Ques: Whether trader can import bulk products for sale to manufacture.

Ans: Yes, with the undertaking that they will sell bulk product only to the manufacturer for further processing.

Ques: Whether NOC from the office of DCGI is required for the approval of manufacturing license from the state licensing authority for the Notified diagnostic kits/reagents and new diagnostic kits / reagents (First in India)?

Ans: Yes, this office is presently issuing NOC for manufacturing of Notified diagnostics kits and new diagnostic kits/reagents (First in India) on the basis of examination of the following documents: - Detailed manufacturing process.

- Developmental studies.
- Stability data
- Testing protocols for raw materials and finished products
- In- house specification
- Labeling Details
- Evaluation Reports.
- Experts opinion (First in India) etc.

Ques: Which authority, an Indian Manufacturing Company should approach for Licence to manufacture IVDs.

Ans: The manufacturing company shall submit their application to the State Drugs Control authority under whose Jurisdiction, the manufacturing Premises is located. The firm shall submit all relevant technical and administrative documents to the SLA requesting for Licence to manufacture IVDs.

Ques: Whether any inspection shall be conducted by the regulatory body before grant of licence for IVD manufacturing?

Ans: The State Drugs Control authority shall constitute a joint Inspection team comprising of DIs from his jurisdiction and DIs deputed by CDSCO and notify the manufacturer about the mutually convenient date for inspection. In critical cases, the said joint inspection team should also co-opt one expert of the related Diagnostic field.

Ques: During the validity period of a manufacturing Licence, how much Inspection shall be warranted?

Ans: One Inspection shall be warranted with a gap of one Year.

Ques: Does any Start-up entrepreneur need Licence to develop trail IVD products for Lab scale testing only?

Ans: Start up entrepreneur can work to develop IVD products after obtaining NOC from CDSCO (HQ) and Intimating the same to the Concerned State Drugs Controller with an

undertaking that the products developed shall not be diverted by any means to the commercial market/path labs.

Ques: Whether PER needs to be conducted on the test batches of IVD before introduction in the market? If so how many batch samples to be forwarded and where?

Ans: Yes. The applicant firm shall obtain Licence in Form-29 to develop three or more trial batches of the IVD product. The prescribed number of sample from three consecutive batches of such IVD products should be forwarded to NIB (NOIDA) or other notified Laboratory. The PER should be submitted to both CDSCO and the concerned State Drugs Control Authority.

Ques: Does the New Rule MDR-2017 mandate the manufacturer to maintain Quality Manual and Plant Master File (PMF)?

Ans: Yes, as per the Schedule-V ref. Clause 4.2.2 these two are mandated.

Ques: Where in MDR-2017 the details of PMF are available?

Ans: The contents of Plant Master File have been detailed in appendix - I of Fourth schedule.

Ques: Is there any requirement to maintain IVD master file?

Ans: for each type of IVD there is a requirement to maintain an "IVD Master File". The Contents of IVD Master File have been detailed in appendix - II of Fourth schedule.

Ques: What is manufacturing under Loan Licence?

Ans: "loan licence" means a licence issued for manufacturing a medical device by the State Licensing Authority or the Central Licensing Authority, as the case may be, to a person who intends to utilise the manufacturing site of other licencee for manufacturing the same medical device as manufactured by the licencee at that site, Reference Rule-3(Z).

Ques: In which form permission to import small quantities of medical devices for personal use can be obtained?

Ans: A patient can apply in Form MD-20 with all requisite documents and permission can be given in Form MD-21.

Ques: What if the classification of a product being imported is different in GHTF countries from the classification in India?

Ans: In such cases, the higher class of Medical device will be considered.

Ques: How will Post Marketing Surveillance (PMS) be managed? Who will have reporting responsibility?

Ans: PMS is the responsibility of the licensed holder/authorized agent.

Ques: Where can we get a list of authorized Notified bodies?

Ans: The list of the registered Notified bodies with CDSCO is available on the CDSCO website.

Ques: If a manufacturing firm is complying with ISO/IEC standards, would it still need to follow BIS standards?

Ans: (i) The medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time.

(ii) Where no relevant standard of any medical device has been laid down under sub-rule (1), such device shall conform to the standard laid down by the International Organization for Standardization (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeial standards.

(iii) In case of the standards which have not been specified under sub-rule (1) and sub-rule (2), the device shall conform to the validated manufacturer's standards.

