MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 31st January, 2017

G.S.R. 78(E).—WHEREAS the draft of the Medical Devices Rules, 2016 was published, as required under sub-section (1) of Section 12 and Sub-section (1) of Section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), *vide* notification number G.S.R. 983(E), dated the 17th October, 2016, by the Central Government, after consultation with the Drugs Technical Advisory Board, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which copies of the said Gazette containing the said notification were made available to the public;

AND WHEREAS, copies of the Gazette containing the said notification were made available to the public on the 17th October, 2016;

AND WHEREAS, all objections and suggestions received in response to the said draft notification have been duly considered by the Central Government;

NOW, THEREFORE, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules, namely,-

CHAPTER I
PRELIMINARY

1. Short title and commencement.—(1) These rules may be called the Medical Devices Rules, 2017.

(2) These rules shall, unless specified otherwise, come into force with effect from 1st day of January, 2018.

2. Application.— These rules shall be applicable in respect of,-

(i) 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);

(ii) substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii); and

(iii) devices notified from time to time under sub-clause (iv),

of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940);

3. Definitions.— In these rules, unless the context otherwise requires,-

(a) "academic clinical study" means a clinical study conducted for academic purpose on a medical device for the approved or a new intended use, new material of construction, new improved design or new population;

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

(c) "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;

(d) "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;

(e) "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;

(f) "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;

(g) "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;

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

(i) "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;

(j) "change in the constitution of a licencee" in relation to,-

(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;

(k) "clinical evidence" means, in relation to,-
(i) an *in vitro* diagnostic medical device, is all the information derived from specimen collected from human that supports the scientific validity and performance for its intended use;
(ii) a medical device, the clinical data and the clinical evaluation report that supports the scientific validity and performance for its intended use;

(l) "clinical investigation" means the systematic study of an investigational medical device in or on human participants to assess its safety, performance or effectiveness;

(m) "clinical investigation plan" means a document which contains the information about the rationale, aims and objective, design and the proposed analysis, conduct, methodology including performance, management, adverse event, withdrawal and statistical consideration and record keeping pertaining to clinical investigation;

(n) "clinical performance evaluation" means the systematic performance study of a new *in vitro* diagnostic medical device on a specimen collected from human participants to assess its performance;

(o) "clinical research organisation" means any entity to whom a sponsor may transfer or delegate one or more of its functions and duties regarding conduct of clinical investigation or clinical performance evaluation;

(p) "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;

(q) "controlling officer" means the officer designated under rule 10;

(r) "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;

(s) "Ethics Committee" means the committee referred to in rule 50;

(t) "Form" means forms specified in Appendix to these rules;

(u) "Good Clinical Practices Guidelines" means Good Clinical Practices Guidelines issued by Central Drugs Standards Control Organisation, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India;

(v) "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;

(w) "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;

(x) "investigational medical device" in relation to a medical device, other than *in vitro* diagnostic medical device, means a medical device specified in clause (zb),-
(i) which does not have its predicate device as defined in clause (zm); or
(ii) which is licenced under sub-rule (4) or sub-rule (6) of rule 20, sub-rule (1) of rule 25, or sub-rule (1) of rule 36 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.

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

(z) "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;

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

(zb) "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),
(B) substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified in the Official Gazette under sub-clause (ii),
(C) devices notified from time to time under sub-clause (iv),
of clause (b) of section 3 of the Act;

Explanation: For the purpose of these rules, substances used for *in vitro* diagnosis shall be referred as *in vitro* diagnostic medical device.

(zc) "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;

(zd) "Medical Device Officer" means an officer appointed or designated by the Central Government or the State Government, as the case may be, under sub-rule (2) of rule 18;

(ze) "medical devices testing laboratory" means any institute, organisation registered under sub-rule (3) of rule 83 for carrying out testing or evaluation of any medical device on behalf of a licencee for manufacture for sale;

(zf) "Medical Device Testing Officer" means an officer appointed or designated by the Central Government under sub-rule (1) of rule 18;

(zg) "near-patient testing" means any investigation carried out in a clinical setting or at the patient's home for which the result is available without reference to a laboratory and rapidly enough to affect immediate patient management;

(zh) "new *in vitro* diagnostic medical device" 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;

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

(zj) "Notified Body" means a body corporate or other legal entity, registered under rule 13 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;

(zk) "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;

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

(zm) "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;

(zn) "Quality Management System" means requirements for manufacturing of medical devices as specified in the Fifth Schedule;

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

(zp) "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,—

(a) is hazardous to health; or

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

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

(zq) "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;

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

(zs) "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;

(zt) "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;

(zu) "State Licensing Authority" means the authority designated by the State Government under sub-rule (2) of rule 8;

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

(zw) "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.

(zx) words and expressions used but not defined in these rules, shall have the meanings respectively assigned to them in the Act and the Drugs and Cosmetics Rules, 1945.

CHAPTER II
REGULATION OF MEDICAL DEVICE.

4. Classification of medical devices.— (1) Medical devices other than *in vitro* diagnostic medical devices shall be classified on the basis of parameters specified in Part I 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.

(2) *In vitro* diagnostic medical devices shall be classified 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.

(3) The Central Licencing Authority shall, classify medical devices referred to in rule 2, based on the intended use of the device and other parameters specified in the First Schedule.

(4) Based on the classification referred to in sub-rule (3), class wise list of medical devices shall be published on the website of the Central Drugs Standard Control Organisation:

Provided that the Central Licencing Authority may, from time to time, make additions or deletions in such list of medical devices or modify the class of any medical device.

5. Medical device grouping.— Any person who intends to apply for grant of licence in respect of medical devices for,-

(i) import;
(ii) manufacture for sale or for distribution; and
(iii) sale, stock, exhibit or offer for sale,

may group all or any medical device in accordance with the guidelines to be issued from time to time by the Ministry of Health and Family Welfare in the Central Government, by taking into consideration the technological changes or development in the field of medical devices and *in vitro* diagnostic medical devices.

6. Essential principles for manufacturing medical devices.—Medical device manufacturer shall follow the essential principles of safety and performance of medical devices as may be specified in the guidelines issued by the Ministry of Health and Family Welfare in the Central Government, from time to time keeping in view the contemporary scientific and technological knowledge and development:

Provided that the guidelines to be so specified shall be in conformity with the provisions of the Act and these rules.

7. Product standards for medical device.— (1) 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.

(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 Organisation 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.

CHAPTER III
AUTHORITIES, OFFICERS AND BODIES.

8. Licensing Authorities.— (1) The Central Licensing Authority shall be the competent authority for enforcement of these rules in matters relating to,-

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

(2) 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,-

(i) manufacture for sale or distribution of Class A or Class B medical devices;
(ii) sale, stock, exhibit or offer for sale or distribution of medical devices of all classes.

9. 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.

10. Controlling officer.— Any officer not below the rank of Assistant Drugs Controller, by whatever name called, shall be the controlling officer to supervise and give instructions to any officer subordinate to such controlling officer to exercise powers and functions under these rules for areas and purposes specified, by an order, of the Drugs Controller General of India or the Drugs Controller, by whatever name called, of the State concerned.

11. 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 rule 13, 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.

12. 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.

13. 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 referred to in rule 11 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.

14. Duties of Notified Body.— A registered Notified Body, referred to in rule 13, shall carry out its duties and functions, in respect of Class A or Class B medical devices as specified in Part II of the Third Schedule.

15. Procedure to be adopted by Notified Body.— A registered Notified Body shall carry out its duties and functions either by itself or by any other qualified person on its behalf as per specified procedure as detailed in Part II of the Third Schedule.

16. Fees to be charged by Notified Body.— A registered Notified Body may charge fee from the applicant for the services rendered by it as may be determined by the Central Government.

17. Suspension and cancellation of registration certificate of Notified Body. — (1) The Central Licensing Authority may, after giving an opportunity to show cause as to why such an order should not be passed, by an order in writing stating the reasons therefor, cancel the registration of a Notified Body or suspend it for such period as the Central Licensing Authority thinks fit, if in its opinion, the Notified Body has failed to comply with any provision of these rules.

(2) A registered Notified Body whose registration has been suspended or cancelled under sub-rule (1) may, within thirty days of the receipt of a copy of the order by it, prefer an appeal to the Central Government and the Central Government may, after giving the Notified Body an opportunity of being heard, confirm, reverse or modify such order.

(3) The registration of a Notified Body with the Central Licensing Authority shall be deemed to have been cancelled with effect from the expiry of the date of the validity of its accreditation by a National Accreditation Body.

18. Medical Device Testing Officer and Medical Device Officer.— (1) The Central Government may designate a Government Analyst appointed under section 20 of the Act as Medical Device Testing Officer.

(2) The Central Government or, as the case may be, the State Government, may designate an Inspector appointed under section 21 of the Act as Medical Device Officer.

(3) The Medical Device Testing Officer and Medical Device Officer designated under sub-rule (1) and sub-rule (2) respectively, while exercising powers and duties under the Act and these rules, shall be deemed to have been appointed as the Government Analyst and the Inspector, respectively.

19. Central medical device testing laboratory.— (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 sub-rule (1), 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 sub-rule (1):

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.

CHAPTER IV
MANUFACTURE OF MEDICAL DEVICES FOR SALE OR FOR DISTRIBUTION

20. Application for manufacture for sale or for distribution of Class A or Class B medical device.— (1) Any person who intends to manufacture a Class A or Class B medical device including *in vitro* diagnostic medical device shall make an application for grant of licence or loan licence to manufacture for sale or for distribution to the State Licensing Authority.

(2) The application under sub-rule (1) shall be made through an identified online portal of the Ministry of Health and

Family Welfare in the Central Government in Form MD-3 for licence or in Form MD-4 for loan licence accompanied with a fee, as specified in the Second Schedule along with respective documents as specified in Part II of the Fourth Schedule.

(3) The application made under sub-rule (1), shall, amongst others, be accompanied with an undertaking to the effect that the requirements of Quality Management System as specified in the Fifth Schedule have been complied with.

(4) The State Licensing Authority shall, after scrutiny of documents and on being satisfied that the requirements of these rules have been complied with, grant a licence to manufacture Class A medical devices in Form MD-5 or loan licence in Form MD-6, as the case may be, or if not satisfied, reject the application for reasons to be recorded in writing, within forty five days from the date, the application is made under sub-rule (1).

Provided that,—

(i) 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 medical device; and

(ii) the required audit of such manufacturing site by the registered Notified Body in the manner as specified in the Third Schedule shall be carried out within one hundred and twenty days from the date on which the licence was granted by the State Licencing Authority.

(5) Manufacturing site of the applicant, in respect of Class B device, shall conform to the requirements of Quality Management System as specified under the Fifth Schedule and applicable standards as specified under these rules and such conformance shall be verified through an audit by a Notified Body as referred under rule 13 before grant of licence.

(6) In case of application for grant of licence or loan licence to manufacture for sale or for distribution of Class B medical devices,—

(i) the audit of the manufacturing site shall be carried out within ninety days from the date of application by the registered Notified Body in the manner specified in the Third Schedule;

(ii) the Notified Body shall furnish its report to the State Licensing Authority within thirty days of the completion of audit;

(iii) the State Licensing Authority shall, after scrutiny of documents, audit report as referred to in clause (ii) and on being satisfied that the requirements of these rules have been complied with, grant a licence to manufacture Class B medical devices in Form MD-5 or loan licence in Form MD-6, as the case may be, or if not satisfied, reject the application for reasons to be recorded in writing, within a period of twenty days from the date of receipt of the report of audit by the Notified Body.

(7) If the application for grant of licence or loan licence to manufacture for sale or for distribution is rejected under sub-rule (4) or sub-rule (6), the aggrieved person may file an appeal before the State Government within forty-five days from the date of receipt of such rejection, which may, after such enquiry and after giving an opportunity of being heard to the appellant, be disposed of within a period of sixty days.

(8) Where the Central Licensing Authority or the State Licensing Authority has reason to believe or it has been alleged or suspected that the medical device does not conform to the standards of quality, or the provisions of the Fifth Schedule are not complied with, the State licensing Authority, in case of Class A or Class B medical device, or the Central Licensing Authority, in case of any Class of medical device, may direct a team of officers referred to in rule 23 to cause inspection of licenced manufacturing site.

21. Application for manufacturing Class C or Class D devices.— (1) An application shall be made to the Central Licensing Authority through an identified online portal of the Central Government for licence or loan licence to manufacture for sale or for distribution, as the case may be, of Class C or Class D medical device in Form MD-7 or Form MD-8, respectively.

(2) The application in Form MD-7 or Form MD-8 referred to in sub-rule (1) relating to Class C or Class D medical device, as the case may be, shall be accompanied with a fee as specified in the Second Schedule along with documents as specified in clause (ii) of Part II of the Fourth Schedule.

(3) The Central Licensing Authority may, wherever required, in case of Class C or Class D medical devices, use the services of any expert in the relevant field for scrutiny of application and other technical documents.

(4) The scrutiny referred to in sub-rule (3) shall be completed by the Central Licensing Authority within a period of forty five days from the date of online submission of application.

(5) In case, where the documents are found to be complete and in order, the Central Licensing Authority shall cause an inspection of the manufacturing site carried out under rule 23 by a team of officers accompanied by such experts, as may be considered necessary.

(6) The Central Licensing Authority may, where required, avail the services of a Notified Body referred to in sub-rule (4) of rule 13 for inspecting the manufacturing site of Class C and Class D medical devices.

(7) In case, where the documents furnished with the application referred to in sub-rule (1) are not found to be complete and in order, the Central Licensing Authority shall reject the application and inform the applicant of the reasons for such rejection electronically:

Provided that where deficiencies that can be rectified, are pointed out by the Central Licensing Authority within the stipulated period, the period referred to in sub-rule (4) shall reckon from the date these deficiencies have been removed.

22. Requirements for grant of manufacturing licence or loan licence.— While making application for grant of licence or loan licence under rule 20 or rule 21, the applicant shall meet the following requirements, namely:—

(i) the manufacturing site shall comply with the requirements of the Quality Management System as specified under the Fifth Schedule;

(ii) appoint competent technical staff under whose direction and supervision the manufacturing activity of a medical device shall be undertaken and such staff shall possess the following educational qualification and experience,-

(a) degree in engineering in relevant branch or in pharmacy or in science in appropriate subject from a recognised University and shall have experience of not less than two years in manufacturing or testing of medical devices; or

(b) diploma in engineering (in relevant branch) or in pharmacy from a recognised institute and shall have the experience of not less than four years in manufacturing or testing of medical devices;

(iii) appoint competent technical staff with degree or diploma in engineering (in relevant branch) or in pharmacy or in science in relevant subject and having experience of not less than two years in testing of medical devices under whose direction and supervision, the testing activity of a medical device shall be undertaken.

23. Inspection for grant of licence or loan licence for Class C or Class D medical device.— (1) Before grant of licence to manufacture for sale or for distribution in respect of Class C or D medical device, the manufacturing site shall be inspected within a period of sixty days from the date of application by a team comprising not less than two Medical Device Officers which may include any officer senior to the Medical Device Officer with or without an expert, or a Notified Body referred to in sub-rule (4) of rule 13:

Provided that no inspection of a medical device manufacturing site for grant of loan licence to manufacture such medical device shall be required to be carried out if the manufacturing site is already licenced to manufacture such medical device for sale or for distribution.

(2) The composition of the inspection team referred to in sub-rule (1) shall be determined by the controlling officer and no inspection shall be carried out without prior approval of the controlling officer.

24. Inspection report.— After completion of inspection as referred to in rule 23, the inspection team shall forward a descriptive report containing findings on each aspect of inspection along with the recommendations to the Central Licensing Authority, through online portal of the Ministry of Health and Family Welfare in the Central Government and forward a copy of the same to the applicant.

25. Grant of licence or loan licence to manufacture for sale or for distribution.— (1) If the Central Licensing Authority, after receipt of the report as referred to in rule 24, and such further enquiry, if any, as may be considered necessary, is satisfied that the requirements of these rules have been complied, that Authority shall grant a licence in Form MD-9, or loan licence in Form MD-10 or may reject the application for reasons to be recorded in writing, within a period of forty five days from the date the inspection report has been received.

(2) If the application for grant of licence or loan licence to manufacture for sale or for distribution is rejected under sub-rule (1), the aggrieved person may file an appeal before the Central Government within forty five days from the date of receipt of such rejection, which may, after such enquiry and after giving an opportunity of being heard to the appellant, be disposed of within a period of sixty days.

(3) In case, a licencee or loan licencee intends to manufacture additional medical devices in the licensed manufacturing site, the manufacturer shall make an application for grant of permission to manufacture such medical devices to the Central Licensing Authority or State Licensing Authority, as the case may be, along with the fee as specified in the Second Schedule and the documents as referred to in rule 20 or rule 21, as the case may be.

(4) In case of investigational medical device or new *in vitro* diagnostic medical device, the applicant shall obtain prior permission in Form MD-27 or Form MD-29 from the Central Licensing Authority and no licence to manufacture any class of such medical device shall be granted without such permission.

26. Conditions for manufacturing licence or loan licence.— After grant of licence or loan licence in Form MD-5, Form MD-6, Form MD-9 or MD-10, as the case may be, the licence holder shall comply with the following conditions, namely:-

(i) licence shall be produced when requested by the Medical Device Officer or any other senior officer under the control of Central Licensing Authority or State Licensing Authority, as the case may be;

(ii) the licence holder shall inform the State Licensing Authority or the Central Licensing Authority, as the case may be, of the occurrence of any suspected unexpected serious adverse event and action taken thereon including any recall within fifteen days of such event coming to the notice of licence holder;

(iii) the licence holder shall obtain prior approval from the Central Licensing Authority or the State Licensing Authority, as the case may be, before any major change as specified in the Sixth Schedule is carried out and the Central Licensing Authority or the State Licensing Authority, as the case may be, shall indicate its approval or rejection within forty five days and in case where no communication is received within the stipulated time from

such Authority, such change shall be deemed to have been approved;

(iv) the licence holder shall inform any minor change as specified in the Sixth Schedule to the State Licensing Authority or Central Licensing Authority, as the case may be, within a period of thirty days after such minor change take place;

(v) the licence holder shall carry out test of each batch of product manufactured prior to its release for compliance with specifications either in his own laboratory or in any other laboratory registered under sub-rule (3) of rule 83;

(vi) the licence holder shall, on being informed by the Central Licensing Authority or State Licensing Authority, as the case may be, that any part of any lot of the medical device has been found not conforming with the provisions specified under the Act and these rules, and on being directed so to do by such licensing authority, withdraw the remainder of that lot from sale and, so far as may, in the particular circumstances of the case, be practicable, recall the issues already made from that lot;

(vii) the licence holder shall maintain an audit or inspection book in Form MD-11 to enable the Notified Body or Medical Device Officer to record his observations and non-conformity, if any;

(viii) the licence holder shall maintain at least one unit of sample from each batch of invasive medical device and *in vitro* diagnostic medical device manufactured for reference purpose for a period of one hundred and eighty days after the date of expiry of such batch;

(ix) the licence holder shall maintain records of manufacturing and sales which shall be open to inspection by a Medical Device Officer;

(x) the medical device, when offered for sale, shall be accompanied by either its package insert or user manual, wherever applicable;

(xi) the manufacturing or testing activity of medical device shall be undertaken only under the direction and supervision of the competent technical staff;

(xii) if the manufacturer has stopped manufacturing activity or closed the manufacturing site for a period of thirty days or more, the same shall be intimated to the Central Licensing Authority or the State Licensing Authority, as the case may be.

27. Change in constitution.— In case of change in constitution of a licencee, after grant of licence under sub-rule (4) of rule 20 or sub-rule (6) of rule 20 or sub-rule (1) of rule 25, as the case may be, the manufacturer inform the Central Licensing Authority or the State Licensing Authority, as the case may be, within forty five days and shall shall make an application under sub-rule (1) of rule 20 or sub-rule (1) of rule 21, as the case may be, for grant of licence within a period of one hundred eighty days from the date of such change in constitution:

Provided that the existing licence shall be deemed to be valid till such time, a fresh licence is issued or application is rejected by the State Licensing Authority or the Central Licensing Authority, as the case may be:

Provided further that if the application is rejected, the manufacturer may appeal to the Central Government or the State Government, as the case may be, within a period of sixty days.

28. Unannounced inspection by State Licensing Authority.— The State Licensing Authority shall, in cases where licence has been granted for manufacturing Class A and Class B medical devices under rule 20, cause an inspection of the manufacturing site to be carried out by a Medical Device Officer on a random basis and such inspection shall not be less than two per cent. of the total audits carried out by Notified Bodies within that State for that class of medical device.

29. Validity of licence.— (1) A licence or loan licence issued in Form MD-5, Form MD-6, Form MD-9 or Form MD-10 shall remain valid in perpetuity, subject to payment of licence retention fee as specified in the Second Schedule before completion of the period of five years from the date of its issue, unless, it is suspended or cancelled by State Licensing Authority or the Central Licensing Authority, as the case may be.

(2) If the licence holder fails to pay the required licence retention fee on or before due date as referred to in sub-rule (1), the licence holder shall, in addition to the licence retention fee, be liable to pay a late fee calculated at the rate of two per cent. of the licence retention fee for every month or part thereof within one hundred and eighty days and in the event of non-payment of such fee during that period, the licence shall be deemed to have been cancelled.

30. Suspension and cancellation of licence.— (1) Where the licencee contravenes any provision of the Act and these rules, the State Licensing Authority or the Central Licensing Authority, as the case may be, shall, after giving the licencee an opportunity to show cause as to why such an order should not be passed, shall by an order and for reasons to be recorded in writing, suspend it for such period as it considers necessary either wholly or in respect of any of the medical device or cancel the licence or loan licence.

(2) A licencee whose licence or loan licence has been suspended or cancelled by the State Licensing Authority or the Central Licensing Authority, as the case may be, under sub-rule (1), may within forty-five days of the receipt of a copy of the order by such authority, prefer an appeal to the State Government or the Central Government, as the case may be, and the State Government or the Central Government, shall after giving the licencee an opportunity of being heard, confirm, reverse or modify such order.

(3) The State Licensing Authority or the Central Licensing Authority, as the case may be, may revoke suspension order issued under sub-rule (2) for reasons to be recorded in writing.

(4) Orders of suspension issued or revoked; or cancellation of licence shall be duly published on the concerned websites of the State Licensing Authority or the Central Licensing Authority, as the case may be.

31. Test licence to manufacture for test, evaluation, clinical investigations, etc.,—(1) Small quantity of Class A or Class B or Class C or Class D of medical devices may be manufactured for the purpose of clinical investigations, test, evaluation, examination, demonstration or training for which an application shall be made in Form MD-12 to the Central Licensing Authority and shall be accompanied with a fee as specified in the Second Schedule.

(2) The application made under sub-rule (1) shall also be accompanied with the following documents, namely:—

(a) brief description of the medical device including intended use, material of construction, design and an undertaking stating that the required facilities including equipment, instruments, and personnel have been provided to manufacture such medical devices;

(b) list of equipment, instruments;

(c) list of qualified personnel;

(d) copy of manufacturing licence issued under these rules, if any;

(e) approval letter authorising to undertake research and development activities issued by any Government organisation, if any.

(3) The Central Licensing Authority, after enquiry, if any, as may be considered necessary, on being satisfied that the requirements of these rules have been complied, shall grant a test licence in Form MD-13, or may reject the application for reasons to be recorded in writing, within a period of thirty days from the date the application is made under sub-rule (1).

(4) The licencee shall maintain a record of the details of quantity of the product manufactured under test licence.

(5) A licence granted under sub-rule (3) shall, unless cancelled earlier, remain in force for a period of three years from the date of its issuance.

32. Conditions of test licence to manufacture for test, evaluation, clinical investigations, etc.,— A licence in Form MD-13 under rule 31 shall be subject to the following conditions, namely:—

(a) the licencee shall use the medical device manufactured under licence granted under sub-rule (3) of rule 31 exclusively for the purpose of clinical investigations, test, evaluation, examination, demonstration or training at the place specified in the licence;

(b) the licencee shall allow any Medical Device Officer to enter, with or without notice, the premises where the medical device are manufactured and to satisfy himself that only clinical investigations, test, evaluation, examination, demonstration or training is being conducted on such device;

(c) the licencee shall maintain a record of the quantity of medical device manufactured, tested and stocked and its disposition.

33. Cancellation of test licence to manufacture for test, evaluation, clinical investigations, etc.,— (1) Where any licencee under rule 31 contravenes any provision of these rules, the Central Licensing Authority, shall, issue a show cause notice to such licencee asking, as to why an order should not be made to cancel the licence.

(2) The Central Licensing Authority shall, after giving an opportunity to the licencee to explain in writing licencee's defence, pass an order for cancellation or otherwise and record the reasons therefor in the said order.

(3) A licencee, whose licence has been cancelled, may appeal to the Central Government within forty five days from the date of the order.

CHAPTER V
IMPORT OF MEDICAL DEVICES

34. Application for grant of import licence.— (1) An authorised agent having licence to manufacture for sale or distribution or wholesale licence for sale or distribution under these rules, shall make an application for grant of import licence for medical device to the Central Licensing Authority through an identified online portal of the Ministry of Health and Family Welfare in the Central Government in Form MD-14 for obtaining a licence.

(2) The application under sub-rule (1) shall be accompanied with the fee as specified in the Second Schedule along with respective documents as specified in the Fourth Schedule:

Provided that any change in the documents submitted at the time of application and prior to grant of licence shall be informed, in writing, to the Central Licensing Authority.

(3) Where the Central Licensing Authority, has reason to believe that the quality of the medical device is compromised, and decides to subject it to evaluation, test or examination, the authorised agent shall pay a fee for such evaluation, test or examination, to the testing laboratory as specified by the Central Licensing Authority.

(4) Any subsequent application for,-

(i) grant of licence for additional manufacturing site for the same medical device by the same authorised agent

shall be accompanied with a fee and documents as referred in sub-rule (2);

(ii) licence for additional medical device manufactured at the same manufacturing site shall be made by the same authorised agent accompanied with fee as specified in the Second Schedule and respective documents as specified in the Fourth Schedule.

35. Inspection of overseas manufacturing site.— (1) On receipt of an application under sub-rule (1) of rule 34, the Central Licensing Authority, may cause an inspection of the overseas manufacturing site either by itself or by any other person or body to whom the power has been delegated for the purpose.

(2) The applicant shall be liable to pay a fee as specified under the Second Schedule in respect of expenditure required in connection with the visit to the overseas manufacturing site under sub-rule (1).

36. Grant of import licence.— (1) After examination of documents furnished with the application under sub-rule (1) of rule 34 and on the basis of the inspection report, if inspection has been carried out, the Central Licensing Authority may, on being satisfied, grant licence in Form MD-15 or, may reject such application for which reasons shall be recorded in writing, within a period of nine months from the date of application.

(2) In the event of rejection, the applicant may appeal to the Central Government within a period of forty five days and that Government, may, after such enquiry into the matter, as considered necessary, pass orders in relation thereto within a period of ninety days from the date of appeal.

(3) Where, a free sale certificate has already been issued in respect of any medical device by the national regulatory authority or other competent authority of any of the countries namely, Australia, Canada, Japan, European Union Countries, or the United States of America, a licence shall be granted under sub-rule (1) to the applicant without carrying out clinical investigation.

(4) Where a medical device is imported from countries other than those referred to in sub-rule (3), the licence in case of Class C and Class D medical devices may be granted after its safety and effectiveness has been established through clinical investigation in India as specified under provisions of Chapter VII of these rules.

(5) Where a medical device, is imported from countries other than those referred to in sub-rule (3), the licence in case of Class A or Class B medical devices 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.

(6) In case of investigational medical device or new *in vitro* diagnostic medical device, the applicant shall obtain prior permission in Form MD-27 or in Form MD-29 from the Central Licensing Authority and no licence to import any class of such medical device shall be granted without such permission.

37. Validity of licence.— A licence granted under sub-rule (1) of rule 36 shall remain valid in perpetuity, unless, it has been cancelled or surrendered, provided the authorised agent deposits the licence retention fee with the Central Licensing Authority as specified in the Second Schedule for each overseas manufacturing site and for each licenced medical device after completion of every five years from the date of its issue:

Provided that the Central Licensing Authority may permit to deposit the licence retention fee after due date but before expiry of ninety days with a late fee calculated at the rate of two per cent. per mensem:

Provided further that if the licencee fails to deposit the licence retention fee within the above stipulated period, the licence shall be deemed to have been cancelled.

38. Conditions to be complied with by Licence holder.— (1) The licencee shall comply with the following conditions, namely:-

(i) licence shall be produced when requested by the Medical Device Officer or any other senior officer under the control of Central Licensing Authority or the State Licensing Authority, as the case may be;

(ii) the licencee shall inform the licensing authority forthwith and, in all circumstances, within a period of fifteen days of any administrative action taken on account of any adverse reaction, such as market withdrawal, regulatory restrictions, cancellation of authorisation or declaration of the medical device as not of standards quality by the regulatory authority of the country of origin or by any regulatory authority of any other country, where the medical device is marketed, sold or distributed;

(iii) authorised agent in cases referred in clause (ii), shall stop immediately the despatch and marketing of the medical device referred in that clause;

(iv) the Central Licensing Authority, after due consideration of the information as referred in clause (ii), may issue directions to the licencee in respect of marketing, sale or distribution of the medical device including withdrawal of medical device from the Indian market within a period as may be specified by the Central Licensing Authority;

(v) the authorised agent shall obtain prior approval from the Central Licensing Authority before any major change, as specified in the Sixth Schedule, is carried out and the Central Licensing Authority shall indicate its approval or rejection within sixty days;

(vi) in case, no communication of approval or rejection as referred to in clause (v) is received within the stipulated time from the Central Licensing Authority, such change shall be deemed to have been approved;

(vii) licencee shall inform, any minor change as specified in the Sixth Schedule to the Central Licensing Authority

within a period of thirty days, after such minor change took place;
(viii) authorised agent shall inform the Central Licensing Authority in writing within a period of thirty days in the event of any change in the constitution of the overseas manufacturer or the authorised agent;
(ix) the consignment of medical device shall be accompanied by an invoice or statement showing the name and quantity of the medical device;
(x) the licencee shall supply the medical device for sale or offer it for sale along with its package insert or user manual, wherever applicable.
(2) Where the Central Licensing Authority is satisfied that any medical device is not in conformity with the provisions of the Act and these rules, it may issue directions that the entire batch of such medical device may not be sold or offered for sale or may be recalled from the market including hospitals, if any, where it has been stocked:

Provided that where the Central Licensing Authority considers it necessary or expedient, more than one batch or all batches of such medical device may be directed to be recalled.

39. Fresh application in case of change in constitution. — In case of change in constitution of a licencee, after grant of licence under sub-rule (1) of rule 36, an application shall be made under sub-rule (1) of rule 34 for grant of licence within a period of one hundred and eighty days from the date of such change in constitution:

Provided that the existing licence shall be deemed to be valid till such time, the fresh licence is issued or application is rejected by the Central Licensing Authority.

Explanation.- For the purpose of this rule, the licencee shall include overseas manufacturer who executed the power of attorney in favour of authorised agent.

40. Test licence for import for test, evaluation, clinical investigations, etc.— (1) Notwithstanding anything contained in these rules, any medical device or *in vitro* diagnostic medical device may be imported for the purpose of clinical investigations or test or evaluation or demonstration or training.
(2) The person who desires to import medical device under sub-rule (1), shall apply for an import licence for test, evaluation or demonstration or training to the Central Licensing Authority in Form MD-16, accompanied by such fee as specified in the Second Schedule.
(3) On receipt of the application under sub-rule (2), the Central Licensing Authority shall determine, the quantity of the medical devices, after taking into account the requirement for clinical investigation, approved clinical investigation plan, and information and documents submitted by the applicant.

41. Grant of test licence for import for test, evaluation, clinical investigations, etc.— (1) If the Central Licensing Authority, after such enquiry, if any, is satisfied that the requirements of these rules have been complied, the said authority shall grant a test licence in Form MD-17, or may reject the application for reasons to be recorded in writing, within a period of thirty days from the date the application under sub-rule (2) of rule 40.
(2) The medical device for which a test licence has been granted under sub-rule (1), shall be used exclusively for purposes of clinical investigation, test, evaluation, demonstration or training, as the case may be, and such clinical investigations or test or evaluation or training, shall be conducted at a place specified in such test licence:

Provided that in cases where the medical device is required to be taken to any place other than the ones mentioned in the test licence, the Central Licensing Authority shall be informed in writing before doing so.
(3) The holder of the test licence shall maintain record of the activities undertaken including the name of manufacturer, quantity imported and date of import.
(4) The consignment of medical device shall be accompanied by an invoice or statement showing the name and quantity of medical device.
(5) A licence in Form MD-17 shall, unless cancelled earlier, be in force for a period of three years from the date of its issue.
(6) The medical devices including *in vitro* diagnostic medical device referred to in sub-rule (2) that are not used, may be permitted to be exported or destroyed under intimation to the Central Licensing Authority.
(7) Where any licencee under sub-rule (1) contravenes any provision of these rules, the Central Licensing Authority, shall, issue a show cause notice to such licencee asking, as to why an order should not be made to cancel the licence.
(8) The Central Licensing Authority shall after giving an opportunity to the licencee to explain, in writing, licencee's defence, pass an order for cancellation or otherwise and record the reasons therefor in the said order.
(9) A licencee, whose licence has been cancelled under sub-rule (8), may appeal to the Central Government within forty five days from the date of such order.

42. Import of investigational medical device by Government hospital or statutory medical institution for treatment of patient.— (1) Small quantity of investigational medical device, the import of which is not allowed, but approved in the country of origin, may be allowed to be imported by the Central Licensing Authority for treatment of a patient suffering from a life threatening disease or disease causing serious permanent disability or disease requiring therapy for unmet medical need, on an application made by a Medical Officer through the medical superintendent of a Government hospital or a statutory medical institution in Form MD-18 and such application shall be accompanied by documents required and the fee as specified in the Second Schedule.

(2) On receipt of an application under sub-rule (1), the Central Licensing Authority shall, on being satisfied about the information and the documents enclosed with the application, grant import licence for treatment of patient in Form MD-19.

(3) The medical device for which the licence is granted under sub-rule (2), shall, be used exclusively for the purpose of treatment of the patient referred to in sub-rule (1).

(4) The holder of licence shall maintain record of the name of the manufacturer, quantity imported and used, date of import, name and address of the patient and diagnosis.

(5) The holder of the licence shall allow the medical device officer authorised by the Central Licensing Authority in this behalf to enter, with or without prior notice, the premises where the medical devices are stocked and to inspect the premises and relevant records and investigate the manner in which the medical device is being used and to take, if required, samples thereof.

(6) The quantity considered necessary shall be determined by the Central Licensing Authority after taking into account the recommendation of the hospital concerned for treatment of patient suffering from a life threatening disease or disease causing serious permanent disability or disease requiring therapy for unmet medical need.

(7) Where the Central Licensing Authority is satisfied, it may, in exceptional and special circumstances, allow import of larger quantity of medical devices for use by the patient.

(8) The consignment of medical device shall be accompanied by an invoice or a statement showing the name and quantity of medical device.

43. Import of medical device for personal use.—(1) Small quantity of medical device, the import of which is otherwise prohibited under section 10 of the Act, may be imported for personal use subject to the following conditions, namely,-

(i) the medical device shall form part of a personal baggage of a passenger and be intended for the exclusive use of such passenger;

(ii) the medical device shall be declared as personal baggage of the passenger to the customs authorities, if they so direct;

(iii) the quantity of any single medical device so imported shall not exceed the quantity specified by the registered medical practitioner;

(iv) the medical device has been prescribed by a registered medical practitioner; and

(v) the medical device so imported shall be accompanied with an invoice or a statement showing the name and quantity of medical device.

(2) Small quantity of medical device, the import of which is otherwise prohibited under section 10 of the Act, and which is not forming a part of bona fide personal baggage, may be imported for personal use, on an application made by the applicant in Form MD-20 and such application shall be accompanied by documents confirming that the device is for *bona fide* personal use and a prescription to that effect by a registered medical practitioner.

(3) On receipt of an application under sub-rule (2), the Central Licensing Authority shall, on being satisfied about the information and the documents enclosed with the application, grant permission in Form MD-21 or may reject the application for reasons to be recorded in writing within a period of seven days from the date of application under sub-rule (2).

(4) Medical devices as referred to in sub-rule (2) shall be subject to the following conditions, namely,-

(i) the medical device shall be declared to the Customs Authorities if they so direct;

(ii) the consignment of the medical device so imported shall be accompanied with an invoice or statement showing the name and quantity of medical device.

CHAPTER VI
LABELLING OF MEDICAL DEVICES

44. 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 sterilisation 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.

45. 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.

46. 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.

47. 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.

48. 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.

CHAPTER VII
CLINICAL INVESTIGATION OF MEDICAL DEVICE AND CLINICAL PERFORMANCE EVALUATION OF NEW *IN VITRO* DIAGNOSTIC MEDICAL DEVICE

49. Conduct of clinical investigation.—No person or sponsor shall conduct any clinical investigation in respect of investigational medical device in human participants except in accordance with these rules and in accordance with the permission granted by the Central Licensing Authority.

50. Application of rule 122DD of Drugs and Cosmetics Rules, 1945 with regard to Ethics Committee.—
(1) The Ethics Committee constituted under rule 122DD of the Drugs and Cosmetics Rules, 1945 shall perform the functions and duties under these rules and shall be deemed to be constituted under these rules.
(2) The provisions of Ethics Committee provided in rule 122DD of the Drugs and Cosmetics Rules, 1945 shall, except where specifically provided under these rules, be applicable *mutatis mutandis*, for the purpose of clinical investigation and clinical performance evaluation under this Chapter.

51. Application for grant of permission to conduct clinical investigation.—(1) An application for grant of permission to conduct clinical investigation for investigational medical device shall be made to the Central Licensing Authority in Form MD-22 by a sponsor and shall be accompanied with information specified in the Seventh Schedule.
(2) An application for grant of permission to conduct,-

(a) a pilot clinical investigation on an investigational medical device as referred to in sub-rule (1) shall be accompanied with a fee as specified in the Second Schedule along with information as specified in the Seventh Schedule.
Explanation.— For the purposes of these rules, the pilot clinical investigation means clinical investigation to be carried out for the first time in human participants;

(b) a pivotal clinical investigation on an investigational medical device shall be made on the basis of data emerging from pilot clinical investigation, accompanied with a fee as specified in the Second Schedule:
Provided that no fee shall be payable by any institute, organisation, hospital run or funded by the Central Government or the State Government, as the case may be, for conduct of clinical investigation.

(3) No permission for conduct of academic clinical study on licenced medical device shall be required, where,-

(a) the Ethics Committee approves such a study; and
(b) the data generated during the study shall not be used to furnish to the Central Licensing Authority to manufacture or to import for marketing any investigational medical device in the country.

(4) The Central Licensing Authority may, in public interest, abbreviate, defer, or waive the requirement of animal data or clinical data for conducting clinical investigation for reasons to be recorded in writing before granting permission to conduct clinical investigation.
(5) Medical devices requiring clinical investigation but claiming substantial equivalence to a predicate device shall not be marketed unless the Central Licensing Authority has approved it.
Explanation 1.- For the purposes of this sub-rule, a device shall be deemed to be substantially equivalent in comparison to a predicate device, if it has.—

(i) the same intended use and technological characteristics; or
(ii) same intended use and different technological characteristics, and demonstrate that the device is as safe and effective as the predicate device.

Explanation 2.- A claim of substantial equivalence does not mean that the proposed medical device and predicate device are identical. Substantial equivalence shall be established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable.

52. Permission to conduct clinical investigation.—The Central Licensing Authority, after such further enquiry, if any, as considered necessary, may,-

(i) if satisfied, that the requirements of these rules have been complied with, grant permission to conduct clinical investigation for an investigational medical device in Form MD-23;
(ii) if not satisfied with the requirements as referred to in sub-clause (i), reject the application, for reasons to be recorded in writing,

within a period of ninety days, from the date of application made under sub-rule (1) of rule 51.

53. Conditions for permission.—After grant of permission referred to in rule 52, the following conditions shall be complied with by the applicant, namely:—

(i) clinical investigation shall be initiated after approval of clinical investigation plan by the registered Ethics Committee;

(ii) clinical investigation shall be conducted in accordance with the approved clinical investigation plan, Good Clinical Practices Guidelines issued by the Central Drugs Standard Control Organisation and provisions of the Seventh Schedule;

(iii) clinical investigation shall be registered with the Clinical Trial Registry of India before enrolling the first participant for such clinical investigation;

(iv) annual status report of each clinical investigation, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licensing Authority by the sponsor, and, in case of termination of any clinical investigation, the detailed reasons for the same shall be communicated to the Central Licensing Authority within thirty days of such termination;

(v) information about any report of suspected unexpected serious adverse event occurring during clinical investigation on the subject shall, after due analysis, be submitted by the sponsor to the Central Licensing Authority within fourteen days of the knowledge of its occurrence as specified in the Seventh Schedule and in compliance with the procedure specified in these rules;

(vi) in case of an injury or death during clinical investigation of a subject of a clinical investigation, the applicant shall provide complete medical management or compensation in accordance with these rules;

(vii) the premises of the sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical investigation sites shall be open for inspection by officers of the Central Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts, to verify compliance of the requirements of these rules for conduct of clinical investigation;

(viii) the clinical investigation shall be initiated by enrolling first participant within a period of one year from the date of grant of permission, failing which prior permission from the Central Licensing Authority shall be required to initiate clinical investigation;

(ix) the Central Licensing Authority may impose or exempt any condition while granting permission in respect of specific clinical investigations, if considered necessary, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of clinical investigation.

54. Suspension, cancellation, etc. of permission.—(1) If any person to whom permission has been granted under rule 52 fails to comply with any of the conditions of permission or any of the provisions of the Act or these rules, the Central Licensing Authority may,—

(a) issue warning letter giving details of deficiency found; or

(b) debar the investigator or sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors to conduct any clinical investigation for such period as it thinks fit; or

(c) suspend the permission for such period as it thinks fit or cancel either wholly or partly the permission.

(2) Any person who is aggrieved by the order passed under sub-rule (1), may file an appeal within thirty days of the receipt of such order 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.

55. Medical management and compensation related to clinical investigation.—(1) Where any participant is injured on account of participation in clinical investigation, the sponsor permitted under rule 52 shall provide medical management to that participant.

(2) Where an injury is caused to the participant in a clinical investigation of any investigational medical device and such injury is attributable to the use of investigational medical device, the sponsor permitted under rule 52 shall provide to that participant, medical management and such compensation in the manner as specified under rule 122DAB of the Drugs and Cosmetics Rules, 1945.

(3) Where death of a participant is related to clinical investigation and is attributable to the use of an investigational medical device, the sponsor, permitted under rule 52 shall provide to the legal heir of that participant, such compensation, in such manner as specified under rule 122DAB of the Drugs and Cosmetics Rules, 1945.

56. Powers of search and seizure, etc.—The Medical Devices Officer may enter any premises related to clinical investigation or clinical performance evaluation, with or without an expert, with prior approval of the Central Licensing Authority, with or without prior notice, to inspect the facilities, search and seize, record, data, documents, books, and medical devices including investigational medical devices or new *in vitro* diagnostic medical device.

57. Maintenance of record.—Every person, sponsor, clinical research organisation, any other organisation or investigator conducting a clinical investigation or his agent holding a permission under this Chapter shall maintain such data, record, registers and other documents for a period of seven years after completion of such investigation and shall furnish such information as may be required by the Central Licensing Authority or any other officer authorised by it in this behalf under rule 56.

58. Disclosure of name, address, etc., of persons involved in clinical investigation or clinical performance evaluation.—Every person, sponsor, clinical research organisation, any other organisation or investigator conducting a clinical investigation or clinical performance evaluation or any agent authorised by any of them, as the case may be, shall, if so required, disclose to the Medical Device Officer or any other officer authorised by the Central Licensing Authority, the names, addresses and other particulars of persons involved in clinical investigation.

59. Permission to conduct clinical performance evaluation for new *in vitro* diagnostic medical device.— (1) No person or sponsor shall conduct any clinical performance evaluation in respect of a new *in vitro* diagnostic medical device on any specimen, including blood or tissue derived from human body except under, and in accordance with, the permission granted by the Central Licensing Authority subject to such conditions and in such form and manner as specified in these rules.

(2) An application for grant of permission to conduct, clinical performance evaluation of new *in vitro* diagnostic medical device shall be made to the Central Licensing Authority in Form MD-24 by the sponsor and shall be accompanied with a fee as specified in the Second Schedule along with information specified in sub-rule (3) duly signed by the sponsor in India:

Provided that no fee shall be required to be paid by the institutes, organisation, hospitals, run by the Central Government or the State Government, involved in conduct of clinical performance evaluation of new *in vitro* diagnostic medical devices.

(3) The information required under sub-rule (2) shall contain the following, namely,-

(i) approval from an Ethics Committee, which is registered with the Central Licensing Authority, as specified in Appendix VIII of the Schedule Y of the Drugs and Cosmetics Rules, 1945 and referred to in the Seventh Schedule;

(ii) source and quantity of samples which shall be used during evaluation;

(iii) device description including specification of raw material and finished product, data allowing identification of the device in question, proposed instruction for use, labels and regulatory status in other countries, if any;

(iv) in house performance evaluation data used to establish stability, specificity, sensitivity, repeatability and reproducibility;

(v) clinical performance evaluation plan stating in particular the purpose, scientific, technical or medical grounds and scope of evaluation;

(vi) Case Report Form as specified in Table 6 of the Seventh Schedule;

(vii) undertaking by investigators as specified in Table 9 of the Seventh Schedule;

(viii) the list of laboratories or other institutions taking part in the evaluation study;

(ix) the scheduled duration for evaluation and, in case of devices for self-testing, the location and number of lay persons involved;

(x) an undertaking that the device in question conforms to the requirements of these rules, apart from aspects covered by evaluation and apart from those specifically itemised in the undertaking, and that every precaution has been taken to protect the health and safety of the patient, user and other persons.

(xi) performance evaluation report from a laboratory designated under sub-rule (1) of rule 19.

(4) The Central Licensing Authority may, in public interest, abbreviate, defer, or waive the requirements of conducting clinical performance evaluation for reasons to be recorded in writing for grant of permission to conduct clinical performance evaluation.

(5) If the Central Licensing Authority, after such further enquiry, if any, as may be considered necessary, is satisfied that the requirements of these rules have been complied, may grant permission to conduct clinical performance evaluation for a new *in vitro* diagnostic medical device in Form MD-25 or may reject the application, for reasons to be recorded in writing, within a period of ninety days from the date of application.

60. Conditions for permission to conduct of clinical performance evaluation.— After grant of permission referred to in sub-rule (5) of rule 59, the following conditions shall be complied with by the applicant,—

(i) clinical performance evaluation shall be conducted in accordance with the approved clinical performance evaluation plan and Good Clinical Practices Guidelines;

(ii) clinical performance evaluation shall be initiated after approval of clinical investigation plan by the registered Ethics Committee;

(iii) clinical performance evaluation shall be registered with the Clinical Trial Registry of India before enrolling the first participant for such clinical performance evaluation;

(iv) annual status report of each clinical performance evaluation, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licensing Authority by the sponsor, and in case of termination of any clinical performance evaluation, the detailed reasons for the same shall be communicated to the Central Licensing Authority within thirty days of the date of termination;

(v) the laboratories or other institutions taking part in the evaluation study or the sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors, and clinical investigation sites shall be open for inspection by officers of the Central Licensing Authority authorised in this behalf who may be accompanied by officers of State Licensing Authority or outside experts under these rules to verify compliance of the requirements of these rules for conduct of clinical performance evaluation;

(vi) the clinical performance evaluation shall be initiated within a period of one year from the date of grant of permission, failing which prior permission from the Central Licensing Authority shall be required to initiate such clinical performance evaluation;

(vii) the Central Licensing Authority may impose or exempt any condition while granting permission in respect of specific clinical performance evaluation, if considered necessary, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of clinical performance evaluation.

61. Suspension or cancellation of permission.—(1) If any person to whom permission has been granted under sub-rule (5) of rule 59 fails to comply with any of the conditions of permission, the Central Licensing Authority may, suspend the permission for such period as it thinks fit or cancel either wholly or partly.

(2) Any person who is aggrieved by the order passed under sub-rule (1), may file an appeal within thirty days 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.

62. Medical management.—Where any participant is injured on account of his participation in the clinical performance evaluation, the sponsor permitted under sub-rule (5) of rule 59 shall provide medical management to that participant.

CHAPTER VIII

IMPORT OR MANUFACTURE MEDICAL DEVICE WHICH DOES NOT HAVE PREDICATE DEVICE

63. Permission to import or manufacture medical device which does not have its predicate device.—(1) Save as otherwise provided in these rules, for import or manufacture of medical device which does not have predicate medical device, an application for grant of permission for such medical device after completion of its clinical investigation under Chapter VII shall be made to the Central Licensing Authority in Form MD-26 either by an authorised agent in case of import or a manufacturer, as the case may be, which shall be accompanied with fee as specified in the Second Schedule along with information specified in Part IV of the Fourth Schedule:

Provided that the medical device which does not have predicate medical device indicated in life threatening, serious diseases or diseases of special relevance to the Indian health scenario, national emergencies, extreme urgency, epidemic and medical devices indicated for conditions, diseases for which there is no therapy, the animal data or clinical data requirements may be abbreviated, deferred or omitted, as deemed appropriate by the Central Licensing Authority:

Provided further that in respect of investigational medical device of Class A, data on clinical investigation may not be required, except in cases, where depending on the nature of the medical device, the Central Licensing Authority, for reason to be recorded in writing, considers such data necessary:

Provided also that subject to other provisions of these rules, in case of medical device of which drugs are also a part, the submission of requirements relating to animal toxicology, reproduction studies, teratogenic studies, perinatal studies, mutagenicity and carcinogenicity may be relaxed in case of drugs already approved and marketed in India and supported by adequate published evidence regarding safety of the drug.

Provided also that, the results of clinical investigation may not be required to be submitted where the investigational medical device is approved by the regulatory authorities of either the United Kingdom or the United States of America or Australia or Canada or Japan and the said device has been marketed for at least two years in that country and the Central Licencing Authority is satisfied with the data of safety, performance and pharmacovigilance of the device, and,-

(a) there is no evidence or theoretical possibility, on the basis of existing knowledge, of any difference in the behavior and performance in Indian population;

(b) the applicant has given an undertaking in writing to conduct post marketing clinical investigation with the objective of safety and performance of such investigational medical device as per protocol approved by the Central Licensing Authority.

(2) The Central Licensing Authority, after being satisfied with the information furnished along with application under sub-rule (1), may grant permission to import or manufacture medical device which does not have predicate medical device in Form MD-27, or may reject the application for reasons to be recorded in writing, within a period of one hundred and twenty days or such extended period, not exceeding a further period of thirty days, from the date of application:

Provided that the Central Licensing Authority shall, where the information is inadequate with regard to the requirements as referred to in sub-rule (1), intimate the applicant in writing within the said period, for reasons to be recorded in writing, the conditions which shall be satisfied before considering the permission:

Provided further that if the applicant has not furnished the required information sought by the Central Licensing Authority within ninety days from the date of intimation and the said Authority is satisfied that the information sought was possible to be furnished within the said period, it may reject the application for reasons to be recorded in writing.