Ques: Will e-IFU (electronic Instructions for use) be permitted under the new regulations?

Ans: In Medical Device Rules 2017, e-IFU is not specified.

Ques: Can the date of manufacture/sterilization/expiry be mentioned as DD/MM/YY or MM/YY?

Ans: As per Rule- 44 (e) the date of expiry shall be in terms of the month and the year and it shall mean that the medical device is recommended till the last day of the month and the date of expiry shall be preceded by the words "Expiry date" or "Shelf Life".

Ques: Will change in authorized Agent require fresh License?

Ans: Change in Indian agent will require fresh License.

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Note: Any suggestions with respect to this document may be communicated to this office through e-mail ipclab@vsnl.net

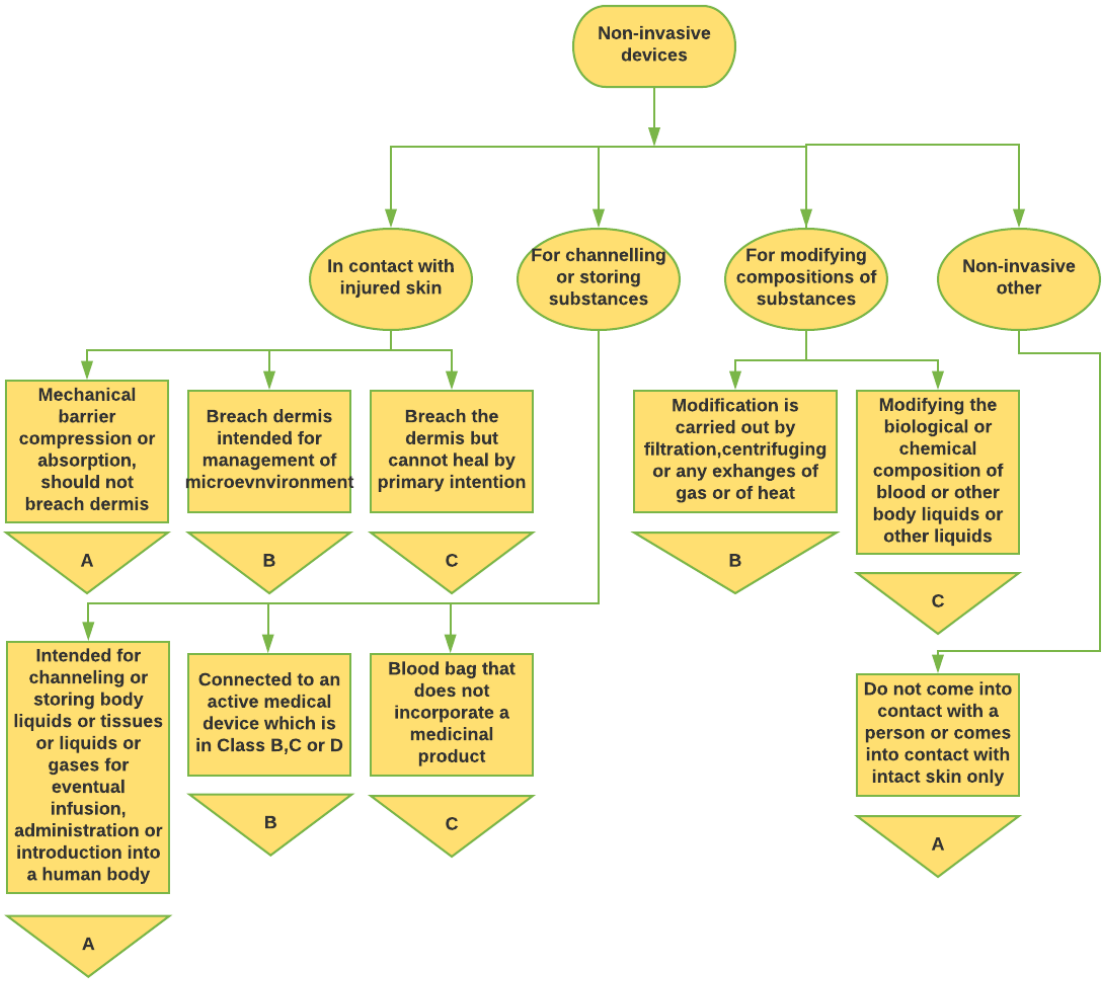

Fig.1 Non-invasive Medical Device classification

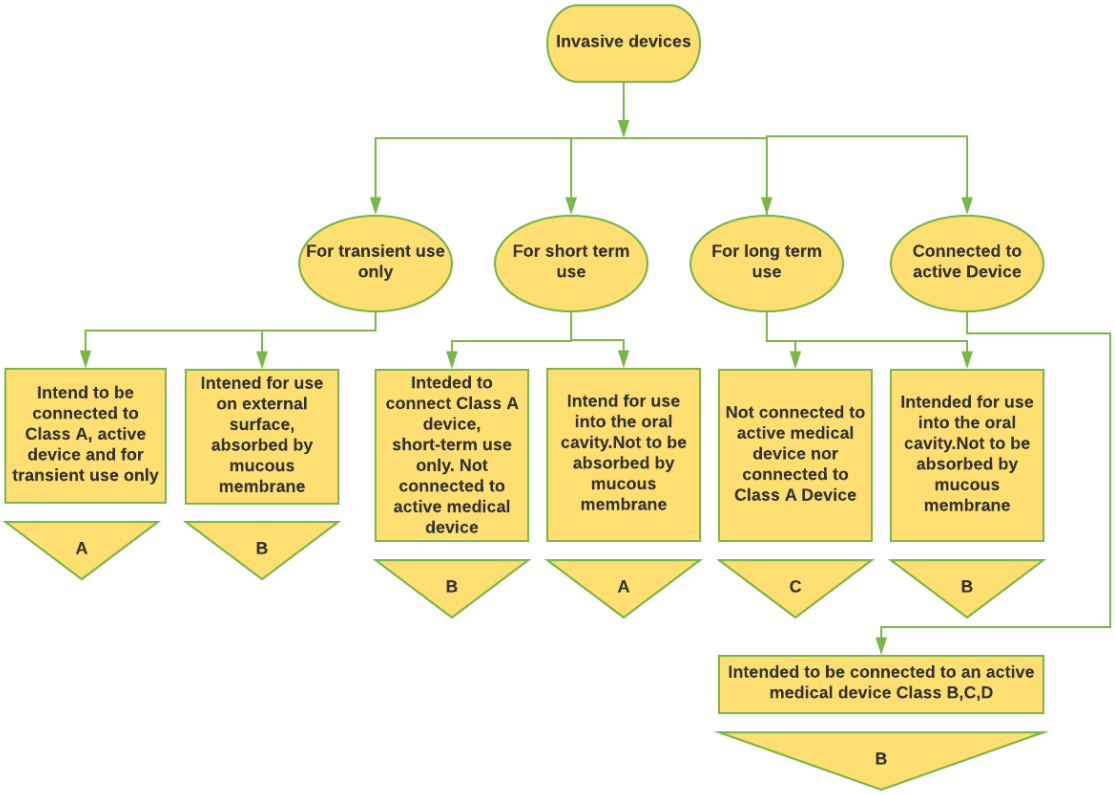