(3) If the applicant does not receive permission or if the application is rejected within the specified period as referred to in sub-rule (2), the applicant may appeal to the Central Government and that Government may, after such enquiry, as it considers necessary, pass such orders in relation thereto as it thinks fit within a period of sixty days from the date of appeal.

64. Permission to import or manufacture new *in vitro* diagnostic medical device.—(1) An application for grant of permission to import or manufacture a new *in vitro* diagnostic medical device may be made to the Central Licensing Authority in Form MD-28 either by an authorised agent in case of import or a manufacturer himself, as the case may be, and shall be accompanied with fee as specified in the Second Schedule along with information specified in Part IV of the Fourth Schedule:

Provided that the new *in vitro* diagnostic medical device used for diagnosis of life threatening, serious diseases or diseases of special relevance to the Indian health scenario, national emergencies, extreme urgency, epidemic and diagnostic medical devices used for diagnosis of conditions, diseases for which there is no diagnostic medical device available in the country, the clinical data requirements may be abbreviated, deferred or omitted, as deemed appropriate by the Central Licensing Authority:

Provided further that for new *in vitro* diagnostic medical device classified under Class A, data on clinical performance evaluation may not be necessary, except in cases, where the Central Licensing Authority, for reasons to be recorded in writing, considers it necessary depending on the nature of the medical device.

(2) The Central Licensing Authority, may, after being satisfied with the information furnished along with application under sub-rule (1), grant permission to import or manufacture new *in vitro* diagnostic medical device in Form MD-29 or may reject the application, for reasons to be recorded in writing, within a period of ninety days or such extended period, not exceeding a further period of thirty days, from the date of application:

Provided that the Central Licensing Authority shall, where the information is inadequate with regard to the requirements as referred to in sub-rule (1), intimate the applicant in writing within the said period, for reasons to be recorded in writing, the conditions which shall be satisfied before considering permission:

Provided further that if the applicant has not furnished the required information sought by the Central Licensing Authority within ninety days from the date of intimation and the said Authority is satisfied that the information sought was possible to be furnished within the said period, it may reject the application for reasons to be recorded in writing.

65. Condition of permission to import or manufacture medical device which does not have its predicate device and new *in vitro* diagnostic medical device.—A Permission under rules 63 in Form MD-27 and rule 64 in Form MD-29 shall be subject to the following conditions, namely:—

(a) the medical device shall conform to the specifications submitted along with the application;

(b) the permission holder of Form MD-27 shall submit the Periodic Safety Update Report to the Central Licensing Authority from the date of launch in the market and such report shall be submitted every six months for first two years followed by submission of the said report annually for the two more successive years;

(c) the permission holder shall inform the date of launch of medical device in the market to the Central Licensing Authority;

(d) the permission holder of Form MD-27 shall submit the suspected unexpected serious adverse event within fifteen days of the awareness of the event to the Central Licensing Authority.

CHAPTER IX
DUTIES OF MEDICAL DEVICE OFFICER, MEDICAL DEVICE TESTING OFFICER AND NOTIFIED BODY

66. Duties of Medical Device Testing Officer.—The Medical Device Testing Officer shall cause the sample of medical device or portion thereof tested or evaluated as may be sent in a sealed package by the Medical Device Officer or any other person under the provisions of Chapters IV, V, VII and XI of these rules, and shall furnish the report of the result of the test or evaluation in accordance with these rules.

67. Test or evaluation of sample under sub-section (4) of section 25 of the Act.—(1) The sample of medical device for test or evaluation under sub-section (4) of section 25 of the Act shall be sent by registered post in the outer cover addressed to the Director of central medical device testing laboratory in a sealed packet with a memorandum in Form MD-30.

(2) The packet as well as the outer cover shall be marked with a distinguishing number.

(3) A copy of the memorandum in Form MD-30 and a specimen impression of the seal used to seal the packet shall be separately sent by registered post to the Director of central medical device testing laboratory.

(4) After test or evaluation, the result of the test or evaluation shall be sent forthwith to the sender in Form MD-31.

68. Procedure to be adopted by medical device testing officer on receipt of sample.—(1) On receipt of the sealed package of medical device or portion thereof, from a Medical Device Officer or any other person for test or evaluation, the Medical Device Testing Officer shall compare the seals on the packet or on portion thereof with the specimen impression received separately and shall note the condition of the seals on the packet or on portion thereof.

(2) After completion of test or evaluation, the Medical Device Testing Officer shall forthwith furnish a report to the Medical Device Officer in triplicate in Form MD-32 of the result of the test or evaluation along with full protocols of the test or evaluation applied.

69. Application for test or evaluation of medical device.—For the purpose of these rules, an application from a purchaser for test or evaluation of a medical device or portion of medical device under section 26 of the Act shall be made in Form MD-33 and the report of such test or evaluation of the medical device which is prepared on such application shall be supplied to the applicant in Form MD-32.

70. Duties of Medical Device Officer.—Subject to the instructions of the Central Licensing Authority or State Licensing Authority, as the case may be, it shall be the duty of Medical Device Officer to,—

(i) Inspect, not less than once in a year, all manufacturing sites licenced by the Central Licensing Authority or State Licensing Authority, as the case may be, within the area assigned to him;

(ii) conform that the conditions of licence are being observed;

(iii) take samples of medical device manufactured or imported for sale, or stocked or exhibited for sale in respect of which the Medical Device Officer has reason to suspect contravention of the provisions of the Act or these rules and send them for test or evaluation:

Provided that in case of large sized medical device, wherein the opinion of the Medical Device Officer drawing samples of such a device may not be physically practical, such large sized medical device shall be inspected at the place where these are kept by the Medical Device Officer with or without expert and evaluated or tested by the Medical Device Testing Officer, for any suspect contravention, after approval of the Central Licensing Authority or the State Licensing Authority, as the case may be;

(iv) maintain a record of all inspections undertaken, drawing of samples, seizure of stocks and action taken by Medical Device Officer in exercise and performance of duties and to furnish copies of such record to the Central Licensing Authority or the State Licensing Authority, as the case may be;

(v) make such enquiries and inspections as may be necessary to detect the manufacture or sale of medical device in contravention of any provision of the Act and these rules;

(vi) investigate any complaint made in writing relating to medical device to the Medical Device Officer or any other senior officer in accordance with the direction of the controlling officer;

(vii) institute prosecution in relation to contravention of the provisions of the Act and these rules;

(viii) review technical dossier of medical device furnished with the application under these rules or any other duties assigned by the Central Licensing Authority or State Licensing Authority, as the case may be, related to these rules.

71. Prohibition of disclosure of information.—Except for the purpose of official business or when required by a Court, a Medical Device Officer or Medical Device Testing Officer shall not, without the previous sanction, in writing, of his official superior, disclose to any person any information acquired while exercising such official duties.

72. Form of order not to dispose of stock.—An order in writing by a Medical Device Officer under clause (c) of sub-section (1) of section 22 of the Act requiring a person not to dispose of any stock in his possession shall be in Form MD-34.

73. Prohibition of sale.—No person in possession of a medical device in respect of which a Medical Device Officer has made an order under clause (c) of sub-section (1) of section 22 of the Act shall, in contravention of that order, sell or otherwise dispose of any stock of such medical device.

74. Form of receipt for seized medical devices, record, register, documents or any other material objects.—A receipt by a Medical Device Officer for the stock of any medical device or for any record, register, document or any other material object seized under clause (c) or clause (cc) of sub-section (1) of section 22 of the Act shall be in Form MD-35.

75. Manner of certifying copies of seized documents.—The Medical Device Officer shall return the document, seized under section 22 of the Act, within a period of twenty days from the date of such seizure, to the person from whom they were recovered or produced, after copies thereof or extracts therefrom have been signed by the concerned Medical Device Officer and the person from whom they were recovered or produced.

76. Purpose for which samples have been taken.—When a Medical Device Officer takes a sample of a medical device other than medical device specified in proviso to clause (iii) of rule 70 for the purpose of test or evaluation, the Medical Device Officer shall inform such purpose in writing in Form MD-36 to the person from whom the sample has been taken and shall tender the fair price thereof under a written acknowledgement.

77. Form of receipt for samples of medical devices where fair price tendered is refused.—Where the fair price tendered under sub-section (1) of section 23 of the Act for sample of medical device or portion thereof taken for the purposes of test or evaluation has been refused by the person from whom such sample has been taken, the Medical Device Officer shall tender a receipt thereof to such person in Form MD-37.

78. Procedure for dispatch of sample to medical device testing officer.—(1) The sample of medical device or portion thereof sent by the Medical Device Officer to the Medical Device Testing Officer for test or evaluation under sub-section (4) of section 23 of the Act shall be sent by registered post or by courier or by hand in a sealed packet, enclosed with a memorandum in Form MD-38, in an outer cover addressed to the Medical Device Testing Officer.

(2) A copy of the memorandum and a specimen impression of the seal used to seal the packet shall be sent to the Medical Device Testing Officer separately by registered post or handed over by hand and a copy of the memorandum shall be endorsed to the manufacturer.

79. Confiscation of medical devices, implements, machinery, etc.—(1) Where any person has been convicted for contravening any provisions of the Act or any these rules, the stock of medical device in respect of which the contravention has been made, shall be liable to confiscation.

(2) Where any person has been convicted for manufacturing any medical device which is misbranded, adulterated or spurious for sale, stocking or exhibiting for sale or distribution without a valid licence, any implements or machinery used in such manufacture, sale or distribution and any receptable, package or covering in which such medical device is contained and the animals, vehicles, vessels or other conveyances used in carrying such medical device shall be liable to confiscation.

80. Procedure for disposal of confiscated medical device.—(1) The Court may refer the confiscated medical device to the Medical Device Officer concerned for report as to whether they are of standard quality or contravene the provisions of the Act or the rules in any respect.

(2) If the Medical Device Officer, on the basis of Medical Device Testing Officer's report, finds the confiscated medical device to be not of standard quality or to contravene any of the provisions of the Act or rules made thereunder, the Medical Device Officer shall, with the approval of the Central Licensing Authority or State Licensing Authority, as the case may be, report to the Court accordingly and the Court shall thereupon order destruction of such medical devices, which shall take place under the supervision of the Medical Device Officer in the presence of such authority, if any, as may be directed by the Court:

Provided that the convicted person shall be liable to bear the cost of destruction of seized articles.

(3) If the Medical Device Officer finds that the confiscated medical devices are of standard quality and do not contravene the provisions of the Act or the rules made thereunder, the Medical Device Officer shall, after keeping the Central Licensing Authority or the State Licensing Authority, as the case may be, informed, report to the Court accordingly.

(4) The Court may return the confiscated devices to the rightful owner, and in case, the ownership is not established, the same may be given to a hospital or a dispensary maintained or supported by the Government or to a charitable institution.

CHAPTER X
REGISTRATION OF LABORATORY FOR CARRYING OUT TEST OR EVALUATION

81. Application for registration of medical device testing laboratory.—(1) An application for grant of registration of a medical device testing laboratory to carry out testing or evaluation of a medical device on behalf of a manufacturer shall be made to the Central Licensing Authority through online portal of the Central Government in Form MD-39 accompanied with a fee as specified in the Second Schedule along with the information specified in sub-rule (2).

(2) The application made under sub-rule (1) shall be accompanied with the following information, namely:-

(i) constitution of the medical device testing laboratory;

(ii) premises showing location and area of the different sections;

(iii) qualification, experience of technical staff employed for testing and the person in-charge of testing;
(iv) list of equipment; and
(v) valid accreditation certificate issued by the National Accreditation Body for Testing and Calibration Laboratories or any other similar body as may be notified by the Central Government.

82. Conditions for registration of medical device testing laboratory.—The following conditions shall be complied with by the applicant before grant of registration, namely,-
(i) the premises where the test or evaluation shall be carried out shall be well lighted and properly ventilated except where the nature of tests of any medical device warrants otherwise, and wherever necessary, the premises shall be air conditioned so as to maintain the accuracy and functioning of laboratory instruments or to enable the performance of special tests such as sterility tests, microbiological tests, etc;
(ii) the applicant shall provide adequate space having regard to the nature and number of samples of medical devices proposed to be tested and evaluated:

Provided that the approving authority shall determine from time to time whether the space provided continues to be adequate;

(iii) if it is intended to carry out tests requiring the use of animals, the applicant shall provide for an animal house and comply with the following requirements:-

(a) the animal house shall be adequate in area, well lighted and properly ventilated and the animals undergoing tests shall be kept in air conditioned area;

(b) the animals shall be suitably housed in hygienic surroundings and necessary provisions made for removal of excreta and foul smell;
(c) the applicant shall provide for suitable arrangements for preparation of animal feed;
(d) the applicant shall provide for suitable arrangements for quarantining of all animals immediately on their arrival in the institution;
(e) the animals shall be periodically examined for their physical fitness;
(f) the applicant shall provide for isolation of sick animals as well as animals under test;
(g) the applicant shall ensure compliance with the requirements of the Prevention of Cruelty to Animals Act, 1960 (59 of 1960);
(h) the applicant shall make proper arrangements for disposal of the carcasses of animals in a manner as not to cause hazard to public health.

83. Registration of medical device testing laboratory.—(1) Before grant of registration to any medical device testing laboratory by the Central Licensing Authority, the premises shall be inspected by the Medical Device Officer appointed by the Central Government with or without an expert in the concerned field for adequacy and suitability.
(2) The Medical Device Officer, after completion of the inspection, shall forward a detailed descriptive report giving findings on each aspect of inspection along with recommendations to the Central Licensing Authority with a copy to the applicant.
(3) If on receipt of the application and the report referred to in sub-rule (2), the Central Licensing Authority, is satisfied that the applicant is in a position to fulfill the requirements laid down in these rules, the Central Licencing Authority may grant registration in Form MD-40 or if not satisfied, may, reject the application, for reasons to be recorded in writing, within a period of forty five days from the date of application.
(4) The applicant shall provide and maintain suitable equipment having regard to the nature and number of samples of medical devices intended to be tested which shall be adequate in the opinion of the Central Licensing Authority.
(5) The testing and evaluation of medical devices shall be under active direction of a person whose qualification and experience is considered adequate and who shall be held responsible for reports of test or evaluation issued.
(6) The applicant shall provide standards recognised under the provisions of the Act and these rules and such standards of reference as may be required in connection with the testing or evaluation of the devices for the testing of which approval has been applied for.

84. Validity of registration.—A registration granted under sub-rule (3) of rule 83 in Form MD-40, shall remain valid in perpetuity, unless, it is suspended or cancelled, provided the registration holder deposits a registration retention fee to the Central Licensing Authority as specified in the Second Schedule after completion of every five years from the date of its issue:

Provided, that the Central Licensing Authority may permit to deposit the registration retention fee after due date but before the expiry of six months with a late fee at the rate of two per cent. per mensem or part thereof:

Provided further that, if the registration holder fails to deposit the registration retention fee within the above stipulated period, the registration shall be deemed to have been cancelled for all purposes.

85. Conditions of registration.—A registration granted under sub-rule (3) of rule 83 in Form MD-40~~,~~ shall be subject to the following conditions, namely:—
(i) the registration certificate shall be kept on the approved premises and shall be produced at the request of the medical device officer;

(ii) the person holding registration certificate shall provide and maintain necessary qualified staff, adequate premises and equipment;
(iii) the person holding registration certificate shall provide proper facilities for storage so as to preserve the properties of samples picked up for testing;
(iv) the person holding registration certificate shall maintain records of tests for evaluation and performance carried out on all samples of medical devices and the results thereof together with protocols of tests and the reports showing readings and calculations and such records shall be retained, in case of substances for which an expiry date is assigned, for a period of two years beyond the expiry date, and in the case of other substances, for a period of six years;
(v) the person holding registration certificate shall allow the medical device officer appointed under this Act to enter, with or without prior notice, the premises where the testing is carried out and to inspect the premises and the equipment used for test and the testing procedures employed.
(vi) The person holding registration certificate shall allow the medical device officer to inspect records maintained and shall make available such information as may be required for ascertaining whether the provisions of the Act and these rules have been complied with;
(vii) the registration holder shall inform forthwith, any change of existing expert staff or person-in-charge of the testing or evaluation to the Central Licensing Authority for its approval;
(viii) in case, any sample of a medical device is found on test, to be not of standard quality, the person in-charge of the registered medical device testing laboratory shall furnish a copy of the test or evaluation report on the sample with the protocols of tests applied to the Central Licensing Authority;
(ix) the person holding registration certificate shall maintain an inspection book to enable the Medical Device Officer to record non-compliance with the provisions of the Act and these rules;
(x) the registered medical device testing laboratory shall inform to the Central Licensing Authority in writing in the event of any change in its constitution and where such change in the constitution takes place, the current registration shall be deemed to be valid for a maximum period of ninety days from the date on which the change took place unless, in the meantime, a fresh approval has been taken from the Central Licensing Authority with the changed constitution;

86. Suspension and cancellation of registration.—(1) Where any registered medical device testing laboratory fails to comply with any of the conditions of approval, or any provisions of the Act and these rules, the Central Licensing Authority, may issue a show cause notice for suspension or cancellation of the registration of the said medical device testing laboratory.
(2) On receipt of the show cause notice under sub-rule (1), the registered medical device testing laboratory shall, furnish its reply in writing, within fifteen days of the receipt of such show cause notice.
(3) After considering the reply of the registered medical device testing laboratory furnished under sub-rule (2), the Central Licensing Authority may pass an order in writing for suspension or cancellation of the registration of the said medical device testing laboratory registered under sub-rule (3) of rule 83.
(4) While passing orders under sub-rule (3), the Central Licensing Authority may suspend or cancel the registration wholly or partly in respect of medical device and its variant for testing for such period as may be specified in the order.
(5) An applicant, who is aggrieved by an order of suspension or cancellation of registration under sub-rule (3), may file an appeal within thirty days from the date of receipt of such order before the Central Government, which may, after such enquiry and after giving an opportunity of being heard, dispose of the appeal within a period of sixty days.

CHAPTER XI
SALE OF MEDICAL DEVICES

87. Provisions for sale of medical devices.—(1) Subject to the provisions of these rules, Part VI relating to "Sale of Drugs Other than Homeopathic Medicines" of the Drugs and Cosmetics Rules, 1945, shall be applicable *mutatis mutandis* in respect of sale of medical devices.
(2) The licence granted or renewed under Part VI of the Drugs and Cosmetics Rules, 1945 for sale of drugs, prior to commencement of these rules, shall be deemed to continue to be valid for the purpose of sale of medical devices.

88. Supply of medical device to hospitals against delivery challan.—(1) Notwithstanding anything contained in the Drugs and Cosmetics Rules, 1945, any person having a valid licence to sell, stock, exhibit or offer for sale or distribute by retail or wholesale, may, supply invasive medical devices to be implanted through surgical intervention to a hospital for its patient against a delivery challan:

Provided that in respect of supplies made against delivery challan of such medical devices, the licencee shall ensure that specified storage conditions are met.

(2) A cash or credit memo shall be generated for such medical devices supplied under sub-rule (1), used in the surgical intervention and record of the same shall be maintained by the licencee as per condition of licence.

89. Recall of medical device.—(1) If a manufacturer or authorised agent, as the case may be, considers or has reasons to believe that a medical device, which has been imported, manufactured, sold or distributed, is likely to pose risk to the health of a user or patient during its use and therefore may be unsafe, such manufacturer or authorised agent shall immediately initiate procedures to withdraw the medical device in question from the market and patients, indicating reasons for its withdrawal and inform the competent authority the details thereof.

(2) A manufacturer or authorised agent, as the case may be, shall immediately inform the competent authority and co-operate with them, if there are reasons to believe that a medical device which has been placed in the market, may be unsafe for the patients.

(3) The manufacturer or importer or authorised agent, as the case may be, shall inform the competent authority of the action taken to prevent risk to the patient and shall not prevent or discourage any person from cooperating, in accordance with the provisions of the Act and these rules, with the competent authorities, where this may prevent, reduce or eliminate a risk arising due to use of such medical device.

CHAPTER XII
MISCELLANEOUS

90. Exemption from provisions related to medical devices.—(1) The medical devices specified in the Eighth Schedule shall be exempt from the provisions of these rules to the extent and subject to the conditions specified in that Schedule.

(2) The Central Government may, by notification, from time to time, amend or modify the entries in the Eighth Schedule.

91. Export of medical devices.—Where a person intends to export any medical device, manufactured in India, and for that purpose, requests a certificate in the nature of free sale certificate or a certificate about quality, safety and performance in relation to that medical device as required by the authority concerned of the importing country, such person, may apply to the Central Licensing Authority for the purpose along with a fee as specified in the Second Schedule and the said authority shall, if the requirements are fulfilled, issue a certificate to the applicant.

92. Rejection of application.—If any document submitted by an applicant for grant of licence for import or manufacture or test licence or permit for personal use or permission to import or manufacture investigational medical device or new *in vitro* diagnostic medical device or permission to conduct of clinical investigation or clinical performance evaluation is found to be misleading, or fake, or fabricated, the application, after giving an opportunity to the applicant of being heard, shall be summarily rejected.

93. Debarment of applicant.—(1) Whoever himself or, any other person on his behalf, or applicant is found to be guilty of submitting misleading, or fake, or fabricated documents, may, after giving him an opportunity to show cause as to why such an order should not be made, in writing, stating the reasons thereof, be debarred by the Central Licensing Authority or the State Licensing Authority, as the case may be, for such period as it may deem proper.

(2) Where an applicant is aggrieved by an order made by the Central Licensing Authority or the State Licensing Authority, as the case may be, under sub-rule (1), such applicant may, within thirty days of the receipt of the order, make an appeal to the Central Government or the State Government, as the case may be, and that Government may, after such enquiry as it considers necessary, and after affording an opportunity of being heard, make such order as it may deem proper.

94. Mode of payment of fee.—(1) The fees prescribed under these rules, in case of application made to the Central Licensing Authority, shall be paid through challan or by electronic mode, in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110001 or any other branch of Bank of Baroda, or any other bank, notified by the Ministry of Health and Family Welfare in the Central Government, to be credited under the Head of Account "0210- Medical and Public Health, 04-Public Health, 104-Fees and Fines.

(2) Where the fee specified is payable to the State Licensing Authority, the same shall be paid through a challan or by electronic mode as may be specified by the State Government concerned.

95. Digitalisation of form.—The Forms prescribed under these rules may be suitably modified for conversion into digital forms by the Central Drugs Standard Control Organization and such modification shall not require any amendment in these rules.

96. Overriding effect.—The provisions of these rules shall have effect, notwithstanding anything inconsistent therewith contained in the Drugs and Cosmetics Rules, 1945.

97. Savings.—Notwithstanding the non-applicability of the Drugs and Cosmetics Rules 1945, for the substances and devices referred to in rule 2,-

(i) the licence or registration certificate, issued under the provisions of the Act and the Drugs and Cosmetics Rules, 1945, prior to commencement of these rules, shall be deemed to be valid till its expiry or for a period of eighteen months from the date these rules are notified, whichever is later, under the corresponding provisions of these rules;

(ii) new drug approval, or things done or any action taken or purported to have been done or taken, including any rule, notification, inspection, order or notice made or issued or any appointment or declaration made or any operation undertaken or any direction given or any proceedings taken or any penalty, punishment, forfeiture or fine imposed under the Drugs and Cosmetics Rules, 1945 shall, be deemed to have been done or taken under the corresponding provisions of these rules and shall always remain valid for all purposes.

First Schedule

[See rule 4]

Parameters for classification of medical devices and *in vitro* diagnostic medical devices

Part I

Parameters for classification of medical devices other than *in vitro* diagnostic medical devices Basic Principles for classification.

(i) Application of the classification provisions shall be governed by the intended purpose of the device.

(ii) 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.

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

(iv) 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.

(v) 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.

1. Parameters for classification of medical devices.

(i) 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.

(ii) 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.

(iii) 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.

(iv) 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.

(v) 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,-

(1) it is intended for transient use; and

(2) it is not intended to be connected to an active medical device; or

(3) 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,-

(1) it is intended for use on the external surface of an eyeball; or

(2) it is liable to be absorbed by the mucous membrane.

(vi) 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,-

(1) it is intended for short term use; and

(2) it is not intended to be connected to an active medical device; or

(3) 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,-

(1) 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

(2) it is not liable to be absorbed by the mucous membrane.

(vii) 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,-

(1) 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

(2) it is not liable to be absorbed by the mucous membrane.

(viii) 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.

(ix) 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.

(x) 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.

(xi) 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,-

(1) to be used in direct contact with the heart, the central circulatory system or the central nervous system;

(2) to be life supporting or life sustaining;

(3) to be an active medical device;

(4) to be wholly or mainly absorbed by the human body;

(5) for the administration of any medicinal product; or

(6) 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.

(xii) 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.

(xiii) 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,-

(1) to be used to supply energy which will be absorbed by the human body;

(2) to be used to capture any image of the *in vivo* distribution of radiopharmaceuticals; or

(3) 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,-

(1) 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

(2) 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,

(1) the nature of the medicinal product, body liquid or substance;

(2) the part of the body concerned; and

(3) the mode and route of the administration or removal.

(xiv) 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.

(xv) 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,-

(1) if used separately, may be considered to be a medicinal product; and

(2) 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 thereunder.

(xvi) 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,-

(1) 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

(2) 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.

(xvii) 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,-

(1) the sterilization of any other medical device;

(2) the end-point disinfection of any other medical device; or

(3) 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.

(xviii) 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.

Part II

Parameters for 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 2.

(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,-

(1) test results that are not for the determination of a medically-critical status; or

(2) 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:

(1) 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;

(2) an instrument intended specifically to be used for an *in vitro* diagnostic procedure; or

(3) 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.

Second Schedule

[See rules 13(5), 13(7), 20(2), 21(2), 25(3), 29(1), 31(1), 34(2), 34(4), 35(2), 37, 40(2), 42(1), 51(2), 59(2), 63(1), 64(1), 81(1), 84, 91]

Fee payable for licence, permission and registration certificate

Sr. No.	Rule	Subject	In rupees (INR) except where specified in dollars ($)
(1)	(2)	(3)	(4)
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; or	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

Third Schedule

[See rules 13(5), 13(9), 14, 15, 20(4), 20(6)]

Documents required for registration of Notified Body, its duties and functions.

Part I

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.

Part II

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.

3. Procedure for audit:

The notified body shall carry out the audit in the following manner,-

(i) technical review of respective documents as prescribed in the Fourth Schedule;

(ii) on-site audit of the manufacturer's quality management system to establish conformity by examination of objective evidence, and that of sub-contractor wherever applicable, the requirements of the Fifth Schedule;

(iii) establish conformity by examination and provision of objective evidences to the essential principles laid down by the Central Government from time to time. ;

(iv) establish design conformity by review of the design documents during assessment of medical device to ensure its quality, safety, and performance;

(v) record post approval changes, if any;

(vi) assess conformity to the product and process standards as per provisions of these rules;

(vii) inform the manufacturer about the observed noncompliances during audit, if any, and provide a copy of the audit report to the manufacturer;

(viii) when any major non-compliance is observed during audit by the notified body which may affect quality of the device, it may provide reasonable time to rectify the non-compliance followed by compliance verification of the manufacturing site;

(ix) The Notified Body, after assessment and verification, shall submit detailed report giving its findings on each aspect of audit along with its recommendations after completion of audit to the State Licensing Authority and a copy of the same to the manufacturer.

Fourth Schedule

[See rule 20(2), 21(2), 34(2), 34(4), 63(1) and 64(1)]

Documents required for grant of licence to manufacture for sale or for distribution or import

Part I

Power of Attorney

(To be authenticated in India either by a Magistrate of First Class or by Indian Embassy in the country of origin or by an equivalent authority through apostille**)**

Power of Attorney to accompany an application for issuance of import licence

I ……...… working as …… authorised to sign this Power of Attorney, on behalf of M/s …… (full address/ telephone no., e-mail) having manufacturing site at ……. (full address, telephone no., e-mail), hereby delegate Power of Attorney to M/s……..……., (full address, as per wholesale licence or manufacturing licence, with telephone, fax and e-mail address**),** hereinafter to be known as authorised agent, intends to apply for import licence under the provisions of these rules, to import into India for the following medical devices manufactured at below manufacturing site.

Sr. No.	Name & address of foreign manufacturer (full address with telephone, fax and e-mail address)	Name & address of manufacturing site (full address with telephone, fax and e-mail address of the manufacturing site)

Following are the details of medical device proposed to be imported (A separate list may be annexed, if required in below given format).

S. No.	Generic name	Brand Name (if any)	Model No. (if any)	Dimension	Intended use	Shelf life	Sterile or Non sterile	Class of medical device

(2) Our Authorised agent shall,-

(a) act as the official representative for obtaining import licence in India.

(b) submit all necessary documents, as defined in the Fourth Schedule, for the import licence of medical device.

(3) I shall comply with all the conditions imposed on the import licence and with provisions of the Medical Devices Rules, 2017.

(4) I declare that M/s …….. is carrying on the manufacture of the listed medical device at the manufacturing site specified above.

(5) I shall allow the Central Licensing Authority or any person authorized by it in that behalf to enter and inspect or audit the manufacturing premise and to examine the process, procedure and documents in respect of any manufacturing site or to take sample of listed medical device for which the application for import licence has been made.

(6) In case of any violation of Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017, the authorised agent shall continue to be responsible even after withdraw of this Power of Attorney for the devices imported in India.

(7) I do hereby state and declare that all the photocopies or scanned copies in the application are true copies of the original documents.

(8) I do hereby state and declare that all the documents submitted by the undersigned are true and correct.

Place:
Date:

Signature of the manufacturer
(Name and Designation)
Seal/Stamp

Undertaking from the authorised agent

I ……..…., age…….., working as …… at M/s …… (Full address/ telephone no., e-mail) agrees to act upon the Power of Attorney as the authorized agent on behalf of M/s …… (Full address/ telephone no., e-mail) having manufacturing site at ……. (Full address, telephone no., e-mail).

Place:
Date:

Signature of the authorised agent
(Name and Designation)
Seal/Stamp

Part II

(i) Documents to be submitted with the application for grant of Import Licence or licence to manufacture for sale or for distribution of a Class A medical device,-

(a) The applicant shall submit documents as specified in the Table below.-

S.N.	For medical devices other than *in vitro* diagnostic medical device	For *in vitro* diagnostic medical device
1.	device description, intended use of the device, specification including variants and accessories;	device description, intended use of the device, specification including variants and accessories;
2.	material of construction;	a summary of analytical technology, relevant analytes and test procedure;
3.	working principle and use of a novel technology (if any);	working principle and use of a novel technology (if any);

4.	labels, package inserts (IFU, etc.,), user manual, wherever applicable,	labels and package inserts (IFU, etc.,), user manual, wherever applicable;
5.	summary of any reported Serious Adverse Event in India or in any of the countries where device is marketed and action taken by the manufacturer and National Regulatory Authority concerned;	analytical performance summary including sensitivity and specificity;
6.	site or plant master file as specified in Appendix I of this Schedule;	site or plant master file as specified in Appendix I of this Schedule;
7.	constitution details of the firm (of domestic manufacturer or authorised agent);	constitution details of the firm (of domestic manufacturer or authorised agent);
8.	essential principles checklist for demonstrating conformity to the essential principles of safety and performance of the medical device;	essential principles checklist for demonstrating conformity to the essential principles of safety and performance of the *in vitro* medical device;
9.	undertaking signed by the manufacturer stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule*;*	undertaking signed by the manufacturer stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule*;*

(b) In case of application for import licence, the authorised agent shall submit

A. notarized copy of overseas manufacturing site or establishment or plant registration, by whatever name called, in the country of origin issued by the competent authority and Free Sale Certificate issued by the National Regulatory Authority or equivalent competent authority of the country concerned as referred under rule 36.

B. notarised copy of Quality Management System certificate or Full Quality Assurance certificate or Production Quality Assurance certificate issued by the competent authority, in respect of the manufacturing site.

C. self-attested copy of valid whole sale licence or manufacturing licence issued under these rules.

D. copy of latest inspection or audit report carried out by Notified bodies or National Regulatory Authority or Competent Authority within last 3 years, if any.

(ii) Documents to be submitted with the application for grant of licence to manufacture or import Class B, Class C or Class D medical device,-

The domestic manufacturer or authorised agent shall submit the duly signed following information pertaining to Manufacturing site.

(a) Constitution details of domestic manufacturer or authorised agent;

(b) Site or plant master file as specified in Appendix I of this Schedule;

(c) Device master file as specified in Appendix II for medical devices other than *in vitro* diagnostic medical devices, or Appendix III for *in vitro* diagnostic medical devices of this Schedule;

(d) Essential Principles checklist for demonstrating conformity to the Essential Principles of Safety and Performance of the Medical Device including *in vitro* diagnostic medical device;

(e) Test licence obtained for testing and generation of quality control data (for domestic manufacturers only), if any;

(f) Undertaking signed stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule.

(g) Documents as specified in the clause (b) of paragraph (i) of this part.

(h) In case of *in vitro* diagnostic medical devices, a copy of performance evaluation report issued by the central medical device testing laboratory or medical device testing laboratory registered under sub-rule (3) of rule 83.

Part III

Appendix I

Contents of a site or plant master file

The manufacturer shall prepare a succinct document in the form of site 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;

(xi) brief description of testing facility;

2. Personnel:

(i) organisation chart showing the arrangements for key personnel

(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 equipment.

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.

(vi) Brief description of sterilisation facility;

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.

Appendix II

DEVICE MASTER FILE FOR MEDICAL DEVICES OTHER THAN *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

EXECUTIVE SUMMARY:

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

1.1 Introductory descriptive information on the medical device, 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.

1.2 Information regarding sterilization of the device (whether it is sterile or non-sterile; if sterile, mode of sterilization).

1.3 Risk Management Plan, Risk Analysis, evaluation and control documents.

1.4 Clinical Evidence and evaluation (if applicable).

1.5 Regulatory status of the similar device in India (approved or not approved in India).

1.6 Design Examination Certificate, Declaration of Conformity, Mark of Conformity Certificate, Design Certificate (if applicable). Copy of such certificate(s) shall be enclosed.

1.7 Marketing history of the device from the date of introducing the device in the market.

1.8 Domestic price of the device in the currency followed in the country of origin.

1.9 List of regulatory approvals or marketing clearance obtained (submit respective copies of approval Certificates):

Country	Approved Indication	Approved Shelf life	Class of Device	Date of First Approval
USA				
Australia				
Japan				
Canada				
European Union				
Others*				

*Optional

Status of market clearance pending, rejected or withdrawn

Regulatory Agency of the country	Indication for use	Registration status and date	Reason for rejection/ withdrawal, if any

1.10 Safety and performance related information on the device:

(a) Summary of reportable event and field safety corrective action from the date of introduction:-

For Serious Adverse Event:

S.N.	Serious Adverse Event (SAE)	Duration		Number of the SAE reported	Total Units sold	Lot/Batch No.
		From	To			

For Field Safety Corrective Action (FSCA):

Date of FSCA	Reason for FSCA	Countries where FSCA was conducted	Description of the action taken

(b) If the device contains any of the followings, then descriptive information on the following need to be provided.

1. Animal or human cells tissues or derivatives thereof, rendered non-viable (e.g. Porcine Heart Valves).
2. Cells, tissues or derivatives of microbial recombinant origin (e.g. Dermal fillers based on Hyaluronic acid derived from bacterial fermentation process).
3. Irradiating components, ionising or non-ionizing.

2. Device description and product specification, including variants and accessories

2.1 The dossier should contain the following descriptive information for the device:-

(a) A general description including its generic name, model name, model no., materials of construction, intended use, indications, instructions for use, contraindications, warnings, precautions and potential adverse effects;

(b) the intended patient population and medical condition to be diagnosed or treated and other considerations such as patient selection criteria;

(c) principle of operation or mode of action, accompanies by animation or videos (if available);

(d) an explanation of any novel features;

(e) a description of the accessories, other medical device and other product that are not medical device, which are intended to be used in combination with it and it should also be clarified whether these accessories or device are supplied as a system or separate components;

(f) a description or complete list of the various configurations or variants of the device that will be made available;

(g) a general description of the key functional elements, e.g. its parts or components (including software if appropriate), its formulation, its composition, its functionality and where appropriate, this will include: labeled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts or components, including sufficient explanation to understand the drawings and diagrams;

(h) a description of the materials incorporated into key functional elements and those making either direct contact with a human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids. Complete chemical, biological and physical characterization of the material (s) of the medical device;

(i) for medical devices intended to emit ionizing radiation, information on radiation source (e.g. radioisotopes) and the material used for shielding of unintended, stray or scattered radiation from patients, users and other persons shall be provided.

2.2 Product Specification:

The dossier should contain a list of the features, dimensions and performance attributes of the medical device, its variants and accessories, that would typically appear in the product specification made available to the end user, e.g. in brochures, catalogues etc.

2.3 Reference to predicate or previous generations of the device:

Where relevant to demonstrating conformity to the essential principles, and to the provision of general background information, the dossier should contain an overview of:

(a) the manufacturer's previous generation of the device, if such exist;

(b) predicate devices available on the local and international markets; and

(c) comparative analysis to prove substantial equivalence to the predicate device(s) as claimed.

3.0 LABELLING:

The dossier should typically contain a complete set of labeling associated with the device as per the requirements of Chapter VI of these rules. Information on labelling should include the following:-

(a) Copy of original label of the device, including accessories if any, and its packaging configuration;

(b) Instructions for use (Prescriber's manual);
(c) Product brochure; and
(d) Promotional material.

4. DESIGN AND MANUFACTURING INFORMATION:

4.1 Device Design:

The dossier should contain information to allow the reviewer to obtain a general understanding of the design stages applied to the device. The information may take in form of flow chart. Device design validation data should be submitted.

4.2 Manufacturing Processes:

The dossier should contain information to allow the reviewer to obtain a general understanding of the manufacturing processes. The information may take the form of flow chart showing an overview of production, manufacturing environment, facilities and controls used for manufacturing, assembly, any final product testing, labelling and packaging and storage of the finished medical device. If the manufacturing process is carried out at multiple sites, the manufacturing activities at each site should be clearly specified.

5. ESSENTIAL PRINCIPLES CHECKLIST:

(i) The dossier should contain the following:-
  (a) the essential principles;
  (b) whether each essential principle applies to the device and if not, why not;
  (c) the method used to demonstrate conformity with each essential principle that applies;
  (d) a reference for the method employed (e.g., standard); and
  (e) the precise identity of the controlled document that offers evidence of conformity with each method used.

(ii) Methods used to demonstrate conformity may include one or more of the following:
  (a) conformity with standards as referred to in rule 7;
  (b) conformity with an in-house test method;
  (c) the evaluation of pre-clinical and clinical evidence;
  (d) comparison to a similar device already available on the market.

(iii) The essential principles checklist should incorporate a cross-reference to the location of such evidence both within the full technical documentation held by the manufacturer and within the dossier. A template for a checklist is shown in as under:

Essential Principle	Relevant Yes/No	Specification/standard Sub-clause/reference	Complies Yes/No	Document Reference Justification and/or comments

6. Risk analysis and control summary:

The dossier should contain a summary of the risks identified during the risk analysis process and how these risks have been controlled to an acceptable level. This risk analysis should be based on prescribed standards and be part of the manufacturer's risk management plan based on complexity and risk class of the device. The technique used to analyse the risk must be specified, to ensure that it is appropriate for the medical device and risk involved. The risks and benefits associated with the use of the medical device should be described. The risk analysis submitted shall have periodic updation of the risks identified as per risk management plan.

7. Verification and validation of the medical device

7.1 General:

(A) The dossier should contain product verification and validation documentation. The dossier should summarize the results of verification and validation studies undertaken to demonstrate conformity of the device with the essential principles that apply to it. Such information would typically cover wherever applicable:
  (a) engineering tests;
  (b) laboratory tests;
  (c) simulated use testing;
  (d) any animal tests for demonstrating feasibility or proof of concept of the finished device;
  (e) any published literature regarding the device or substantially similar devices.

(B) Such summary information may include:
  (i) declaration or certificate of conformity to a recognised standard and summary of the data if no acceptance criteria are specified in the standard;
  (ii) declaration or certificate of conformity to a published standard that has not been recognised, supported by a rationale for its use, and summary of the data if no acceptance criteria is specified in the standard;

(iii) declaration or certificate of conformity to a professional guideline, industry method, or in-house test method, supported by a rationale for its use, a description of the method used, and summary of the data in sufficient detail to allow assessment of its adequacy;

(iv) a review of published literature regarding the device or substantially similar devices.

(C) In addition, where applicable to the device, the dossier should contain detailed information on:

(a) biocompatibility studies data as per prescribed standards;
(b) medicinal substances incorporated into the device, including compatibility of the device with the medicinal substance;
(c) biological safety of devices incorporating animal or human cells, tissues or their derivatives;
(d) sterilisation;
(e) software verification and validation;
(f) animal studies that provide direct evidence of safety and performance of the device, especially when no clinical investigation of the device was conducted;
(g) clinical evidence.

(D) Detailed information will describe test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions. Where no new testing has been undertaken, the dossier should incorporate a rationale for that decision, e.g. biocompatibility testing on the identical materials was conducted when these were incorporated in a previous, legally marketed version of the device. The rationale may be incorporated into the Essential Principle checklist.

7.2 Biocompatibility:

(i) The dossier should contain a list of all materials in direct or indirect contact with the patient or user.

(ii) Where biocompatibility testing has been undertaken (as per prescribed standards) to characterize the physical, chemical, toxicological and biological response of a material, detailed information should be included on the tests conducted, standards applied, test protocols, the analysis of data and the summary of results. At a minimum, tests should be conducted on samples from the finished, sterilized (when supplied sterile) device.

(iii) Depending on nature and intended use of the investigational medical device, device performance for its actions (including mechanical, electrical, thermal, radiation and any other of this type) and safety should be assessed in healthy or diseased animal model (intended to be treated by such medical device), as appropriate, demonstrating reaction to active and basic parts of the devices on absolute tissue, local tissue as well as whole organ, clearly recording local, general and systemic adverse reactions, risks or potential risks and performance of device in line with intended use. Wherever possible, histopathology, pathophysiology and path anatomy should be carried out.

(iv) ISO-10993, Biological Evaluation of Medical Devices, should be followed for conducting bio-compatibility study for invasive medical devices should be carried out. A report of biocompatibility study along with rationale for selecting specific tests carried out should be prepared including conclusion of the study.

7.3 Medicinal substances:

Where the medical device incorporates a medicinal substance, the dossier should provide detailed information concerning that medicinal substance, its identity and source, the intended reason for its presence, and its safety and performance in the intended application.

7.4 Biological safety:

(i) The dossier should contain a list of all materials of animal or human origin used in the device. For these materials, detailed information should be provided concerning the selection of sources or donors; the harvesting, processing, preservation, testing and handling of tissues, cells and substances of such origin should also be provided. Process validation results should be included to substantiate that manufacturing procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents. Transmissible Spongiform Encephalopathies (TSE) or Bovine Spongiform Encephalopathy (BSE) Certificates should also be submitted.

(ii) The system for record-keeping to allow traceability from sources to the finished device should be fully described.

7.5 Sterilization:

(i) Where the device is supplied sterile, the dossier should contain the detailed information of the initial sterilization validation including sterilizer qualification, bioburden testing, pyrogen testing, testing for sterilant residues (if applicable) and packaging validation as per prescribed standards. Typically, the detailed validation information should include the method used, sterility assurance level attained, standards applied, the sterilization protocol developed in accordance with prescribed standards, and a summary of results.

(ii) Evidence of the ongoing revalidation of the process should also be provided. Typically this would consist of arrangements for, or evidence of, revalidation of the packaging and sterilization processes.

7.6 Software verification and validation:

The dossier should contain information on the software design and development process and evidence of the validation of the software, as used in the finished device. This information should typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.

7.7 Animal studies:

(i) Where studies in an animal model have been undertaken to provide evidence of conformity with the Essential Principles related to functional safety and performance, detailed information should be contained in the dossier.

(ii) The dossier should describe the study objectives, methodology, results, analysis and conclusions and document conformity with Good Laboratory Practices. The rationale (and limitations) of selecting the particular animal model should be discussed.

7.8 Stability data:

If available, real-time aging data shall be submitted to support the claimed shelf life. However, if real-time data is not available, accelerated stability data shall be submitted to support the claimed shelf life. Such a provisional claimed shelf life may be approved provided that the manufacturer immediately initiates real-time stability testing to validate the proposed shelf life. After completion of the real time stability analysis, real-time stability data shall be submitted in support of the claimed shelf life.

7.9 Clinical evidence:

The dossier should contain the clinical evidence that demonstrates conformity of the device with the Essential Principles that apply to it. It needs to address the elements contained in the Clinical Investigation, as specified under the Seventh Schedule. If a predicate device is available, the manufacturer needs to submit the substantial equivalence evaluation along with relevant published literature in accordance with these rules.

7.10 Post Marketing Surveillance data (Vigilance reporting):

The dossier should contain the Post Marketing Surveillance or Vigilance Reporting procedures and data collected by the manufacturer encompassing the details of the complaints received and corrective and Preventive actions taken for the same.

NOTE:

1. All reports submitted as a part of the dossier should be signed and dated by the responsible person.
2. Batch Release Certificates and Certificate of Analysis of finished product for minimum 3 consecutive batches should be submitted.
3. All certificates submitted must be within the validity period.
4. Any information which is not relevant for the subject device may be stated as 'Not Applicable' in the relevant Sections/Columns of the above format, and reasons for non-applicability should be provided.

Appendix III
DEVICE MASTER FILE FOR *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

1. EXECUTIVE SUMMARY:

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

1.1 Introductory descriptive information on the *in vitro* diagnostic medical device, the intended use and risk Class of *in vitro* diagnostic medical device, novel features (if any), claimed shelf life and a synopsis on the content of the dossier.

1.2 Regulatory status of the similar device in India (approved or new in vitro diagnostic medical device).

1.3 Domestic price of the in vitro diagnostic medical device in the currency followed in the country of origin.

1.4 Marketing history of the in vitro diagnostic medical device from the date of introducing the in vitro diagnostic medical device in the market.

1.5 List of regulatory approvals or marketing clearance obtained in below format (submit respective copy of approval certificate).

S.N.	Name of the country	Approved indication	Approved shelf life	Composition	Risk Class	Date of first approval

1.6 Status of pending request for market clearance

Regulatory Agency of the country	Intended use	Indication for use	Registration status and date	Reason for rejection/withdrawal, if any

1.7 Safety and performance related information on the *in vitro* diagnostic medical device:

(a) Summary of reportable events and field safety corrective action from the date of introduction

For adverse event (false diagnosis or any other hazard during its use)

Adverse event (false diagnosis)	Frequency of occurrence during the period (number of report/total units sold)

For Field Safety Corrective Action (FSCA)

Date of FSCA	Reason for FSCA	Countries where FSCA was conducted	Description of the action taken

(b) If the *in vitro* diagnostic medical device contains any of the following then descriptive information on the following need to be provided.

(1) Animal or human fluids or derivatives thereof, rendered non-viable.

(2) Cells, tissues and/or derivatives of microbial recombinant origin.

2. Description and specification, including variants and accessories of the in vitro diagnostic medical device

2.1 Description

The device master file should include the following device descriptive information:

(a) it may include:-

(1) what is detected;

(2) its function (for example screening, monitoring, diagnostic or aid to diagnosis, staging or aid to staging of disease);

(3) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;

(4) whether it is automated or not;

(5) whether it is qualitative or quantitative;

(6) the type of specimen required (eg. serum, plasma, whole blood, tissue biopsy, urine);

(7) testing population;

(b) the intended user (lay person or professional);

(c) a general description of the principle of the assay method;

(d) the risk based Class of the device;

(e) a description of the components (e.g. reagents, assay controls and calibrators) and where appropriate, a description of the reactive ingredients of relevant components (such as antibodies, antigens, nucleic acid primers) where applicable;

(f) a description of the specimen collection and transport materials provided with the *in vitro* diagnostic medical device or descriptions of specifications recommended for use;

(g) for instruments of automated assays; a description of the appropriate assay characteristics or dedicated assays;

(h) for automated assays; a description of the appropriate instrumentation characteristics or dedicated instrumentation;

(i) a description of any software to be used with the *in vitro* diagnostic medical device;

(j) a description or complete list of the various configurations/variants of the *in vitro* diagnostic medical device that will be made available;

(k) a description of the accessories, other *in vitro* diagnostic medical device and other products that are not *in vitro* diagnostic medical device, which are intended to be used in combination with the *in vitro* diagnostic medical device.

Reference to the manufacturer's previous device generation(s) or similar devices or device history.

2.2 For a new *in vitro* diagnostic medical device:

Where relevant to demonstrating conformity to the essential principles, and to provide general background information, the device master file may provide a summary of Clinical Performance Evaluation reports.

2.3 For an in vitro diagnostic medical device already available on the market in India:

(i) This information may include a summary of the number of adverse event reports related to the safety and performance of this *in vitro* diagnostic medical device in relation to the number of *in vitro* diagnostic medical devices placed on the market.

(ii) External certificates and documents which give written evidence of conformity with the essential principles may be annexed to the device master file.

(iii) comparative analysis to prove substantial equivalence to the predicate device(s), if claimed in the application.

3. Essential principles checklist:

(i) The device master file should include an essential principles checklist that identifies:

(a) the essential principles of safety and performance;

(b) whether each essential principle applies to the *in vitro* diagnostic medical device and if not, why not;

(c) the method used to demonstrate conformity with each essential principle that applies; and

(d) the reference to the actual technical documentation that offers evidence of conformity with each method used.

(ii) The method used to demonstrate conformity may include one or more of the following:-

(a) conformity with recognized or other standards;

(b) conformity with a commonly accepted industry test method (reference method);

(c) conformity with appropriate in house test methods that have been validated and verified;

(d) comparison to an *in vitro* diagnostic medical device already available on the market.

(iii) The essential principles checklist should include a cross-reference to the location of such evidence both within the full technical documentation held by the manufacturer and within the Device master file (when such documentation is specifically required for inclusion in the Summary Technical Documentation as outlined in this guidance).

4. Risk analysis and control summary:

The device master file should contain a summary of the risks identified during the risk analysis process and a description of how these risks have been controlled to an acceptable level. Preferably, this risk analysis should be based on recognised standards and be part of the manufacturer's risk management plan.

The summary should address possible hazards for the *in vitro* diagnostic medical device such as the risk from false positive or false negative results, indirect risks which may result from *in vitro* diagnostic medical device-associated hazards, such as instability, which could lead to erroneous results, or from user-related hazards, such as reagents containing infectious agents. The results of the risk analysis should provide a conclusion with evidence that remaining risks are acceptable when compared to the benefits.

5. Design and manufacturing information:

5.1 Device design:

The Device master file should contain information to allow a reviewer to obtain a general understanding of the design applied to the *in vitro* diagnostic medical device.

It should include a description of the critical ingredients of an assay such as antibodies, antigens, enzymes and nucleic acid primers provided or recommended for use with the *in vitro diagnostic* medical device,

This section is not intended to take the place of the more detailed information required for a QMS audit or other conformity assessment activity. If design takes place at multiple sites, a controlling site must be identified.