Fig.2 Invasive Medical Device classification

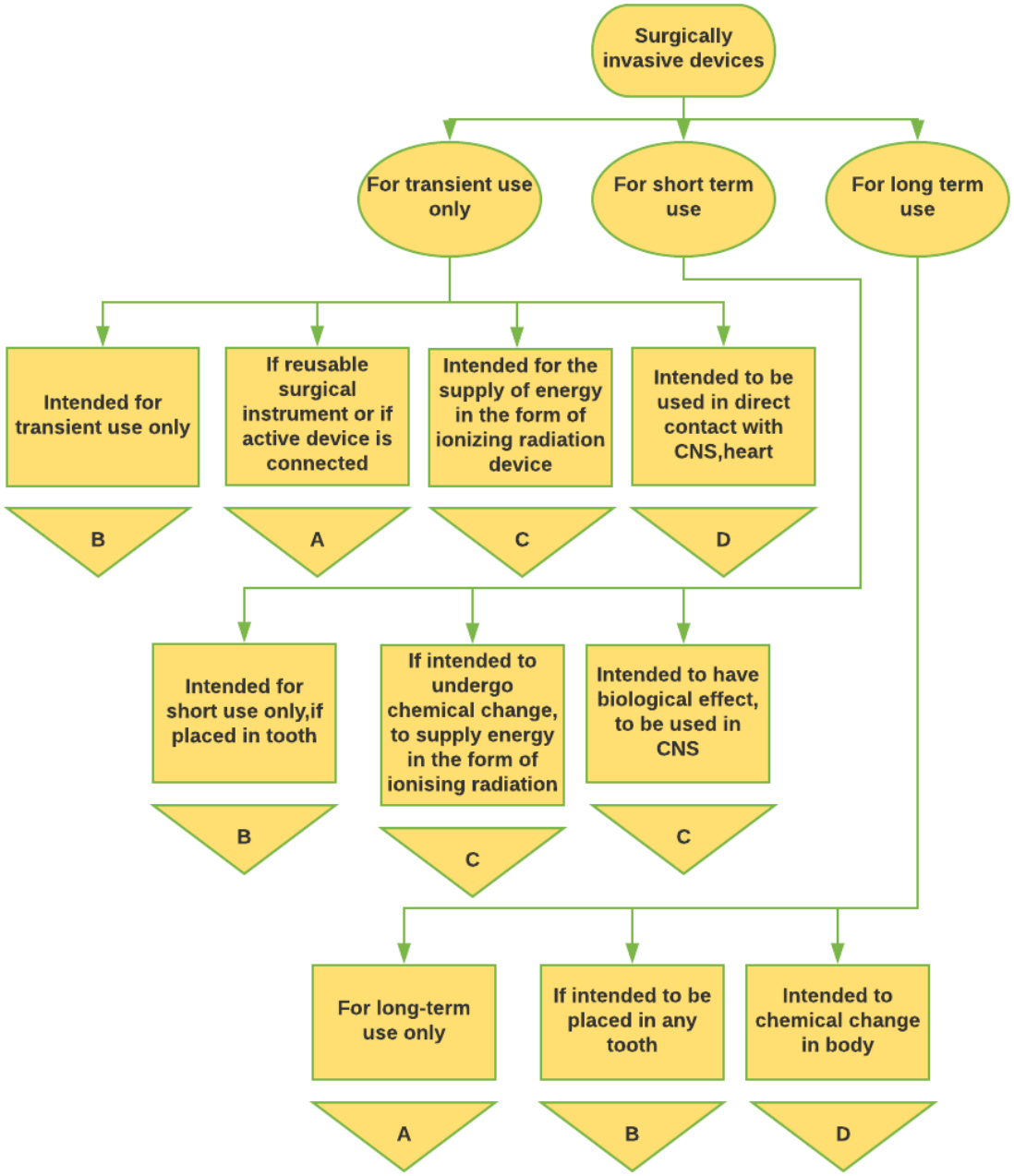

Fig.3 Surgical Medical Device classification

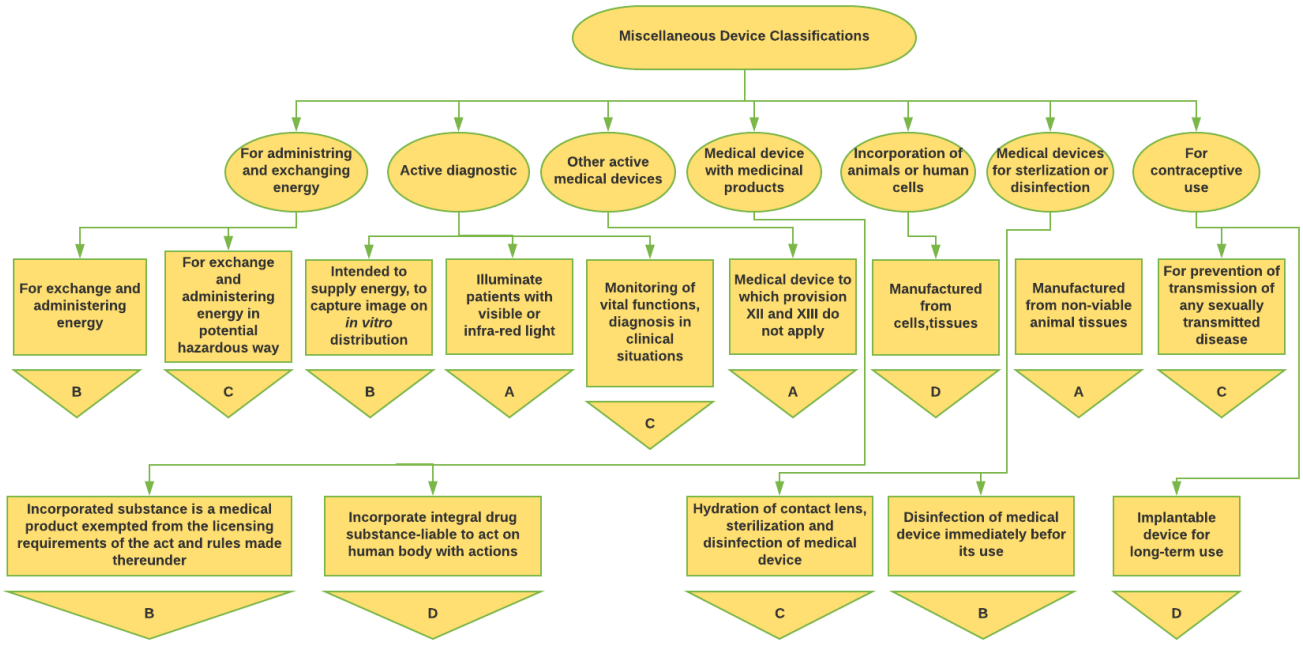

Fig.4 Miscellaneous Medical Device classification

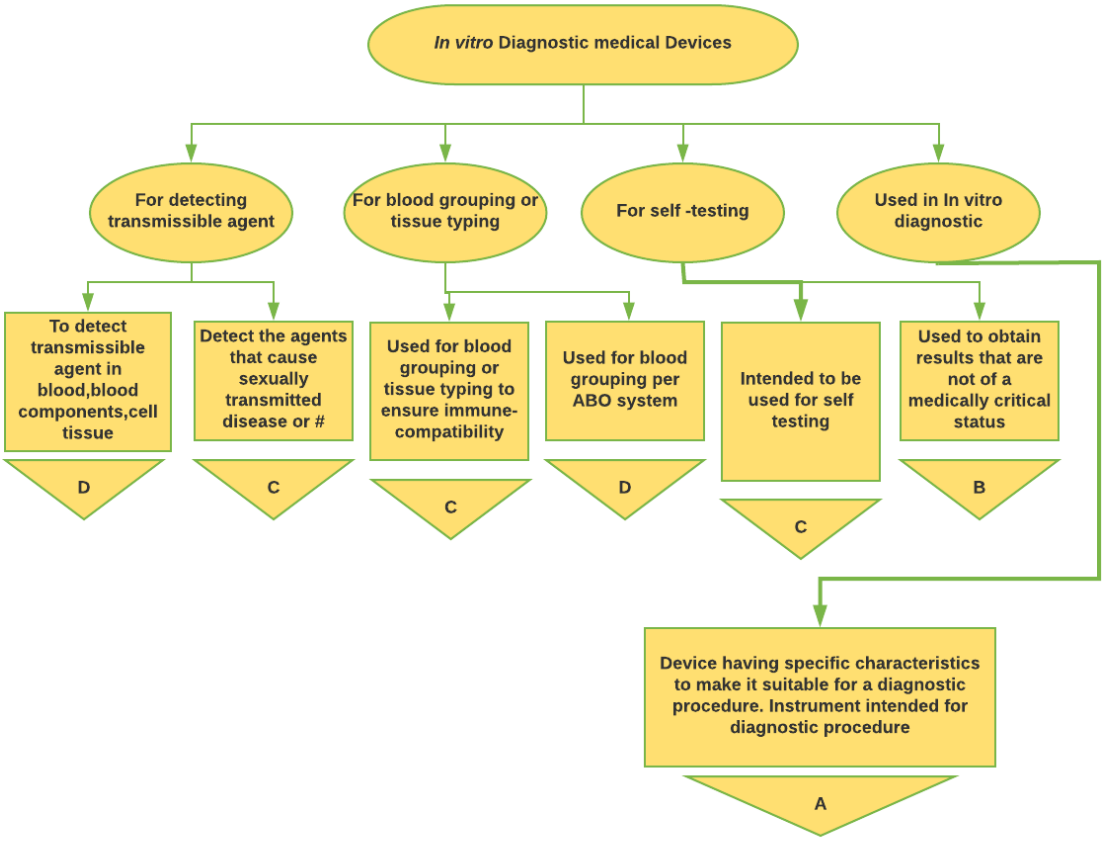

Fig.5 *In-vitro* Medical Device classification