5.2 Manufacturing processes:

The device master file should contain information to allow a reviewer to obtain a general understanding of the manufacturing processes. It is not intended to take the place of the more detailed information required for a QMS audit or other conformity assessment activity. The information may take the form of a process flow chart

showing, for example, an overview of production including the technologies used, assembly, any in-process and final product testing, and packaging of the finished *in vitro* medical device.

5.3 Manufacturing sites:

The device master file should identify the sites where these activities are performed (this does not include the sites of all suppliers of raw materials but only the sites that are involved in critical manufacturing activities). If Quality Management System certificates, or the equivalent, exist for these sites, they may be annexed to the device master file.

6. Product validation and verification:

The information provided in the product validation and verification section of the device master file will vary in the level of detail as determined by the class of the device. The device master file should summarize the results of validation and verification studies undertaken to demonstrate conformity of the *in vitro* diagnostic medical device with the essential principles that apply to it. Where appropriate, such information might come from literature.

For the purpose of the device master file document, summary and detailed information are defined as follows:

(i) Summary information:

A summary should provide enough to assess the validity of that information by the regulatory authorities. This summary should contain a brief description of:

(a) the study protocol;
(b) the study results;
(c) the study conclusion.

This summary may include:

(a) Where a recognized standard exists, a declaration/certificate of conformity to a recognized standard can be provided with a summary of the data if no acceptance criteria are specified in the standard;
(b) In the absence of a recognized standard, a declaration/certificate of conformity to a published standard that has not been recognized might be provided if it is supported by a rationale for its use, and summary of the data, and a conclusion, if no acceptance criteria are specified in the standard;
(c) In the absence of a recognized standard and non-recognized published standards, a professional guideline, industry method, or in-house standard may be referred to in the summarized information. However, it should be supported by a rationale for its use, a description of the method used, a summary of the data in sufficient detail and a conclusion to allow assessment of its adequacy;
(d) A review of relevant published literature regarding the device/analyte (measurand) or substantially similar *in vitro* diagnostic medical devices.

(ii) Detailed information:

Detailed information should include:

(a) complete study protocol;
(b) method of data analysis;
(c) complete study report;
(d) study conclusion.

For detailed information, when a recognized standard exists that contains the protocol and the method of data analysis, this information can be substituted by a declaration or certificate of conformity to the recognized standard along with a summary of the data and conclusions. where appropriate, actual test result summaries with their acceptance criteria should be provided and not just pass/fail statements.

7. Analytical Studies:

The statements and descriptions in the following sections refer to all *in vitro* diagnostic medical devices. It must be noted however that there are applicability differences between instrumentation and reagent-based assays, and that the assays themselves may be quantitative, semi-quantitative or qualitative in nature. There may be limited applicability of some of the following subsections for qualitative or semi-quantitative assays. Where possible, comments regarding instrumentation or qualitative assays appear in the subsections.

8. Specimen type:

(a) This section should describe the different specimen types that can be used. This should include their stability and storage conditions. Stability includes storage and where applicable transport conditions. Storage includes elements such as duration, temperature limits and freeze/thaw cycles.
(b) This section should include summary information for each matrix and anticoagulant when applicable, including a description of the measurement procedure for comparison or determination of measurement accuracy. This

includes information such as specimen type tested, number of samples, sample range (using spiked samples as appropriate) or target concentrations tested, calculations and statistical methods, results and conclusions.

9. Analytical performance characteristics.

9.1 Accuracy of measurement:

This section should describe both trueness and precision studies.

Explanation.- The general term measurement accuracy is currently used to cover both trueness and precision, whereas this term was used in the past to cover only the one component now named trueness.

While measurement trueness, affected by systematic error, is normally expressed in terms of bias, measurement precision, affected by random error, is naturally expressed in terms of standard deviation,

Accuracy is affected by a combination of systematic and random effects that contribute as individual components of the total error of measurement.

9.2 Reproducibility:

This section should include reproducibility estimates and information about the studies used to estimate, as appropriate, variability between days, runs, sites, lots, operators and instruments. Such variability is also known as "Intermediate Precision". Reproducibility data is obtained for instrumentation in conjunction with an appropriate assay.

Note 1.- Such studies should include the use of samples that represent the full range of expected analyte (measurand) that can be measured by the test as claimed by the manufacturer.

Note 2.- If a recognized standard is used, a declaration/certificate of conformity to the recognized standard along with a summary of the data and conclusions.

10. Analytical sensitivity:

This section should include information about the study design and results. It should provide a description of specimen type and preparation including matrix, analyte (measurand) levels, and how levels were established. The number of replicates tested at each concentration should also be provided as well as a description of the calculation used to determine assay sensitivity. For example:

(a) Number of standard deviations above the mean value of the sample without analyte (measurand), commonly referred to as limit of blank (LoB).

(b) Lowest concentration distinguishable from zero, based on measurements of samples containing analyte (measurand), commonly referred to as limit of detection (LoD).

(c) Lowest concentration at which precision and/or trueness are within specified criteria, commonly referred to as limit of quantitation (LoQ).

For Class C and D *in vitro* diagnostic medical devices, detailed information would be provided.

11. Analytical specificity:

(i) This section should describe interference and cross reactivity studies to determine the analytical specificity, defined as the ability of a measurement procedure to detect or measure only the analyte (measurand) to be detected, in the presence of other substances/agents in the sample.

(ii) Provide information on the evaluation of potentially interfering and cross reacting substances/agents on the assay. Information should be provided on the substance/agent type and concentration tested, sample type, analyte (measurand) test concentration, and results.

(iii) Interferents and cross reacting substances/agents, which vary greatly depending on the assay type and design, could derive from exogenous or endogenous sources such as:

(a) substances used for patient treatment (e.g. therapeutic drugs, anticoagulants, etc.);
(b) substances ingested by the patient (e.g. over the counter medications, alcohol, vitamins, foods, etc.);
(c) substances added during sample preparation (e.g. preservatives, stabilizers);
(d) substances encountered in specific specimens types (e.g. hemoglobin, lipids, bilirubin, proteins);
(e) analytes of similar structure (e.g. precursors, metabolites) or medical conditions unrelated to the test condition including specimens negative for the assay but positive for a condition that may mimic the test condition (e.g. for a hepatitis A assay: test specimens negative for hepatitis A virus, but positive for hepatitis B virus).

Explanation,- Interference studies involve adding the potential interferent to the sample and determining any bias of the test parameter relative to the control sample to which no interferent has been added.

12. Metrological traceability of calibrator and control material values:

Where applicable, summarize the information about metrological traceability of values assigned to calibrators and trueness control materials. Include, for example, methods and acceptance criteria for the metrological

traceability to reference materials and/or reference measurement procedures and a description of value assignment and validation.

Precision control materials, used when establishing the reproducibility of a measurement procedure do not require the assessment of metrological traceability to a reference material or a reference method.

13. Measuring range of the assay:

This section should include a summary of studies which define the measuring range (linear and non-linear measuring systems) including the limit of detection and describe information on how these were established. This summary should include a description of specimen type, number of samples, number of replicates, and preparation including information on matrix, analyte (measurand) levels and how levels were established. If applicable, add a description of high dose hook effect and the data supporting the mitigation (e.g. dilution) steps.

14. Definition of Assay Cut-off:

This section should provide a summary of analytical data with a description of the study design including methods for determining the assay cut-off, including:

(a) the population(s) studied (demographics / selection / inclusion and exclusion criteria / number of individuals included);

(b) method or mode of characterization of specimens; and

(c) Statistical methods e.g. Receiver Operator Characteristic (ROC) to generate results and if applicable, define gray-zone/equivocal zone.

15. Stability (excluding specimen stability):

This section should describe claimed shelf life, in use stability and shipping studies.

16. Claimed Shelf life:

This section should provide information on stability testing studies to support the claimed shelf life. Testing should be performed on at least three different lots manufactured under conditions that are essentially equivalent to routine production conditions (these lots do not need to be consecutive lots). Accelerated studies or extrapolated data from real time data are acceptable for initial shelf life claim but need to be followed up with real time stability studies. Such detailed information should describe:

(a) the study report (including the protocol, number of lots, acceptance criteria and testing intervals);

(b) when accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies;

(c) conclusions and claimed shelf life.

Explanation,- Shelf life can be derived from the lot with the longest real time stability data as long as accelerated or extrapolated data from all three lots are comparable.

17. In use stability:

This section should provide information on in use stability studies for one lot reflecting actual routine use of the device (real or simulated). This may include open vial stability and/or, for automated instruments, on board stability. In the case of automated instrumentation if calibration stability is claimed, supporting data should be included. Such detailed information should describe:

(a) the study report (including the protocol, acceptance criteria and testing intervals);

(b) conclusions and claimed in use stability.

18. Shipping stability:

This section should provide information on shipping stability studies for one lot to evaluate the tolerance of products to the anticipated shipping conditions. Shipping studies can be done under real and/or simulated conditions and should include variable shipping conditions such as extreme heat or cold. Such information should describe:

(a) the study report (including the protocol, acceptance criteria);

(b) method used for simulated conditions;

(c) conclusion and recommended shipping conditions.

19. Clinical Evidence:

The device master file should contain the Clinical Evidence, Evaluation report that demonstrates conformity of the *in vitro* diagnostic medical device to the Essential Principles that apply to it.

20. Labelling:

The device master file should typically contain a complete set of labeling associated with the *in vitro* medical device as described in Chapter VI.

21. Post marketing surveillance data (vigilance reporting):

The dossier should contain the post marketing surveillance or vigilance reporting procedures and data collected by the manufacturer encompassing the details of the complaints received and corrective and Preventive actions taken for the same.

22. Information required to be submitted for the in vitro diagnostic medical device:

(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 ELISA wells etc. Detailed composition of the *in vitro* diagnostic medical device and manufacturing flow chart process of the *in vitro* diagnostic medical device showing the specific flow diagram of individual components or source of the individual components.

(2) Test protocol of the *in vitro* diagnostic medical device showing the specifications and method of testing. In house evaluation report of sensitivity, specificity and stability studies carried out by the manufacturer.

(3) In case of imported diagnostic *in vitro* diagnostic medical devices, the report of evaluation in details conducted by the National Control Authority of country of origin.

(4) Specimen batch test report for at least consecutive 3 batches showing specification of each testing parameter.

(5) The detailed test report of all the components used/packed in the finished *in vitro* diagnostic medical device.

(6) Pack size and labeling.

(7) Product inserts.

(8) Specific evaluation report, if done by any laboratory in India, showing the sensitivity and specificity of the *in vitro* diagnostic medical device.

(9) 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.

NOTE:

1. All the test reports submitted as a part of the dossier should be signed and dated by the responsible person.
2. Batch Release Certificates and Certificate of Analysis of finished product for minimum 3 consecutive batches should be submitted.
3. All certificates submitted must be within the validity period.
4. Any information which is not relevant for the subject *in vitro* diagnostic medical device may be stated as 'Not Applicable' in the relevant sections/columns of the above format, and reasons for non-applicability should be provided.

Part IV

Information required to be submitted with the Application Form for import or manufacture of medical devices which does not have predicate device.

(a) Data to be submitted along with the application (for medical devices other than new *in vitro* diagnostic):-

1. Design Analysis data including, (whichever applicable)-

(a) design input and design output documents;

(b) mechanical and electrical tests;

(c) reliability tests;

(d) validation of software relating to the function of the device;

(e) any performance tests;

(f) *in vitro* tests.

2. Bio-compatibility tests data, Report of bio-compatibility tests along with rationale for selecting these tests. Summary report of the biocompatibility study including the conclusion of the study.

3. Risk Management data;

4. Animal Performance study data;

5. Pilot or Pivotal Clinical Investigation data, including that carried out in other countries if any;

6. In case, if waiver from clinical investigation is claimed in accordance with the provisions of Medical Device Rules, 2017, the information or supporting data shall be submitted.

7. Regulatory status and Restriction on use in other countries (if any) where marketed or approved;

8. Proposed Instruction for use and labels.

(b) Data to be submitted along with the application (for new *in vitro* diagnostic medical devices):-

1. Device data including, (whichever applicable)-
   (i) design input, design output documents, stability data;
   (ii) device specification including specificity, sensitivity, reproducibility and reputability;
   (iii) product validation and software validation relating to the function of the device (if any);
   (iv) performance evaluation report from a laboratory designated under sub-rule (1) of rule 19.
2. Risk Management data.
3. Clinical Performance Evaluation data carried out in India and in other countries (if any).
4. Regulatory status and Restriction on use in other countries (if any) where marketed or approved.
5. Proposed Instruction for use and labels.

Fifth Schedule

[See rule 20(3), 20(5), 20(8), 22(i)]

Quality Management System for medical devices and *in vitro* diagnostic medical devices

1. General Requirements:

1.1. This schedule 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* diagnostic medical devices. 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 paragraph 7 (product realisation) of this Schedule is not applicable due to the nature of the medical device and *in vitro* diagnostic medical devices 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 medical device, 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 emphasized 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* diagnostic medical devices are encouraged to use appropriate provisions of this schedule as guidance.

2. Applicability:

The provisions of this Schedule shall be applicable to manufacturers of finished devices, *in vitro* diagnostic medical devices, mechanical contraceptives (condoms, intrauterine devices, tubal rings), surgical dressings, surgical bandages, surgical staplers, surgical sutures and ligatures, blood and blood components collection bags with or without anticoagulants.

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 medical devices, to provide supplementary information or to advise what action should be taken in or both in:-

(a) the use of a medical device and *in vitro* diagnostic medical devices;
(b) the modification of a medical device and *in vitro* diagnostic medical devices;
(c) the return of the medical device and *in vitro* diagnostic medical devices to the organization that supplied it; or
(d) the destruction of a medical device and *in vitro* diagnostic medical 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 medical devices that has been placed on the market.

3.5 Implantable medical device. - Medical device intended:-

(a) to be totally or partially introduced into the human or animal body or a natural orifice; or
(b) 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, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled 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 labeling, 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, labeled 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 including substances used for *in vitro* diagnosis referred to in rule 3 of these rules.

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 organizational 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 organisation;

(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 of medical device or *in vitro* diagnostic medical devices, 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* diagnostic medical devices in a form of a Device Master File containing specific information as referred to in Fourth 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 Fourth.

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* diagnostic medical devices 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 medical devices 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* diagnostic medical devices 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 organisation; 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 organisation 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:-

(a) improvements needed to maintain the effectiveness of the quality management system and its processes,
(b) improvement of product related to customer requirements, and
(c) 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. 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- 'A' 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* diagnostic medical devices.

NOTE 1.-If a medical device or *in vitro* diagnostic medical devices 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 labeling and packaging.

The manufacturer shall establish and maintain a record for each batch of medical device or *in vitro* diagnostic medical 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 clause (a) or clause (b) above, the requirements content in clause (a) and (b) of sub-paragraph 6.4 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 medical devices.

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 sterilization process which was used for each sterilization batch. Sterilization 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. Sterilization processes shall be validated prior to initial use. The records of validation of each sterilization 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* diagnostic medical devices 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 records 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 despatched, 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 realization 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 authorising 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 determines that the activities outside the manufacturer's organisation contributed to the customer complaint, relevant information shall be exchanged between the organisations involved.

If any complaint is not investigated, justification shall be documented. Any correction or corrective action resulting from the compliant handling process shall be documented. 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

(a) determining potential nonconformities and their causes,
(b) evaluating the need for action to prevent occurrence of nonconformities,
(c) determining and implementing action needed,
(d) recording of the results of any investigations and of action taken, and
(e) reviewing preventive action taken and its effectiveness.

Annexure 'A'
(refer sub-paragraph 6.4 (b))

Environmental requirement for medical devices and in vitro diagnostic medical devices

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 and Packaging	8
	Laser cutting, Descaling, Annealing and Electro polishing	9
Heart Valves	Valve Packing	5
	Ultrasonic Cleaning and Visual Inspection	7
	Frame and Disc Assembly	7
Intra Ocular Lenses	Primary Packing and Sealing	5
	Final Inspection	7
	Power Checking and Final Cleaning	8
	Tumble Polishing and Lathe Cutting	9
Bone Cements	Final Product Filling	5
	Sieving and Calcinations	7
	Powder Preparation, Granulation and Drying	8
Internal Prosthetic Replacement	Primary Packing	5
	Product Preparation	7
	Component Preparation	8
Orthopaedic Implants	Cleaning and packaging (to be sterilized in factory premises)	7
	Cleaning and packaging (Non Sterile- to be sterilized in Hospital)	8
	Cutting, lathing, and Polishing	9
Catheters /Ablation Device / I V Cannulae / Scalp Vein Set/ Hypodermic Syringes/ Hypodermic Needles / Perfusion Sets	Assembly, Coating, Wrapping and Packing	7
	Component Preparation and 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
	Primary Packing	Air conditioned
Intra Uterine Devices	Moulding	Well ventilated Area with minimum 5 micron filter
	Assembling	7
	Primary Packaging	7
Tubal ring	Extrusion	7
	Cutting and Assembly	7
	Primary Packaging	7
Blood bags	Moulding/Extrusion of components	8
	Assembly	7
	Filing	5
Suture	Extrusion	9
	Assembly	8
	Primary Packing	8
Staplers	Staple formation	9
	Staple assembly	8
	Staple Primary pack	8
Ligatures	Extrusion	9
	Cutting and assembly	8
	Final Primary Packing	8
Surgical dressings	Weaving	9
	Assembly and Gauzing	9
	Final Primary Packing	9
In vitro diagnostic medical devices (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

Sixth Schedule

[See rules 26(iii), 26(iv), 38(v) and 38(vii)]

Post approval change

(A) Changes in respect of following shall be considered as major change in,-

1. material of construction;
2. design which shall affect quality in respect of its specifications, indication for use; performance and stability of the medical device;
3. the intended use or indication for use ;
4. the method of sterilization;
5. the approved Shelf life;
6. the name or address of,-
   (i) the domestic manufacturer or its manufacturing site;
   (ii) overseas manufacturer or its manufacturing site (for import only);
   (iii) authorised agent (for import only);
7. label excluding change in font size, font type, color, label design;
8. manufacturing process, equipment or testing which shall affect quality of the device;
9. primary packaging material.

(B) Changes in respect of following shall be considered as minor change in,-

1. design which shall not affect quality in respect of its specifications, indication for use, performance and stability of the medical device;
2. in the manufacturing process, equipment, or testing which shall not affect quality of the device;
3. packaging specifications excluding primary packaging material.

Seventh Schedule

[See rules 51(1), 51(2), 53(ii), 53(v), 59(3)]

Requirements for permission to import or manufacture investigational medical device for conducting clinical investigation

1. Application for permission.-

(1) an application in Form MD-22 shall be made to the Central Licensing Authority along with following data in accordance with tables, namely:-

(i) Design analysis data as per Table 1.

(ii) Biocompatibility and Animal Performance Study as per Table 2.

(iii) Information specified in Table 3 shall be submitted along with Investigator's Brochure as prescribed in Table 4, Clinical Investigational Plan as prescribed in Table 5, Case Report Form as prescribed in Table 6, Serious adverse event reported, if any, as prescribed in Table 7, Informed Consent Form as prescribed in Table 8, investigator's undertaking as prescribed in Table 9, of this schedule and Ethics Committee approval, if available, as prescribed in Appendix VIII of Schedule Y of the Drugs and Cosmetics Rules, 1945.

(iv) Regulatory status in other countries, including information in respect of restrictions imposed, if any, on use of investigational medical device in other countries, prescription based device, exclusion of certain age groups, warning about adverse device effect. Likewise, if the investigational medical device has been withdrawn in any country by the manufacturer or by regulatory authority, such information shall also be furnished along with reasons and its relevance, if any. This information must continue to be submitted by the sponsor to the Central Licensing Authority during the entire duration of marketing of the said medical device in the Country;

(v) Proposed Instruction for use or direction for use and labels shall be submitted as part of the application. The drafts of label shall comply with provisions of labeling rules specified in Medical Devices Rules, 2017:

Provided that after submission and approval by the Central Licensing Authority, no change in the Instructions for Use shall be effected without such changes having been approved by the Central Licensing Authority;

(vi) Report of clinical investigation should be in consonance with the format as prescribed in Table 10, such reports shall be certified by Principal Investigator.

(2) For investigational medical device developed in India, clinical investigation is required to be carried out in India right from Pilot clinical investigation or first in human study and data generated should be submitted.

(3) For investigational medical devices developed and studied in country other than India, Pilot Clinical Investigation or relevant clinical study data should be submitted along with the application. After submission of such data generated outside India to the Central Licensing Authority, permission may be granted to repeat pilot study or to conduct Pivotal Clinical Investigation. Pivotal Clinical Investigation is required to be conducted in India before permission to market the medical device in India except investigational medical device classified under class A, in exceptional cases, the Central Licensing Authority, may, for reasons to be recorded in writing, if consider it necessary, mandate conduct of clinical investigation, depending on the nature of the medical device.

(4) The number of study subjects and sites to be involved in the conduct of clinical investigation shall depend on the nature and objective of the clinical investigation.

2. CLINICAL INVESTIGATION:

(1) Approval for clinical investigation

(i) Clinical investigation on an investigational medical device shall be initiated only after approval has been obtained from the Ethics Committee(s), registered under rule 122DD of Drugs and Cosmetics Rules, 1945, and

permission granted by Central Licensing Authority. The investigation shall be initiated at the respective sites only after obtaining such approval from the Ethics Committee for that site.

(ii) All investigators should possess appropriate qualification, training and experience and should have access to such investigational and treatment facilities as are relevant to the proposed clinical investigation. A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the investigation, shall be responsible for all investigation related decisions concerning medical or dental issues. Laboratories used for generating data for clinical investigation should be compliant with Good Laboratory Practices or should have accreditation certificate issued by National Accreditation Board for Testing and Calibration Laboratories. In all cases, information about laboratory or facility to be used for the investigation, if other than those at the investigation site, should be furnished to the Central Licensing Authority prior to initiation of investigation at such site.

(iii) Clinical investigational plan amendments, if it becomes necessary, to so amend it, before initiation or during the course of a clinical investigation, shall be notified to the Central Licensing Authority in writing along with approval of the Ethics Committee, if available, which has granted the approval for the study. No deviations from or changes to clinical investigational plan shall be implemented without prior written approval of the Ethics Committee and the Central Licensing Authority except when it is necessary to eliminate immediate hazards to the study subject or when changes involve only logistic or administrative aspects of investigation. All such exceptions shall be immediately notified to the Ethics Committee as well as to the Central Licensing Authority within 30 days.

(2) Responsibilities of Sponsor:

(i) The sponsor is responsible for implementing and maintaining quality assurance system to ensure that the clinical investigation is designed, conducted, monitored, and that data is generated, documented, recorded and reported in compliance with clinical investigational plan and Good Clinical Practices (GCP) Guidelines issued by the Central Drugs Standards Control Organization, Directorate General of Health Services, Government of India and applicable rules.

(ii) The Sponsor is required to submit a status report on Clinical Investigation to the Central Licensing Authority, at the prescribed periodicity including safety summary and deviations.

(iii) Report of any serious adverse event occurring during clinical investigation, after due analysis, shall be forwarded by the sponsor to the Chairman of the Ethics Committee, Central Licensing Authority, and the Head of institution where the clinical investigation has been conducted within 14 calendar days from knowledge of occurrence of the serious adverse event as prescribed in Table 7 of this schedule.

(iv) In case of injury or death occurring to the clinical investigation subject, the sponsor or his representative whosoever, had obtained permission from the Central Licensing Authority for conduct of clinical investigation, shall make payment for medical management of the subject and also provide financial compensation for clinical investigation related injury or death in the manner as specified in the Drugs and Cosmetics Rules, 1945.

(v) The sponsor or his representative, whosoever, had obtained permission from the Central Licensing Authority for conduct of clinical investigation shall submit details of compensation paid for clinical investigation related injury or death to the Central Licensing Authority within thirty days of the receipt of the order from Central Licensing Authority.

(vi) The sponsor shall ensure that the clinical investigation report, whether for a completed or prematurely terminated clinical investigation, is provided to the Ethics Committee, participating investigators and to the Central Licensing Authority.

(vii) In case, an investigation need to be discontinued prematurely for any reason including lack of commercial interest, the sponsor shall need to inform to the Central Licensing Authority and also submit summary report within a period of ninety days having a description of the investigation, the number of patients exposed to the investigational medical device, details of adverse device affect or serious adverse event, compensation paid, if any, and the reason for discontinuation of the investigation or non-pursuit of the investigational medical device application.

(3) Responsibilities of the Investigator:

(i) The investigator shall be responsible for the conduct of the investigation according to clinical investigation plan, GCP guidelines and also for compliance as per the undertaking by the investigator as given in Table 9 of

this schedule. Standard operating procedures are required to be documented by the investigators for the tasks performed by them. During and following a subject's participation in an investigation, the investigator should ensure that adequate medical care is provided to the participant for any adverse events. Investigator shall report all serious adverse events to the Central Licensing Authority, sponsor or his representative, whosoever had obtained permission from the Central Licensing Authority for conduct of the clinical investigation, and the Ethics Committee that accorded approval to the clinical investigation plan, within forty eight hours of their occurrence. In case the Investigator fails to report any serious adverse event within the stipulated period, he shall have to furnish the reason for the delay to the Central Licensing Authority along with the report of the serious adverse event. The detailed report of the serious adverse event, after due analysis, shall be forwarded by the Investigator to Chairman of the Ethics Committee, Central Licensing Authority and the head of the Institution where investigation has been conducted within fourteen calendar days of occurrence of the serious adverse event.

(ii) The Investigator shall provide information to the clinical investigation subject through informed consent process as provided in Table 8 about the essential elements of the clinical investigation and the subject's right to claim compensation in case of investigation related injury or death. He shall also inform the subject or his/ her nominee(s) of their rights to contact the Sponsor or his representative whosoever had obtained permission from the Central Licensing Authority for conduct of the clinical investigation for making claims in case of investigation related injury or death.

(4) Responsibilities of the Ethics Committee:

(i) It is the responsibility of the Ethics Committee that reviews and accords its approval to a Clinical Investigation Plan to safeguard the rights, safety and well-being of all study subjects. The Ethics Committee should exercise particular care to protect the rights, safety and well-being of all vulnerable subjects participating in the study.

Explanation.- The vulnerable subject means the members of a group with hierarchical structure (e.g. prisoners, armed forces personnel, staff and students of medical, nursing and pharmacy institutions), patients with incurable diseases, unemployed or impoverished persons, patients in emergency situation, ethnic minority groups, homeless persons, nomads, refugees, minors or others incapable of personally giving consent. Ethics committee(s) get documented 'standard operating procedures' and should maintain a record of its proceedings.

(ii) Ethics Committee(s) shall, at appropriate intervals, undertake an ongoing review of the investigation of the Clinical Investigation Plan. Such review may be based on periodic study progress reports furnished by investigators or monitoring and internal audit reports furnished by the Sponsor.

(iii) In case, an Ethics Committee revokes sites approval accorded to a Clinical Investigation Plan, it shall record the reasons for doing so and at once, communicate such a decision to the Investigator as well as to the Central Licensing Authority.

(iv) Any report of serious adverse event occurring during clinical investigation, after due analysis, shall be forwarded by the Chairman of Ethics Committee to the Central Licensing Authority and to the Head of institution where the clinical investigation has been conducted within 14 calendar days of the knowledge of occurrence of the serious adverse event.

(5) Informed consent:

(i) In all investigations, a freely given, informed, written consent is required to be obtained from each study subject. The investigator shall provide information about the study verbally and through the patient information sheet, in a language that is non-technical and is understandable by the study subject. The Subject's consent must be obtained in writing using an 'Informed Consent Form'. The patient information sheet as well as the Informed Consent Form shall be approved by the Ethics Committee and furnished to the Central Licensing Authority. Any change in the informed consent documents should be approved by the Ethics Committee and submitted to the Central Licensing Authority before such changes are implemented.

(ii) Where a subject is not able to give informed consent (e.g. an unconscious person or a minor or those suffering from severe mental illness or disability), the same may be obtained from a legally acceptable representative. If the subject or his legally acceptable representative is unable to read or write, an impartial witness should be present during the entire informed consent process who must append his signatures to the consent form.

Explanation: a legally acceptable representative means a person who is able to give consent or authorise an intervention in the patient as provided by the law in India.

(iii) A checklist of essential elements to be included in the study subject's informed consent document as well as a format for the Informed Consent Form for study Subjects is given in Table 8 of this schedule.

(iv) The informed consent process, in case of vulnerable subjects in clinical investigations of an innovative medical device which is not approved anywhere in the world, shall be audio-video recorded.

(6) Pilot Clinical Investigation

(i) Pilot clinical investigation is defined as those clinical investigations which are used to acquire specific essential information about a device before beginning the pivotal clinical investigation. Pilot clinical investigation is exploratory study which may be conducted in a few numbers of patients with the disease or condition being studied before moving to large population and scope that give insight into the performance and safety of a device but cannot provide definitive support for specific mechanistic or therapeutic claims.

(ii) The objectives of a pilot clinical investigation typically include assessing feasibility (e.g, preliminary device performance), exploring eligibility criteria and their practical application for pivotal controlled investigation, ascertaining potential harm (preliminary safety evaluations), studying device mechanism, validating a method for determining an outcome measure, using a defined device mechanism to validate a surrogate outcome measure, and evaluating the logistics of pivotal investigation for performance.

(iii) If the application is for conduct of clinical investigation as a part of multi-national clinical development of medical device, the number of sites and the patients as well as justification to conduct such clinical investigation in India shall be provided to the Central Licensing Authority.

(7) Pivotal Clinical Investigation:

(i) The pivotal clinical investigation is a definitive study in which evidence is gathered to support the safety and effectiveness evaluation of the medical device for its intended use. Pivotal clinical investigation is confirmatory study that may be conducted in large number of patients with disease or condition being studied and scope to provide the effectiveness and adverse effects.

(ii) For investigational medical device which does not have a predicate medical device but has been approved for sale or distribution in any country other than India, pivotal studies need to be carried out primarily to generate evidence of safety and effectiveness of the medical device in Indian patients when used as recommended in the prescribing information except in cases of investigational medical device classified under class A which shall be governed as per permission of para 6 above. Prior to conduct of pivotal clinical investigation in Indian subjects, the Central Licensing Authority may require making the pilot study data available to assess whether the pilot data is in conformity to the data already generated outside the country.

(iii) If the application is for conduct of clinical investigation as part of a Global Clinical Investigation of medical device, the number of sites and patients as well as justification for undertaking such clinical investigation in India shall be provided to the Central Licensing Authority.

(8) Post Marketing Clinical Investigation:

Post marketing clinical investigation is the study other than surveillance performed after marketing approval has been given to the medical device in relation to the approved indication. This investigation may not be considered necessary at the time of medical device approval but may be required by the Central Licensing Authority for optimizing the intended use of the medical device. Post Marketing Clinical investigation includes additional drug-device interaction, safety studies, investigation designed to support use under the approved indication e.g. mortality or morbidity studies, etc,.

(9) Studies in special populations:

The clinical investigation data of the medical device is required to be submitted to support the claim sought to be made for use of medical device in children, pregnant women, nursing women, elderly patients with renal or other organ system failure as given below:

(i) Geriatrics:

Geriatrics patients can be included in pivotal study (and in pilot study at the sponsor's option) in meaningful numbers, if-

(a) the disease intended to be treated is characteristically a disease of aging; or

(b) the population to be treated is known to be included in substantial numbers of geriatric patients; or

(c) there is specific reason to expect that conditions common in the elderly are likely to be encountered; or

(d) the investigational medical device is likely to alter the geriatric patient's response in regard to safety or performance compared with that of non-geriatric patient.

(ii) Paediatrics:

(a) The timing of pediatric studies in the medical device development program shall depend on the device, the type of disease being treated, safety consideration, and the safety and effectiveness of available treatment.

(b) The medical device expected to be used in children; the performance and safety shall be made in the appropriate age group. When clinical investigation is required to be conducted in children, it is usually

appropriate to begin with older children before extending the investigation to younger children and then infants.

(c) If the medical device is predominantly or exclusively used in paediatric patients, clinical investigation data should be generated in paediatric population except for initial safety and performance data, which will usually be obtained in adults unless such initial safety studies in adults would yield little useful information or expose them to inappropriate risk.

(d) If the medical device is intended to treat serious or life-threatening diseases, occurring in both adults and paediatric patients, for which there are currently no or limited therapeutic options, paediatric population may be included in the clinical investigation early, following assessment of initial safety data and reasonable evidence of potential benefit. In circumstances where this is not possible, lack of data has to be justified.

(e) If the medical device has a potential for use in paediatric patient, paediatric studies may be conducted. These studies may be initiated at various stages of clinical development or after post-marketing surveillance in adults, if a safety concern exists. In cases where there is limited paediatric data at the time of submission of application, more data in paediatric patients would be expected after marketing authorization for use in children is granted.

(f) Paediatric subjects are legally unable to provide written informed consent, and are dependent on their parents or legal guardian to assume responsibility for their participation in clinical investigation. Written informed consent shall be obtained from the parent or legal guardian. However, all paediatric participants shall be informed to the fullest extent possible about the study in a language and in terms that they are able to understand. Where appropriate, paediatric participants should additionally assent to enroll in the study. Mature minors and adolescents should personally sign and date a separately designed written consent form. Although a participant's wish to withdraw from a study shall be respected, there may be circumstances in therapeutic studies for serious or life-threatening diseases in which, in the opinion of the investigator and parent or legal guardian, the welfare of a pediatric patient would be jeopardized by his or her failing to participate in the study. In this situation, continued parental or legal guardian consent will be sufficient to allow participation in the study.

(g) For clinical investigations conducted in paediatric population, the reviewing Ethics Committee shall include members who are knowledgeable about pediatric, ethical, clinical and psychosocial issues.

(iii) Pregnant or nursing women:

(a) Pregnant or nursing women shall be included in clinical investigation only when the medical device is intended for use by pregnant or nursing women or fetuses or nursing infants and where the data generated from women who are not pregnant or nursing, would not be suitable.

(b) For medical device intended for use during pregnancy, follow-up data pertaining to a period appropriate for that medical device on the pregnancy, foetus and child will be required.

3. Post Marketing Surveillance:

(i) Subsequent to approval of an Investigational medical device, it shall be closely monitored for their clinical safety once they are marketed. The applicants shall furnish Periodic Safety Update Reports (PSURs) in order to,-

(a) report all the relevant new information from appropriate sources;

(b) relate these data to patient exposure;

(c) summarise the market authorisation status in different countries and any significant variations related to safety; and

(d) indicate whether changes will be made to product information in order to optimize the use of the product.

(ii) One medical device should be covered in one PSUR. Within the single PSUR separate presentation of data for different indications or separate population need to be given.

(iii) All relevant clinical and non-clinical safety data will cover only the period of the report (interval data). The PSURs shall be submitted every six months for the first two years after marketing approval of the medical device. For subsequent two years, the PSURs need to be submitted annually. The Central Licensing Authority may extend the total duration for submission of PSURs if it is considered necessary in the interest of public health. PSURs due for a period must be submitted within thirty calendar days of the last day of the reporting period. However, all cases involving suspected unexpected serious adverse event shall be reported to the licensing authority within fifteen days of initial receipt of information by the applicant. If marketing of the

medical device is delayed by the applicant after obtaining approval to market, such data will have to be provided on the deferred basis beginning from the time the medical device is marketed.

(iv) New studies specifically planned or conducted to examine a safety issue should be described in the PSURs.

(v) A PSUR should be structured as follows:

(a) Title Page:

The title page of PSUR shall capture the name of the Medical device; reporting interval; approved indication of Medical devices; date of approval of the medical device; date of marketing of medical device; licence name and address.

(b) Introduction:

This section of PSUR shall capture the reporting interval; medical device's intended use, mode of action or principle of operation, risk class and a brief description of the approved indication and population.

(c) Current worldwide marketing authorization status:

This section of PSUR shall capture the brief narrative overview including details of countries where the device is currently approved along with date of first approval, date of marketing and if the product was withdrawn in any of the countries with reasons thereof.

(d) Actions taken in reporting interval for safety reasons:

This section of PSUR shall include a description of significant actions related to safety that have been taken during the reporting interval, related to either investigational uses or marketing experience by the licence holder, sponsor of a clinical investigation, regulatory authorities, data monitoring committee, or Ethics Committee.

(e) Changes to reference safety information:

This section of PSUR shall capture any significant changes to the reference safety information within the reporting interval. Such changes will include information relating to contraindications, warnings, precautions, adverse events, and important findings from ongoing and completed clinical investigations and significant non-clinical findings.

(f) Estimated patient exposure:

This section of PSUR shall provide the estimates of the size and nature of the population exposed to the medical device. Brief descriptions of the method used to estimate the subject exposure shall be provided in terms of,-

(i) Cumulative and interval subject exposure in Clinical investigation;

(ii) Cumulative and interval patient exposure from Marketing Experience in India;

(iii) Cumulative and interval patient exposure from Marketing Experience from the rest of the world.

(g) Presentation of individual case histories:

This section of PSUR shall include the individual case information available to a licence holder and provide brief case narrative, medical history indication treated with suspect medical device, causality assessment and provide following information:

(i) Reference prescribing information

(ii) Individual cases received from India

(iii) Individual cases received from rest of the world

(iv) Cumulative and interval summary tabulations of serious adverse events from clinical investigations.

(v) Cumulative and interval summary tabulations from post-marketing data sources

(h) Studies:

This section of PSUR shall capture the brief summary of clinically important emerging efficacy or effectiveness and safety findings obtained from the licence holder sponsored clinical investigation and published safety studies that became available during the reporting interval which has the potential impact the product safety information.

(i) Summaries of Significant Safety Findings from Clinical investigation during the reporting period

(ii) Findings from Non-interventional Studies

(iii) Findings from Non-Clinical Studies

(iv) Findings from Literature

(i) Other information:

This section of PSUR shall include details about signals and Risk Management Plan, if any, put in place by the licence holder.

(a) Signal and risk evaluation: In this section the licence holder shall provide details of signal and risk identified during the reporting period and evaluation of signals identified during the same period.

(b) Risk Management Plan: In this section the licence holder shall provide brief details of safety concerns and necessary action taken by him to mitigate such safety concerns.

(j) Overall Safety Evaluation:

This section of PSUR shall capture the overall safety evaluation of medical device based on its risk benefit evaluation for approved indication.

(i) Summary of Safety Concerns

(ii) Benefit Evaluation

(iii) Benefit Risk Analysis Evaluation

(k) Conclusion:

This section of PSUR shall provide details on the safety profile of medical device and necessary action taken by the licence holder in this regards.

(l) Appendix:

The appendix includes the copy of marketing authorization in India, copy of prescribing information, line listings with narrative of Individual Case Safety Reports (ICSR).

Note: Table means "Table" given below this Schedule.

Table 1

Design Analysis Data

Design Analysis Data for a medical device shall include the following:

(i) Physical and Metrological Standardisation.

(ii) Design control documents and a predefined procedure of the medical device at the time of manufacturing.

The Design Analysis should be carried out in accordance with the Standards as detailed in the Medical Devices Rules, 2017.

A comprehensive report of design analysis including the basic design features of the device, drawings, and tests adapted for design analysis (with specifications) and rationale for selecting those tests and design control procedures shall be prepared.

Table 2

Biocompatibility and Animal Performance Study for investigational medical device

1. Recent version of ISO-10993, Biological Evaluation of Medical Devices shall be followed for conducting bio-compatibility study for invasive medical devices. A report of biocompatibility study along with rationale for selecting specific tests carried out should be prepared including conclusion of the study.

2. Depending on the nature and intended use of investigational medical device, device performance for its actions (including mechanical, electrical, thermal, radiation and any other of this type) and safety shall be assessed in healthy or diseased animal model (intended to be treated by such medical device), as appropriate, demonstrating reaction to active and basic parts of the devices on absolute tissue, local tissue as well as whole organ, clearly recording local, general and systemic adverse reactions, risks or potential risks and performance of device in line with intended use. Wherever possible, histopathology, pathophysiology and path anatomy shall be carried out.

3. If the active component of device is a drug, data for its animal studies as per Schedule Y of the Drugs and Cosmetics Rules, 1945 should be submitted.

Table 3

Information to be submitted along with the application

1. Design Analysis data including, (whichever applicable),-

(a) design input and design output documents;

(b) mechanical and electrical tests;

(c) reliability tests;

(d) validation of software relating to the function of the device;

(e) any performance tests;

(f) *ex vivo* tests.

2. The agreement between the Sponsor and Principal and coordinating investigator(s).
3. Appropriate insurance certificate, if any.
4. Forms for reporting any adverse event and serious adverse event.
5. Report of biocompatibility tests along with rationale for selecting these tests including a summary report and conclusion of the study.
6. Results of the risk analysis.
7. Animal Performance study data
8. Clinical Investigational Plan, Investigator's Brochure as per Table 4, Case Report Form as per Table 6, Informed Consent Form as per Table 8, investigator's undertaking and Ethics Committee clearance.
9. Pilot and Pivotal Clinical Investigation data including that, if any, carried out in other countries.
10. Regulatory status and Restriction on use in other countries, if any, where marketed or approved.
11. Proposed Instructions for use and labels.

Table 4
Investigator's Brochure (IB)

1 General

1.1 Introduction

Information Brochure shall contain, as a minimum, information on all topics listed in this Table.

1.2 Identification of the IB

(a) Name of the investigational medical device.
(b) Document reference number, if any.
(c) Version or date of the IB.
(d) Confidentiality statement, if appropriate.
(e) Summary of the revision history in case of amendments, if appropriate.
(f) A version or issue number and reference number, if any, with page number and the total number of pages on each page of the IB.

1.3 Sponsor or manufacturer

Name and address of the sponsor or manufacturer of the investigational medical device.

2. Investigational medical device information

(a) Summary of literature and evaluation supporting the rationale for the design and intended use of investigational medical device.
(b) Statement concerning regulatory classification of investigational medical device, if relevant.
(c) General description of the investigational medical device and its components including materials used.
(d) Summary of relevant manufacturing processes and related validation processes.
(e) Description of the mechanism of action of investigational medical device, along with supporting scientific literature.
(f) Manufacturer's instructions for installation and use of investigational medical device, including any necessary storage and handling requirements, preparation for use and any intended re-use (e.g. sterilization), any pre-use safety or performance checks and any precautions to be taken after use (e.g. disposal), if relevant.
(g) Description of the intended clinical performance.

3. Preclinical testing

Summary of preclinical testing that has been performed on the investigational medical device, together with an evaluation of results of such testing justifying its use in human subjects.

The summary shall include or, where applicable, refer to the results of:

(a) design input and design output documents,
(b) *in vitro* tests,
(c) mechanical and electrical tests,
(d) reliability tests,
(e) validation of software relating to the function of the device,
(f) any performance tests,
(g) *ex vivo* tests, and
(h) biological safety evaluation.

4. Existing clinical data

(a) Summary of relevant previous clinical experience with the investigational medical device and with medical devices that have similar characteristics, including such characteristics that relate to other indications for use of the investigational medical device.

(b) Analysis of adverse device effects and any history of modification or recall.

5. Risk management

(a) Summary of the risk analysis, including identification of residual risks.

(b) Result of the risk assessment.

(c) Anticipated risks, contra-indications, warnings, etc. for the investigational medical device.

6. Regulatory and other references

(a) List of International Standards, if any, complied with in full or in part.

(b) Statement of conformity with national regulations, where appropriate.

(c) List of references, if relevant.

Table 5
Clinical Investigation Plan

1.1 General

1.1.1 Introduction

This document specifies the content of a clinical investigation plan (herein after to be referred as CIP). If the required information is written in other documentation, for example the IB, such documentation shall be referenced in the CIP. The content of a CIP and any subsequent amendments shall include all the topics listed in this document, together with a justification for each topic if this is not self-explanatory.

1.1.2 Identification of the clinical investigation plan

(a) Title of the clinical investigation.

(b) Reference number identifying the specific clinical investigation, if any.

(c) Version or date of the CIP.

(d) Summary of the revision history in the case of amendments.

(e) Version or issue number and reference number, if any, with the page number and the total number of pages on each page of the CIP.

1.1.3 Sponsor

Name, address and contact details (email id, phone number, etc.) of the sponsor of the clinical investigation.

1.1.4 Principal investigator, coordinating investigator and investigation site

(a) Name, address, and professional position of

(i) Principal Investigator,

(ii) Coordinating investigator, if appointed

(b) Name and address of the investigation site in which the clinical investigation will be conducted.

(c) Name and address of other institutions involved in the clinical investigation.

The sponsor shall maintain an updated list of principal investigators, investigation sites, and institutions.

1.1.5 Overall synopsis of the clinical investigation

A summary or overview of the clinical investigation shall include all the relevant information regarding clinical investigation design such as inclusion or exclusion criteria, number of subjects, duration of clinical investigation, follow-up, objective and endpoint.

1.2 Identification and description of the investigational medical device

(a) Summary description of the investigational medical device and its intended purpose.

(b) Details concerning the manufacturer of the investigational medical device.

(c) Name or number of the model or type, including software version and accessories, if any, to permit full, identification.

(d) Description as to how traceability shall be achieved during and after clinical investigation, for example by assignment of lot numbers, batch numbers or serial numbers.

(e) Intended purpose of the investigational medical device in the proposed clinical investigation.

(f) The populations and indications for which the investigational medical device is intended.
(g) Description of investigational medical device including any materials that will be in contact with tissues or body fluids. (This shall include details of any medicinal products, human or animal tissues or their derivatives, or other biologically active substances.)
(h) Summary of the necessary training and experience needed to use the investigational medical device.
(i) Description of the specific medical or surgical procedures involved in the use of investigational medical device.

1.3 Justification for the design of the clinical investigation

Justification for the design of clinical investigation, which shall be based on conclusions of the evaluation, and shall comprise a section on justification for the design of the clinical investigation and include

(a) an evaluation of the results of the relevant pre-clinical testing or assessment carried out to justify the use of investigational medical device in human subjects; and
(b) an evaluation of clinical data that are relevant to the proposed clinical investigation.

1.4 Risks and benefits of the investigational medical device and clinical investigation

(a) Anticipated clinical benefits.
(b) Anticipated adverse device effects.
(c) Residual risks associated with investigational medical device, as identified in the risk analysis report.
(d) Risks associated with participation in the clinical investigation.
(e) Possible interactions with concomitant medical treatments.
(f) Steps that will be taken to control or mitigate the risks.
(g) Risk-to-benefit rationale.

1.5 Objectives and hypotheses of the clinical investigation

(a) Objectives, primary and secondary.
(b) Hypotheses, primary and secondary, to be accepted or rejected by statistical data from the clinical investigation.
(c) Claims and intended performance of investigational medical device that are to be verified.
(d) Risks and anticipated adverse device effects that are to be assessed.

1.6 Design of the clinical investigation

1.6.1 General

(a) Description of the type of clinical investigation to be performed (e.g. comparative double-blind, parallel design, with or without a comparator group) with rationale for the choice.
(b) Description of the measures to be taken to minimize or avoid bias, including randomization and blinding or masking.
(c) Primary and secondary endpoints, with rationale for their selection and measurement.
(d) Methods and timing for assessing, recording, and analyzing variables.
(e) Equipment to be used for assessing the clinical investigation variables and arrangements for monitoring maintenance and calibration.
(f) Any procedures for replacement of subjects.

1.6.2 Investigational medical device and comparator

(a) Description of the exposure to the investigational medical device or comparator, if used.
(b) Justification of the choice of comparator.
(c) List of any other medical device or medication to be used during clinical investigation.
(d) Number of investigational medical devices to be used, together with a justification.

1.6.3 Subjects

(a) Inclusion criteria for subject selection.
(b) Exclusion criteria for subject selection.
(c) Criteria and procedures for subject withdrawal or discontinuation.
(d) Point of enrolment.
(e) Total expected duration of the clinical investigation.
(f) Expected duration of each subject's participation.

(g) Number of subjects required to be included in clinical investigation.
(h) Estimated time needed to select this number (i.e. enrolment period).

1.6.4 Procedures

(a) Description of all the clinical investigation related procedures that subjects undergo during clinical investigation.
(b) Description of those activities performed by sponsor representatives (excluding monitoring).
(c) Any known or foreseeable factors that may compromise the outcome of clinical investigation or interpretation of results. The follow-up period during clinical investigation shall permit demonstration of performance over a period of time sufficient to represent a realistic test of the performance of the investigational medical device and allow any risks associated with adverse device effects over that period to be identified and assessed.

The Clinical investigation plan shall specifically address what medical care, if any, will be provided to the subjects after the clinical investigation has been completed.

1.6.5 Monitoring plan

General outline of the monitoring plan to be followed, including access to source data and the extent of source data verification planned.

1.7 Statistical considerations

With reference to 1.5 and 1.6, the description of and justification for:-

(a) statistical design, method and analytical procedures;
(b) sample size;
(c) the level of significance and the power of the clinical investigation;
(d) expected drop-out rates;
(e) pass or fail criteria to be applied to the results of the clinical investigation;
(f) the provision for an interim analysis, where applicable;
(g) criteria for the termination of the clinical investigation on statistical grounds;
(h) procedures for reporting any deviation from the original statistical plan;
(i) the specification of subgroups for analysis;
(j) procedures that take into account all the data;
(k) the treatment of missing, unused or spurious data, including drop-outs and withdrawals;
(l) the exclusion of particular information from the testing of the hypothesis, if relevant; and
(m) in multicenter clinical investigations, the minimum and maximum number of subjects to be included for each center.

Special reasoning and sample size(s) may apply for the early clinical investigation(s), e.g. feasibility clinical investigation(s).

1.8 Data management

(a) Procedures used for data review, database cleaning, and issuing and resolving data queries.
(b) Procedures for verification, validation and securing of electronic clinical data systems, if applicable.
(c) Procedures for data retention.
(d) Specified retention period.
(e) Other aspects of clinical quality assurance, as appropriate.

1.9 Amendments to the Clinical investigation plan

Description of the procedures to amend the Clinical investigation plan.

1.10 Deviations from clinical investigation plan

(a) Statement specifying that the investigator is not allowed to deviate from the Clinical investigation plan, except without appropriate notifications or approvals from Ethics Committee and Central Licensing authority, as the case may be.
(b) Procedures for recording, reporting and analyzing Clinical investigation plan deviations.
(c) Notification requirements and time frames.
(d) Corrective and preventive actions and principal investigator disqualification criteria.

1.11 Device accountability.

Description of the procedures for the accountability of investigational medical devices should be maintained.

1.12 Statements of compliance.

(a) Statement specifying that the clinical investigation shall be conducted in accordance with the ethical principles as prescribed in Good Clinical Practices.

(b) Statement specifying that the clinical investigation shall not begin until the required approval from the Ethics Committee.

(c) Statement specifying that any additional requirements imposed by the Ethics Committee or Central Licensing Authority shall be followed, if appropriate.

(d) Statement specifying the type of insurance that shall be provided for subjects, if appropriate.

1.13 Informed consent process.

(a) Description of the general process for obtaining informed consent, including the process for providing subjects with new information, as needed.

(b) Description of the informed consent process in circumstances where the subject is unable to give it; in the case of emergency treatment, process should be clearly specified.

1.14 Adverse events, adverse device effects and device deficiencies.

(a) Definitions of adverse events and adverse device effects.

(b) Definition of device deficiencies.

(c) Definitions of serious adverse events and serious adverse device effects and, where appropriate, unanticipated serious adverse device effects.

(d) Time period in which the principal investigator shall report all adverse events and device deficiencies to the sponsor and, where appropriate, to Ethics Committee and the regulatory authority.

(e) Details of the process for reporting adverse events (date of the adverse event, treatment, resolution, assessment of both the seriousness and the relationship to the investigational medical device).

(f) Details of the process for reporting device deficiencies.

(g) List of foreseeable adverse events and anticipated adverse device effects, together with their likely incidence, mitigation or treatment.

(h) Emergency contact details for reporting serious adverse events and serious adverse device effects.

1.15 Vulnerable population.

(a) Description of the vulnerable population.

(b) Description of the specific informed consent process.

(c) Description of the Ethics Committee specific responsibility.

(d) Description of what medical care, if any, will be provided for subjects after the clinical investigation has been completed.

1.16 Suspension or premature termination of the clinical investigation.

(a) Criteria and arrangements for suspension or premature termination of the whole clinical investigation or of the clinical investigation in one or more investigation sites.

(b) Criteria for access to and breaking the blinding or masking code in case of suspension or premature termination of the clinical investigation, if the clinical investigation involves a blinding or masking technique.

(c) Requirements for subject follow-up.

1.17 Publication policy.

(a) Statement indicating whether the results of the clinical investigation will be submitted for publication.

(b) Statement indicating the conditions under which the results of the clinical investigation will be offered for publication.

Table 6

Case Report Form (CRF)

1. General

(i) Case Report Forms are established to implement the clinical investigation plan, to facilitate subject observation and to record subject and investigational medical device data during the clinical investigation according to the clinical investigation plan. They can exist as printed, optical, or electronic documents and can be organized into a separate section for each subject.

(ii) The Case Report Forms should reflect the clinical investigation plan and take account of the nature of the investigational medical device.

2. Content and format

2.1 Overall considerations

(i) The Case Report Forms can be organized such that they reflect all the data from a single procedure or a single visit or other grouping that makes clinical or chronological sense.

(ii) The format of Case Report Forms shall be such as to minimize errors that can be made by those who enter data and those who transcribe the data into other systems.

(iii) The data categories and format listed in this Table can be considered when designing a Case Report Form.

2.2 Cover page or login screen

(1) Name of sponsor or sponsor logo.

(2) Clinical investigation plan version and date (if required).

(3) Version number of Case Report Forms.

(4) Name of clinical investigation or reference number (if applicable).

2.3 Header or footer or Case Report Form identifier

(a) Name of the clinical investigation or reference number.

(b) Version number of Case Report Forms.

(c) Investigation site/principal investigator identification number.

(d) Subject identification number and additional identification such as date of birth or initials, if allowed by national regulations.

(e) Case Report Form number or date of visit or visit number.

(f) Page/screen number of CRF and total number of pages/screens (e.g. "page *x* of *xx*").

2.4 Types of Case Report Forms

The following is a suggested list of CRFs that may be developed to support a clinical investigation. This is not an exhaustive list and is intended to be used as a guideline.

(a) Screening.

(b) Documentation of subject's informed consent.

(c) Inclusion/exclusion.

(d) Baseline visit:

(1) demographics;

(2) medical diagnosis;

(3) relevant previous medications or procedures;

(4) date of enrolment;

(5) other characteristics.

(e) Intervention(s) or treatment(s).

(f) Follow-up visit(s).

(g) Clinical investigation procedure(s).

(h) Adverse event(s).

(i) Device deficiencies.

(j) Concomitant illness(es)/medication(s).

(k) Unscheduled visit(s).

(l) Subject diary.

(m) Subject withdrawal or lost to follow-up.

(n) Form signifying the end of the clinical investigation, signed by the principal investigator or his/her authorised designee.

(o) CIP deviation(s).

3. Procedural issues

A system shall be established to enable cross-referencing of CRFs and CIP versions.

Supplemental CRFs may be developed for collecting additional data at individual investigation sites in multicenter investigations.

Table 7

Data elements for reporting serious adverse events occurring in a clinical investigation

1. Patient details:
   (a) Initials and other relevant identifier (hospital/Out Patient Department's record number etc.);
   (b) Gender;
   (c) Age and date of birth;
   (d) Weight;
   (e) Height.
2. Suspected device(s):
   (a) Name of the Device;
   (b) Indication(s) for which suspect device was prescribed;
   (c) Device details including model number/size/lot number, if applicable;
   (d) Starting date and time of day;
   (e) Stopping date and time, or duration of treatment;
3. Other treatment(s):
   Provide the same information for concomitant treatment.
4. Details of suspected adverse device reaction(s)
   (a) Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.
   (b) Start date (and time) of onset of reaction.
   (c) Stop date (and time) or duration of reaction.
   (d) Setting (e.g., hospital, out-patient clinic, home, nursing home).
5. Outcome
   (a) Information on recovery and any sequel; results of specific tests and/or treatment that may have been conducted.
   (b) For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.
   (c) Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.
6. Details about the Investigator:
   (a) Name;
   (b) Address;
   (c) Telephone number;
   (d) Profession (specialty);
   (e) Date of reporting the event to Central Licensing Authority;
   (f) Date of reporting the event to Ethics Committee overseeing the site;
   (g) Signature of the Investigator.

Table 8

Informed Consent Form

Checklist for clinical investigation Subject's informed consent documents

1.1 Essential elements:

1. Statement that the study involves research and explanation of the purpose of the research
2. Expected duration of the Subject's participation
3. Description of the procedures to be followed, including all invasive procedures
4. Description of any reasonably foreseeable risks or discomforts to the Subject

5. Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected, subject should be made aware of this.
6. Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
7. Statement describing the extent to which confidentiality of records identifying the subject will be maintained and who will have access to Subject's medical records
8. Clinical investigation treatment schedule(s) and the probability for random assignment to each treatment (for randomised clinical investigation)
9. Statement describing the financial compensation and medical management as under:
   (a) In case of an injury occurring to the subject during the clinical investigation, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical investigation, whichever is earlier.
   (b) In the event of an investigation related injury or death, the Sponsor or his representative, whoever has obtained permission from the Central Licensing Authority for conduct of the clinical investigation, shall provide financial compensation for the injury or death.
10. An explanation about whom to contact for clinical investigation related queries, rights of Subjects and in the event of any injury
11. The anticipated prorated payment, if any, to the Subject for participating in the clinical investigation
12. Subject's responsibilities on participation in the clinical investigation
13. Statement that participation is voluntary, that the Subject can withdraw from the clinical investigation at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled
14. Statement that there is a possibility of failure of investigational medical device to provide intended therapeutic effect.
15. Any other pertinent information.

1.2 Additional elements, which may be required

(a) Statement of foreseeable circumstances under which the Subject's participation may be terminated by the Investigator without the Subject's consent.

(b) Additional costs to the Subject that may result from participation in the clinical investigation.

(c) The consequences of a Subject's decision to withdraw from the investigation and procedures for orderly termination of participation by Subject.

(d) Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings are developed during the course of the investigation which may affect the Subject's willingness to continue participation will be provided.

(e). A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or fetus, if the Subject is or may become pregnant), which are currently unforeseeable

(f) Approximate number of Subjects enrolled in the clinical investigation

2. Format of informed consent form for Subjects participating in a clinical investigation -

Informed Consent form to participate in a clinical investigation

Clinical investigation Title:

Clinical investigation Number:

Subject's Initials: _____ Subject's Name:_____

Date of Birth / Age: _____ Gender: _____

Address of the Subject: _____

Qualification: _____

Occupation: Student/Self-employed/Service/Housewife/Others (Please tick as appropriate)

Annual income of the subject: _____

Name and address of the nominee(s) and his relation to the subject _____ (for the purpose of compensation in case of clinical investigation related death).

	Place initial box (Subject)
(i) I confirm that I have read and understood the information sheet dated ___ for the above clinical investigation and have had the opportunity to ask questions.	[ ]
(ii) I understand that my participation in the clinical investigation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	[ ]
(iii) I understand that the Sponsor of the clinical investigation, others working on the	[ ]

Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current clinical investigation and any further research that may be conducted in relation to it, even if I withdraw from the clinical investigation. I agree to this access.
However, I understand that my identity will not be revealed in any information released to third parties or published.

(iv) I agree not to restrict the use of any data or results that arise from this clinical investigation provided such a use is only for scientific purpose(s). [ ]
(v) I agree to take part in the above clinical investigation. [ ]

(vi) I understand that in case of an injury occurring during the clinical investigation, free medical management shall be given as long as required.
(vii) I understand that in the event of an investigation related injury or death, financial compensation for such injury or death shall be provided in accordance with the provisions of the Medical Device Rules, 2017.

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:_____

Date: _____/_____/_____
Signatory's Name: _____

Signature of the Investigator: _____
Contact Details (Telephone Number/ mobile) on which subject may contact:_____
Date: _____/_____/_____

Clinical investigation Investigator's Name: _____

Signature of the Witness _____ Date:_____/_____/_____
Name of the Witness: _____
Address and contact details of the Witness: _____

(Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject or his/her attendant).

Table 9
Undertaking by the Investigator

1. Full name, address and title of the Principal Investigator (or Investigator(s) when there is no Principal Investigator)
2. Name and address of the medical college, hospital or other facility where the Clinical Investigation will be conducted: Education, training & experience that qualify the Investigator for the clinical investigation (Attach details including medical council registration number, or any other statement(s) of qualification(s))
3. Name and address of all clinical facilities to be used in the clinical investigation.
4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the clinical investigation.
5. Names of the other members of the research team (Co-Investigators or sub-Investigators) who will be assisting the Investigator in the conduct of the investigation (s).
6. Clinical Investigation Plan, Title and Clinical investigation number (if any) of the clinical investigation to be conducted by the Investigator.
7. Commitments:

(i) I have reviewed the clinical investigation plan and agree that it contains all the necessary information to conduct the investigation. I will not begin the clinical investigation until all necessary Ethics Committee and regulatory approvals have been obtained.

(ii) I agree to conduct the investigation in accordance with the current Clinical investigation plan. I will not implement any deviation from or changes of the Clinical investigation plan without agreement by the Sponsor and prior review and documented approval / favorable opinion from the Ethics Committee of

the amendment, except where necessary to eliminate an immediate hazard(s) to the clinical investigation participant or when the change(s) involved are only logistical or administrative in nature.

(iii) I agree to personally conduct and/or supervise the clinical investigation at my site.

(iv) I agree to inform all Subjects that the medical devices are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and Ethics Committee review and approval specified in this *Schedule* are met.

(v) I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory and Good Clinical practice guidelines.

(vi) I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the medical device.

(vii) I agree to ensure that all associates, colleagues and employees assisting in the conduct of the clinical investigation are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the clinical investigation.

(viii) I agree to maintain adequate and accurate records and to make those records available for audit / inspection by the Sponsor, Ethics Committee, Licensing Authority or their authorized representatives, in accordance with regulatory and provisions of these rules. I will fully cooperate with any clinical investigation related audit conducted by regulatory officials or authorized representatives of the Sponsor.

(ix) I agree to promptly report to the Ethics Committee all changes in the CIP activities and all unanticipated problems involving risks to human Subjects or others.

(x) I agree to inform all serious adverse events to the Sponsor, Central Licensing Authority as well as the Ethics Committee within forty eight hours of their occurrence. In case of failure, I will submit the justification to the satisfaction of the Central Licensing Authority. I also agree to report the serious adverse events, after due analysis, to the Central Licensing Authority, Chairman of the Ethics Committee and head of the institution where the investigation has been conducted within fourteen days of the occurrence of serious adverse events.

(xi) I will maintain confidentiality of the identification of all participating clinical investigation patients and assure security and confidentiality of clinical investigation data.

(xii) I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical Investigations

Date: **Signature of Investigator**

Table 10
Clinical Investigation Report

1. General

This table specifies the contents of the clinical investigation report that describes the design, execution, statistical analysis and results of a clinical investigation.

2. Cover page

The page shall be contain the following information:-

(a) title of the clinical investigation;

(b) identification of the investigational medical devices, including names, models, etc. as relevant for complete identification;

(c) if not clear from the title, a single sentence describing the design, comparison, period, usage method, and subject population;

(d) name and contact details of sponsor or sponsor's representative;

(e) CIP identification/protocol code;

(f) name and department of coordinating investigator and names of other relevant parties, e.g. experts, biostatistician, laboratory personnel;

(g) statement indicating whether the clinical investigation was performed in accordance with declaration of Helsinki, Good Clinical Practice guidelines and applicable regulations;

(h) Brief description of investigation design;

(i) Start and end date of patient accrual and names of the sponsor and the participating institutes;

(j) author(s) of report.

3. Table of contents

The table of contents may include the following information:

(a) the page number or locating information of each section, including summary tables, figures, and graphs;

(b) a list of appendices and their location.

4. Summary

The summary may contain the following items:

(a) the title of the clinical investigation;

(b) an introduction;

(c) the purpose of the clinical investigation;

(d) description of the clinical investigation population;

(e) the clinical investigation method used;

(f) the results of the clinical investigation;

(g) the conclusion;

(h) the date of the clinical investigation initiation;

(i) the completion date of the clinical investigation or, if the clinical investigation is discontinued, the date of premature termination.

5. Introduction

The introduction may contain a brief statement placing the clinical investigation in the context of the development of the investigational medical device and relating the critical features of the clinical investigation (e.g. objectives and hypotheses, target population, treatment and follow-up duration) to that development.

6. Investigational medical device and methods

6.1 Investigational medical device description

The description of the investigational medical device should contain the following points:

(a) a description of the investigational medical device;

(b) the intended use of the investigational medical device(s);

(c) previous intended uses or indications for use, if relevant;

(d) any changes to the investigational medical device during the clinical investigation or any changes from the IB, including,-

(i) raw materials;

(ii) software;

(iii) components;

(iv) shelf-life;

(v) storage conditions;

(vi) instructions for use; and

(vii) other changes.

6.2 Clinical investigation plan (CIP)

A summary of the CIP, including any subsequent amendment(s) with a rational for each amendment, should be provided. The summary will include a brief description of the following points:-

(a) the clinical investigation objectives;

(b) the clinical investigation design including,-

(i) the type of clinical investigation;

(ii) the clinical investigation endpoints;

(iii) the ethical considerations;

(iv) the data quality assurance;

(v) the subject population for the clinical investigation, with the,-

(A) inclusion or exclusion criteria; and

(B) sample size; a clear accounting of all participant who entered the clinical investigation shall be mentioned. Mention should also be made of all cases that were dropouts or protocol deviations. Enumerate the patients screened, randomized, and prematurely discontinued. State reasons for premature discontinuation of therapy in each applicable case.

(vi) the treatment and treatment allocation schedule;
(vii) any concomitant medications/treatments;
(viii) the duration of follow-up;
(ix) the statistical analysis including:-
(A) the clinical investigation hypothesis or pass or fail criteria;
(B) a sample size calculation; and
(C) statistical analysis methods.

6.3 Ethics Committee

This section shall document that the clinical investigation was conducted in accordance with the ethical principles of Declaration of Helsinki. A detailed description of the Ethics Committee constitution and date(s) of approvals of investigation documents for each of the participating sites should be provided. A declaration shall state that EC notifications as per Good Clinical Practice Guidelines issued by Central Drugs Standard Control Organization and Ethical Guidelines for Biomedical Research on Human Subjects, issued by Indian Council of Medical Research have been followed. The ethics report shall include the following points:

(a) a confirmation that the CIP and any amendments to it were reviewed by the EC;
(b) a list of all ECs consulted.

6.4 Clinical investigation team

Briefly describe the administrative structure of the clinical investigation (Investigators, site staff, Sponsor/ designates, Central laboratory etc.).

7. Results

The results should include the following points:

(a) the clinical investigation initiation date;
(b) the clinical investigation completion/suspension date;
(c) the disposal of subjects and investigational medical devices;
(d) the subject demographics;
(e) Clinical investigation Plan compliance;
(f) an analysis, which includes,-
(i) a performance analysis as provided in the clinical investigation plan;
(ii) a summary of all adverse events and adverse device effects, including a discussion of the severity, treatment needed, resolution and relevant principal investigator's judgment concerning the causal relationship with the investigational medical devices or procedure;
(iii) a table compiling all observed device deficiencies that could have led to a serious adverse effect, and any corrective actions taken during the clinical investigation, if any;
(iv) any needed subgroup analysis for special populations (i.e. gender, racial/cultural/ethnic subgroups), as appropriate;
(v) an accountability of all subjects with a description of how missing data or deviation(s) were dealt within the analysis, including subjects:-
(A) not passing screening tests;
(B) lost to follow-up;
(C) withdrawn or discontinued from the clinical investigation and the reason.

8. Discussion and overall conclusions

The conclusions may include the following points:

(a) the safety and performance results and any other endpoints;
(b) an assessment of risks and benefits;
(c) a discussion of the clinical relevance and importance of the results in the light of other existing data;
(d) any specific benefits or special precautions required for individual subjects or groups considered to be at risk;
(e) any implications for the conduct of future clinical investigations;
(f) any limitations of the clinical investigation.

9. Abbreviated terms and definitions

A list of abbreviated terms and definitions of specialized or unusual terms should be provided.

10. List of appendices to the clinical investigation report

(a) Protocols and amendments;
(b) Specimen of Case Record Form;
(c) Investigators' name(s) with contact addresses, phone, e-mail etc.;
(d) Patient data listings (e) List of participants treated with investigational product;
(e) Discontinued participants;
(f) Protocol deviations ;
(g) CRFs of cases involving death and life threatening adverse event cases;
(h) Publications from the investigation;
(i) Important publications referenced in the clinical investigation;
(j) Audit certificate, if available;
(k) List of other parties involved (e.g. core labs, contract research organizations (CROs), experts, etc.);
(l) List of monitors involved;
(m) Investigator's certificate that he or she has read the report and that the report accurately describes the conduct and the results of the clinical investigation.

Eighth Schedule

(See rule 90)

Exemptions

S.N.	Class of medical devices	Extent and conditions of exemption
1	Custom made device.	All provisions of Chapter IV and Chapter V of these rules, subject to the condition that the device is being specifically made in accordance with a duly qualified medical practitioner's written prescription under his responsibility, in accordance with specific design, characteristics and the same is intended for the sole use of a particular patient and the label contains the words 'custom made device'. *Explanation*.- Mass produced devices, which only need adoption to meet the specific requirement of a medical practitioner or any other professional user, shall not be considered as custom made device.
2	Medicated dressings and bandages for first aid.	The provisions of Chapter XI of these rules which require them to be covered by a sale licence, subject to condition that such products have been manufactured by licenced manufacturers.
3	Medical devices supplied by a registered medical practitioner to his own patient or any medical device supplied by a registered medical practitioner at the request of another such practitioner if it is specially prepared with reference to the condition and for the use of an individual patient provided the registered medical practitioner is not (a) keeping an open shop or (b) selling across the counter, for distribution or sale of medical devices in	All provisions of Chapter XI of these rules which require them to be covered by a sale licence subject to the following conditions:- (a) The medical devices shall be purchased only from a licenced manufacturer or licenced whole seller or retailer under these rules and records of such purchases showing the name and quantities of such medical devices, together with their batch numbers and names and addresses of the manufacturers shall be maintained. Such records shall be open to inspection by medical device officer appointed under this Act, who may, if necessary make enquiries about purchase of medical device and may also take samples for test. (b) Medical device shall be stored under proper storage conditions as specified in the label. (c) No medical device shall be sold or supplied or dispensed after the date of expiration recorded on its label or in violation of any statement or direction recorded on such label.

	India to a degree which render him liable to the provisions of Chapter IV of the Act and the rules made thereunder.	
4	Medical devices supplied by a hospital or dispensary maintained or supported by Government or local body.	All provisions of Chapter XI of these rules which requires them to be covered by a sale licence subject to the following conditions:- (a) The dispensing and supply of medical devices shall be carried out by or under the supervision of qualified person; (b) The premises where medical devices are supplied or stocked shall be open to inspection by a medical device officer appointed under this Act who can, if necessary, take samples for test. (c) The medical devices shall be stored under proper storage conditions. (d) The medical devices shall be purchased from a manufacturer or a whole seller or retailer licenced under these rules or received as transferred stocks from hospital stores for distribution. Records of such purchases or receipts shall be maintained. (e) No medical device shall be sold or supplied or dispensed after the date of expiration recorded on its label or in violation of any statement or direction recorded on such label.
5	Mechanical contraceptives.	The provisions of Chapter XI of these rules which require them to be covered by a sale licence subject to the condition that the provisions of condition that no medical device shall be sold or supplied or dispensed after the date of expiration recorded on its label or in violation of any statement or direction recorded on such label.
6	Import of small quantity of medical devices donated to a charitable hospital for treatment of patients free of cost by that hospital.	The provisions of Chapter V of these rules which require them to be covered by a licence for import provided that the Central Licensing Authority shall issue a No Objection Certificate for such purpose to the applicant.

Appendix

Form MD-1

[See sub-rule (5) of rule 13]

Application for grant of Certificate of Registration of a Notified Body

1. Name of Applicant:
2. Nature and constitution of Body:

(i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)

3. Corporate/ registered office address including telephone number, mobile number, fax number and e-mail id:
4. Details of accreditation (self-attested copy of certificate to be attached):
5. Standards (BIS/ISO/Others) for which notified body has been accredited under rule 13:
6. Fee paid on _____ Rs_____ receipt/challan/transaction id_____.
7. Documents enclosed, as specified in the Part I of the Third Schedule of the Medical Devices Rules, 2017, duly signed by me.
8. I undertake to comply with the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017 and other terms and conditions for working as a Notified Body as may be specified from time to time.

Place: _____

Date: _____

Signature of designated person in India

(Name and designation)

[To be signed digitally]

Form MD-2

[See sub-rule (6) of rule 13]

Certificate of Registration for a Notified Body under the Medical Devices Rules, 2017

Registration No.: _____

1. M/s, _____(Name of the firm) situated at _____(full address with telephone and e-mail) has been registered as a Notified Body of following Class A and/or Class B medical devices.

2. Details of Medical device(s):

S.N.	Standards for which it is registered	Class of medical devices

3. This Registration is subject to the conditions as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: _____ Central Licensing Authority
Date: _____ [To be signed digitally]

Form MD-3

[See sub-rule (2) of rule 20]

Application for Grant of Licence to Manufacture for Sale and Distribution of Class A or Class B medical device

1. Name of Applicant:
2. Nature and constitution of manufacturer:
   (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
3. (i) Corporate/ registered office address including telephone number, mobile number, fax number and e-mail id:
   (ii) Manufacturing site address including telephone number, mobile number, fax number and e-mail id:
   (iii) Address for correspondence:
   [corporate/ registered office/ manufacturing site]
4. Details of medical device(s) to be manufactured [Annexed]:
5. Whether substantial equivalence to a predicate device is claimed: (Yes/ No)
6. Fee paid on _____ Rs_____ receipt/challan/transaction id_____.
7. I have enclosed the documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.
8. I hereby state and undertake that:
   (i) the manufacturing site is ready for audit or shall be ready for audit on …….. in accordance with the requirements of Medical Devices Rules, 2017.

(ii) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: _____
Date: _____

Signature
(Name and designation)
[To be signed digitally]

Annexure:

S.N.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non sterile	Brand Name (if registered under the Trade Marks Act, 1999)

Form MD-4

[See sub-rule (2) of rule 20]

Application for Grant of Loan Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

1. Name of Applicant:
2. Nature and constitution of manufacturer:
   (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
3. (i) Corporate/ registered office address including telephone number, mobile number, fax number and e-mail id:
   (ii) Name and address of Manufacturing site including telephone number, mobile number, fax number and e-mail id:
   (iii) Address for correspondence:
   [corporate/ registered office/ manufacturing site]
4. Details of medical device(s) to be manufactured [Annexed]:
5. Whether substantial equivalence to a predicate device is claimed: (Yes/ No)
6. Fee paid on _____ Rs_____ receipt/challan/transaction id_____.
7. I have enclosed the documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.
8. I hereby state and undertake that:

(i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: _____
Date: _____

Signature
(Name and designation)
[To be signed digitally]

Annexure:

S.N.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non sterile	Brand Name (if registered under the Trade Marks Act, 1999)

Form MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B Medical Device.

Licence Number: …….

1. M/s _____(Name and full address of manufacturer with telephone, fax and e-mail) has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at _____ (address of manufacturing facility where the manufacturing will be carried out).
2. Details of medical device(s) [Annexed].

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

Place: _____
Date: _____

State Licensing Authority
[To be signed digitally]

Annexure:

S.N.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non sterile	Brand Name (if registered under the Trade Marks Act, 1999)

Form MD-6

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Loan Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Loan Licence Number: …….

1. M/s _____(Name and full address of manufacturer with telephone, fax and e-mail) has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at _____ (address of manufacturing facility where the manufacturing will be carried out along with the licence number) C/o _____ (name of manufacturing site licence holder).

2. Details of medical device(s) [Annexed].

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

Place: _____ State Licensing Authority

Date: _____ [To be signed digitally]

Annexure:

S.N.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non sterile	Brand Name (if registered under the Trade Marks Act, 1999)

Form MD-7

[See sub-rule (1) of rule 21 and sub-rule (2) of rule 21]

Application for Grant of Licence to Manufacture for Sale or for Distribution of Class C or Class D

1. Name of Applicant:
2. Nature and constitution of manufacturer:
   (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
3. (i) Corporate/ registered office address including telephone number, mobile number, fax number and e-mail id:
   (ii) Manufacturing site address including telephone number, mobile number, fax number and e-mail id:
   (iii) Address for correspondence:
   [corporate/ registered office/ manufacturing site]
4. Details of medical device(s) to be manufactured [Annexed]:
5. Whether substantial equivalence to a predicate device is claimed: (Yes/ No)
6. Fee paid on _____ Rs_____ receipt/challan/transaction id_____.
7. I have enclosed the documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.
8. I hereby state and undertake that:
   (i) the manufacturing site is ready for audit or shall be ready for audit on …….. in accordance with the requirements of Medical Devices Rules, 2017.

   (ii) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: _____
Date: _____

Signature
(Name and designation)
[To be signed digitally]

Annexure:

S.N.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non sterile	Brand Name (if registered under the Trade Marks Act, 1999)

Form MD-8

[See sub-rule (1) of rule 21 and sub-rule (2) of rule 21]

Application for Grant of Loan Licence to Manufacture for Sale or for Distribution of Class C or Class D

1. Name of Applicant:
2. Nature and constitution of manufacturer:
   (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
3. (i) Corporate/ registered office address including telephone number, mobile number, fax number and e-mail id:
   (ii) Manufacturing site address including telephone number, mobile number, fax number and e-mail id:
   (iii) Address for correspondence:
   [corporate office/ manufacturing site]
4. Details of medical device(s) to be manufactured [Annexed]:
5. Whether substantial equivalence to a predicate device is claimed: (Yes/ No)
6. Fee paid on _____ Rs_____ receipt/challan/transaction id_____.
7. I have enclosed the documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.
8. I hereby state and undertake that:
   (i) the manufacturing site is ready for audit or shall be ready for audit on …….. in accordance with the requirements of the Medical Devices Rules, 2017.

   (ii) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: _____
Date: _____

Signature
(Name and designation)
[To be signed digitally]

Annexure:

S.N.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non sterile	Brand Name (if registered under the Trade Marks Act, 1999)

Form MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D

Licence Number: …….

1. M/s _____(Name and full address of manufacturer with telephone, fax and e-mail) has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at _____ (address of manufacturing facility where the manufacturing will be carried out).
2. Details of medical device(s) [Annexed].

3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s).

4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

Place: _____
Date: _____

Central Licensing Authority
[To be signed digitally]

Annexure:

S.N.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non sterile	Brand Name (if registered under the Trade Marks Act, 1999)

Form MD-10

[See sub-rule (1) rule 25]

Loan Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Loan Licence Number: …….

1. M/s _____(Name and full address of manufacturer with telephone, fax and e-mail) has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at _____ (address of manufacturing facility where the manufacturing will be carried out along with the licence number) C/o _____ (name of manufacturing site licence holder).

2. Details of medical device(s) [Annexed].

3. The names, qualifications and experience of competent technical staff responsible for the manufacture and testing of the above mentioned medical device:

4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

Place: _____
Date: _____

State Licensing Authority
[To be signed digitally]

Annexure:

S.N.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non sterile	Brand Name (if registered under the Trade Marks Act, 1999)

Form MD-11

[See clause (vii) of rule 26]

Form in which the Audit or Inspection Book shall be maintained.

(A) The cover of the audit or inspection book shall contain the following particulars, namely:-

1. The name and address of the licencee _____
2. Licence Number _____

(B) (i) The pages of the audit or inspection book shall be serially numbered and duly stamped by the Central Licensing Authority*/State Licensing Authority*. The pages, other than the first and the last pages, shall have the following particulars:-

Name and designation of the auditor or medical device officer who audited or inspected the premises:
Date of audit or inspection _____
Observations of the auditor or medical device officer _____

Signature of the auditor or medical device officer

(ii) The first and last pages of the audit or inspection book shall be endorsed by the Central Licensing Authority*/State Licensing Authority* with the following words, namely:-
Audit or inspection book maintained by M/s _____situated at _____ for licence number _____ in Form _____ under the Medical Devices Rules, 2017.

*Central Licensing Authority/
*State Licensing Authority
[To be signed digitally]

*Delete whichever is not applicable.

Notes:

(i) Printed copy of the Inspection Book may be obtained by the licencee from the Licensing Authority on payment of fee as may be specified by the concerned Licensing Authority from time to time.
(ii) The audit or inspection book shall be maintained at the premises of the licencee.
(iii) The original copy of observations made by the auditor or medical device officer shall be maintained in the premises of the licencee and duplicate copy shall be sent to the Central Licensing Authority/ State Licensing Authority. The triplicate copy shall be taken as record by the auditor or medical device officer.

Form MD-12

[See sub-rule (1) of rule 31]

Application for licence to manufacture medical device for purpose of clinical investigations, test, evaluation, examination, demonstration or training

1. Name of Applicant:
2. Nature and constitution of manufacturer:
   (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
3. (i) Corporate/ registered office address including telephone number, mobile number, fax number and e-mail id:
   (ii) Testing or evaluation site address including telephone number, mobile number, fax number and e-mail id:
   (iii) Address for correspondence:
   [corporate office/ testing site]
4. Details of medical device(s) to be manufactured [Annexed]:
5. Fee paid on _____ Rs_____ receipt/challan/transaction id_____.

6. I hereby state and undertake that, I shall comply with all applicable provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: _____ Signature
Date: _____ (Name and designation)
[To be signed digitally]

Annexure:

S.N.	Generic name	Class of medical device	Quantity proposed to be manufactured

Form MD-13
[See sub-rule (3) of rule 31]
Licence to Manufacture Medical Devices for the Purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training

1. M/s ....., of....., is hereby licenced to manufacture the medical device(s) specified below for the purposes of clinical investigations or test or evaluation or demonstration or training at …… (address of the premise).

S.N.	Generic name	Class of medical device	Quantity permitted to be manufactured

2. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

3. This licence shall be in force for a period of three year from the date specified below.

Place: _____ Central Licensing Authority
Date: _____ [To be signed digitally]

Form MD-14
[See sub-rule (1) of rule 34]

Application for issue of import licence to import medical device

1. Name of Authorised agent:
2. Nature and constitution of Authorised agent:
(i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
3. (i) Corporate/ registered office address including telephone number, mobile number, fax number and e-mail id:

(ii) Authorised Agent address including telephone number, mobile number, fax number and e-mail id as per wholesale licence or manufacturing licence:

(iii) Address for correspondence:
[corporate/ registered office/ authorised agent]

4. Particulars of overseas Manufacturer, Manufacturing site(s):

Sr. No.	Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer)	Name and address of manufacturing site (full address with telephone, fax and e-mail address of the manufacturing site)

5. Details of medical device(s) to be imported [Annexed]:

6. Whether substantial equivalence to a predicate device is claimed: (Yes/ No)

7. Fee paid on _____ Rs_____ receipt/challan/transaction id_____.

8. I have enclosed the documents as specified in the Fourth Schedule for grant of licence to import medical device(s).

9. I hereby state and undertake that:

(i) I shall comply with applicable provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: _____ Signature

Date: _____ (Name and designation)

[To be signed digitally]

Annexure:

S.N.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non sterile	Brand Name (if registered under Trade Marks Act 1999)

Form MD-15

[See sub-rule (1) of rule 36]

Licence to Import Medical Device

Licence No.: _____

1. M/s _____(Name, full address, as per wholesale licence/ manufacturing licence, of authorised agent with telephone and e-mail address) is hereby licenced to import the medical device(s) manufactured by overseas manufacturer having manufacturing site as specified below.

2. Details of overseas manufacturer and manufacturing site under this licence.

Sr. No.	Name & address of overseas manufacturer (full address with telephone and e-mail address of the manufacturer)	Name & address of overseas manufacturing site (full address with telephone and e-mail address of the manufacturing site)

3. Details of medical device(s) [Annexed].

4. The authorised agent M/s. _____ will be responsible for the business activities of the overseas manufacturer, in India in all respects.

5. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

Place: _____ Central Licensing Authority
Date: _____ Seal or Stamp

Annexure:

S.N.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non sterile	Brand Name (if registered under Trade Marks Act 1999)

Form MD-16

[See sub-rule (2) of rule 40]

Application for Licence to Import Medical Devices for the Purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training

1. Name of applicant:
2. Address of applicant including telephone number,

mobile number, fax number and e-mail id:
3. Name and Address of device Manufacturer:
4. Name and Address of site(s) where test or evaluation is proposed to be conducted:
5. Details of medical device(s) to be imported [Annexed].
6. Brief description of the medical device
7. Purpose of import
8. Justification for quantity to be imported
9. An undertaking stating that required facilities including equipment, instrument and personnel have been provided to test or evaluate medical device
10. An undertaking stating that the medical device proposed to be imported to be used exclusively for purpose specified at serial number 7 and shall not be used for commercial purpose
11. Fee paid on _____ Rs_____ receipt/challan/transaction id_____.
12. I hereby state and undertake that, I shall comply with all applicable provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: _____
Date: _____

Signature
(Name and designation)
[To be signed digitally]

Annexure:

S.N.	Name of medical device (Generic and brand)	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non sterile	Quantity to be imported

Form MD-17

[See sub-rule (1) of rule 41]

Licence to Import Medical Devices for the Purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training

1. M/s..... is hereby licenced to import the medical device specified below from M/s .....(Name and full address of overseas manufacturer) for the purposes of clinical investigations or test or evaluation or demonstration or training at …… (Name and address, where clinical investigations or test or evaluation or is to be carried out).

S.N.	Generic name	Class of medical device	Quantity permitted to be imported

2. This licence is subject to conditions prescribed under the Medical Devices Rules, 2017.

3. This licence shall, unless previously suspended or revoked, be in force for a period of three year from the date specified below:-

Place: _____ Central Licensing Authority
Date: _____ [To be signed digitally]

Form MD-18
[See sub-rule (1) of rule 42]

Application for licence to import investigational medical devices for the purposes by a government hospital or statutory medical institution for the treatment of patients

1. I .....…… (Name and designation) .....…….. of …… (Name of the Government Hospital or Statutory Medical Institution) hereby apply for a licence to import small quantities of investigational medical device specified below manufactured by M/s. ……. (Name and full address of overseas manufacturer) for the purpose of treatment of patients for the disease..... (Name of the disease)…… at……. (name and address of the hospital).

2. Details of medical device to be imported:

Name of the investigational Medical device	Name and address of the manufacturer	Quantities which may be imported

3. I shall comply with the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

4. A fee of Rs. _____ has been credited to the Government under the Head through Challan/receipt No._____ dated_____ (copy attached).

Place: _____ Signature……..
Date: _____ Name……
Seal or Stamp……

Certificate

Certified that the investigational medical device specified above for import are urgently required for the treatment of patients suffering from ..... and that the said medical device is not available in India.

Place: _____
Signature……..
Date: _____ Medical Superintendent of the Government Hospital / Head of Statutory Medical Institution Seal or Stamp

Form MD-19

[See sub-rule (2) of rule 42]

Licence to import investigational medical device by a government hospital or statutory medical institution for the treatment of patients

Licence No._____

1. Dr_____ (Name and designation) of _____ (Name of Hospital or Statutory Medical Institution) here by grant licence to import from M/s …….. (Name and full address of manufacturer) the medical devices specified below for the purpose of treatment of patients for the disease _____(name of the disease) at …….(name and address of the hospital).

2. Details of medical device to be imported:

Name of medical device	Quantities which may be imported

3. This licence shall, unless previously suspended or revoked, be in force for a period of one year from the date of issue specified above.

Place: _____ Central Licensing Authority

Date: _____ Seal or Stamp

Form MD-20

[See sub-rule (2) of rule 43]

Application for permission to import small quantity of medical devices for personal use

To

The Central Licensing Authority,

_____

_____

Sir/Madam,

1. I …… resident of…….. by occupation……. hereby apply for a permission to import the medical device specified below for personal use manufactured by .....(Name and full address of manufacturer) for the treatment of …… (name of the disease).

Name of medical device	Quantity which may be imported

2. The prescription from a registered medical practitioner prescribing the need for the said medical device is attached.

3. The particular of the patients is specified below.

Name	Age	Gender	Complete Address

Place: _____ Signature of applicant

Date: _____

Form MD-21

[See sub-rule (3) of rule 43]

Permission to import of small quantity of medical devices for personal use

Permit No._____ Date_____

1. ……is hereby permitted to import the medical device manufactured by..... (Name and full address of manufacturer) specified below for personal use.

Name of the medical device	Quantity

2. This licence is subject to conditions prescribed in the Medical Devices Rules, 2017.
3. This licence shall, unless previously suspended or revoked, be in force for a period of one hundred and eighty days from the date of issue specified above.

Central Licensing Authority
Seal or Stamp

Form MD-22

[See sub-rule (1) of rule 51]

Application for Grant of permission to conduct clinical investigation of an investigational medical device

1. Name of Applicant:
2. Nature and constitution of applicant:
   (i.e. proprietorship, partnership including Limited Liability Partnership, company, society, trust, other to be specified)
3. (i) Sponsor address including telephone number, mobile number, fax number and e-mail id:
   (ii) Clinical investigation site address including telephone number, mobile number, fax number and e-mail id:
   (iii) Address for correspondence:
4. Details of investigational medical device(s) and Clinical investigation site [Annexed].
5. Clinical investigation plan number with date:
6. Fee paid on _____ Rs_____ receipt/challan/transaction id_____.
7. I have enclosed the documents as specified in the Seventh Schedule of Medical Devices Rules, 2017.
8. I hereby state and undertake that:

(i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2017.

Place: _____ Signature
Date: _____ (Name and designation)
[To be signed digitally]

Annexure:

S. N.	Generic name	Intended use	Class of medical device

S. N.	Name and address of site(s)	Ethics Committee details	Name of Principle Investigator

Form MD-23

[See clause (i) of rule 52]

Permission to conduct Clinical Investigation

Permission No. _____

1. M/s._____ (Name and full address) is hereby granted permission to conduct clinical investigation for following investigational medical device as per clinical investigation plan _____ dated _____ in the below mentioned clinical investigation sites.

2. Details of investigational medical device(s) and Clinical investigation site [Annexed].

3. This permission is subject to conditions as prescribed under Medical Devices Rules, 2017.

Place: _____ Central Licensing Authority
Date: _____ [To be signed digitally]

Annexure:

Details of investigational medical device(s):

S. N.	Generic name	Intended use	Class of medical device

Details of Clinical investigation site:

S. N.	Name and address of site(s)	Ethics Committee details	Name of Principle Investigator

Form MD-24

[See sub-rule (2) of rule 59]

Application for grant of permission to conduct clinical performance evaluation of new *in vitro* diagnostic medical device

1. Name of Applicant:
2. Nature and constitution of applicant:
   (i.e. proprietorship, partnership including Limited Liability Partnership, company, society, trust, other to be specified)
3. (i) Sponsor address including telephone number, mobile number, fax number and e-mail id:
   (ii) Laboratory(s) or institution(s) address including telephone number, mobile number, fax number and e-mail id:
   (iii) Address for correspondence:
4. Details of new *in vitro* diagnostic medical device and laboratory(s) or institution(s) [Annexed].
5. Clinical performance evaluation plan number with date:
6. Fee paid on _____ Rs_____ receipt/challan/transaction id_____.
7. I have enclosed the documents as specified in sub-rule (3) of rule 59 of Medical Devices Rules, 2017.
8. I hereby state and undertake that:
   (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2017.

Place: _____ Signature
Date: _____ (Name and designation)
[To be signed digitally]

Annexure:

Details of new *in vitro* diagnostic medical device

S. N.	Generic name	Intended use	Class of medical device

Details of laboratory(s)/institution(s) involved

S. N.	Name and address of laboratory(s)/ institution(s)	Ethics Committee details	Name of Principle Investigator

Form MD-25

[See sub-rule (5) of rule 59]

Permission to conduct clinical performance evaluation of new *in vitro* diagnostic medical device

Permission No. _____

1. M/s _____(Name and full address of manufacturer with telephone and e-mail) is hereby granted permission to conduct clinical performance evaluation of following new *in vitro* diagnostic device as per clinical performance evaluation plan _____ dated: _____on the below mentioned laboratory(s) or institution(s) involved.

2. Details of new *in vitro* diagnostic medical device and laboratory(s) or institution(s) [Annexed].

3. This permission is subject to conditions as prescribed under Medical Devices Rules, 2017.

Place: _____ Central Licensing Authority

Date: _____ [To be signed digitally]

Annexure:

Details of new *in vitro* diagnostic medical device:

S. N.	Generic name	Intended use	Class of medical device

Details of laboratory(s)/institution(s) involved.

S. N.	Name and address of laboratory(s)/ institution(s)	Ethics Committee details	Name of Principle Investigator

Form MD-26

[See sub-rule (1) of rule 63]

Application for grant of permission to import / manufacture for sale or for distribution of medical device which does not have predicate medical device

1. Name of applicant:
2. Nature and constitution of applicant:
   (i.e. proprietorship, partnership including Limited Liability Partnership, company, society, trust, other to be specified)
3. (i) Corporate/ registered office address including telephone number, mobile number, fax number and e-mail id:
   (ii) Manufacturing site/ Authorised Agent address including telephone number, mobile number, fax number and e-mail id as per wholesale licence or manufacturing licence:
   (iii) Address for correspondence:
   [Corporate/ registered office/ Manufacturing site / authorised agent]
4. Particulars of Manufacturer, Manufacturing site(s):

Sr. No.	Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer)	Name and address of manufacturing site (full address with telephone, fax and e-mail address of the manufacturing site)

5. Details of medical device(s) to be imported or manufactured [Annexed].
6. Fee paid on _____ Rs_____ receipt/challan/transaction id_____.
7. I have enclosed the documents as specified in the Part IV of the Fourth Schedule to the Medical Devices Rules, 2017.

Place: _____
Date: _____

Signature
(Name and designation)
[To be signed digitally]

Annexure:

S.N.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non sterile

Form MD-27

[See sub-rule (2) of rule 63]

Permission to import or manufacture for sale or for distribution of medical device which does not have predicate medical device

Permission No. _____

1. M/s. _____ (Name and full address of manufacturer with telephone, and e-mail) having manufacturing site _____ (address of manufacturing site), is hereby permitted to import / manufacture for sale or for distribution of following medical devices.

2. Details of medical device(s) to be imported or manufactured [Annexed].

3. This permission is subject to conditions as specified in the Drugs and Cosmetics Act (23 of 1940) and the Medical Devices Rules, 2017.

Place: _____
Date: _____

Central Licensing Authority
[To be signed digitally]

Annexure:

S.N.	Generic Name	Brand name	Model No.	Dimension	Intended Use	Shelf life	Sterile/ Non Sterile	Class of medical device

Form MD-28

[See sub-rule (1) of rule 64]

Application for grant of permission to Import or Manufacture for sale or for distribution of new *in vitro* diagnostic medical device

1. Name of applicant:
2. Nature and constitution of applicant:
   (i.e. proprietorship, partnership including Limited Liability Partnership, company, society, trust, other to be specified)
3. (i) Corporate/ registered office address including telephone number, mobile number, fax number and e-mail id:
   (ii) Manufacturing site/ authorised agent address including telephone number, mobile number, fax number and e-mail id as per wholesale licence or manufacturing licence:
   (iii) Address for correspondence:
   [Corporate/ registered office/ Manufacturing site / authorised agent]
4. Particulars of Manufacturer, Manufacturing site(s):

Sr. No.	Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer)	Name and address of manufacturing site (full address with telephone, fax and e-mail address of the manufacturing site)

5. Details of new *in vitro* diagnostic medical device to be imported or manufactured [Annexed].
6. Fee paid on _____ Rs_____ receipt/challan/transaction id_____.
7. I have enclosed the documents as specified in the part IV of the Fourth Schedule Medical Devices Rules, 2017.

Place: _____
Date: _____

Signature
(Name and designation)
[To be signed digitally]

Annexure:

S.N.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non sterile

Form MD-29

[See sub-rule (2) of rule 64]

Permission to Import or Manufacture New *In Vitro* Diagnostic Medical Device

Permission No. _____

1. The new *in vitro* diagnostic medical device(s) specified below manufactured by M/s. _____(Name and full address of manufacturer with telephone, and e-mail) having manufacturing site _____ (address of manufacturing site), is hereby permitted to import or manufacture.

2. Details of new *in vitro* diagnostic medical device to be imported or manufactured [Annexed].

3. This permission is subject to conditions as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: _____ Central Licensing Authority
Date: _____ [To be signed digitally]

Annexure:

S.N.	Generic Name	Brand name	Model No.	Dimension	Intended Use	Shelf life	Sterile/ Non Sterile	Class of medical device

Form MD-30

[See sub-rule (1) of rule 67]

Memorandum to the Central Medical Device Testing Laboratory

Serial Number …….

To

The Director,
Central Medical Device Testing Laboratory,
…….
…….

From…….....

1. I send herewith, under the provisions of sub-section (4) of section 25 of the Drugs and Cosmetics Act, 1940 (23 of 1940), sample(s) of a medical device purporting to be …….. for test or evaluation and request that a report of the result of the test or evaluation may be supplied to this Court.

2. The distinguishing number on the packet is ……..

3. Particulars of offence alleged …….

4. Matter on which opinion is required ……

5. A fee of Rs. …….. has been deposited in Court.

Date……..

……..
Magistrate

Form MD-31

[See sub-rule (4) of rule 67]

Certificate of test or evaluation by the Central Medical Device Testing Laboratory

1. Certified that the samples, bearing number …… purporting to be a sample of …… received on …….. with memorandum No. …….. dated ……. from …….. has been tested/evaluated and that the result of such test/evaluation is as stated below.

2. The condition of the seals on the packet on receipt was as follow.

*3. In the opinion of the undersigned the sample is of standard quality/not of standard quality as defined in the Drugs and Cosmetics Act, 1940 (23 of 1940) and Medical Devices Rules, 2017 for the reasons given below.

Date……..

Director of Central Medical Device Testing Laboratory/ other Authorised Officer

Details of results of testing or evaluation with protocols of test or evaluation applied

Date……..

Director of Central Medical Device Testing Laboratory/ other Authorised Officer

*If opinion is required on any other matter, the paragraph should be suitably amended.

Form MD-32

[See sub-rule (2) of rule 68]

Report of Test or Evaluation of Medical Devices by Medical Device Testing Officer

1. It is certified that the samples having serial number of memorandum or receipt number …… dated: …… purporting to be sample of ……. received on …….. from ……. has been tested or evaluated and the results of tests or evaluation is as stated below.

2. The conditions of seals on the packet or on portion of sample or container were as follows …….

2. Based upon the test or evaluation and in the opinion of undersigned the sample is of standard quality/ not of standard quality/ adulterated/misbranded/spurious, as defined in the Drugs and Cosmetics Act, 1940 (23 of 1940) for the reasons given below:-

Date…….

Medical Device Testing Officer
Seal or Stamp

Form MD-33

[See rule 69]

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)

To

The Central Licensing Authority,

_____

_____

Sir/Madam,

1. Full name and address of the applicant .....
2. Occupation.....
3. Name of medical device purporting to be contained in the sample.....
4. Name and full address of the pharmacy or concern where the medical device was purchased.
5. Date on which purchased ..... (invoice attached)
6. Reasons why the medical device is being submitted for test or evaluation…….
7. A fee of rupees .....as charged by medical device testing laboratory has been paid under receipt number …….. dated: ……..

I hereby declare that the medical device being submitted for test or evaluation was purchased by or for me. I further declare that the sample of the medical device being sent for test or evaluation is exactly as it was purchased and has not been tampered with in any way to reduce its potency.

Date:……. Signature

Seal or Stamp

Form MD-34

[See rule 72]

Order under clause (c) of sub-section (1) of section of the Drugs and Cosmetics Act, 1940, (23 of 1940) requiring a person not to dispose of stock in his possession

Whereas, I have reason to believe that the stocks of medical devices in your possession, detailed below contravenes the provisions of Section 18 of the Drugs and Cosmetics Act, 1940 (23 of 1940);

Now, therefore, I hereby require you under clause (c) of sub-section (1) of Section 22 of the said Act, not to dispose of the said stock for a period of.....days from the date of this order.

Date:..... Medical Device Officer

Seal or Stamp

Details of stock of medical devices.

Date:..... Medical Device Officer

Seal or Stamp

Form MD-35
[See rule 74]
Receipt for stock of medical devices for record, register, document or material object seized under clause (c) or clause (cc) of sub-section (1) of Section 22 of the Drugs and Cosmetics Act (23 of 1940)

The stock of medical devices or records, registers, documents or material objects, detailed below has/have this day been seized by me under the provisions of clause (c) or clause (cc) of sub-section (1) of section 22 of the Drugs and Cosmetics Act, 1940 (23 of 1940), from the premises of ..... situated at .....

Date:..... Medical Device Officer
Seal or Stamp

Details of stock of medical devices or records, registers, documents or material objects seized.

Date:..... Medical Device Officer
Seal or Stamp

Form MD-36
[See rule 76]

Intimation of Person from Whom Sample is taken

To
……..
I have this day taken from the premises of ……. situated at ……. samples of medical devices specified below for the purpose of test or evaluation.

Date: ..... Medical Device Officer
Seal or Stamp

Details of sample of medical devices.

Date:..... Medical Device Officer
Seal or Stamp

Form MD-37
[See rule 77]

Receipt for Sample of medical device(s) taken where fair price tendered thereof under sub-section (1) of Section 23 of the Drugs and Cosmetics Act, 1940 is refused

To
……..
Whereas I, this …….. day of ……., have taken from the premises situated at ……. samples of medical devices as specified below:
Details of samples-

And whereas I had offered to you rupees …….. as the fair price of the samples of aforesaid medical devices taken:
And whereas, you have refused to accept the fair price tendered thereof;
Now, therefore, I give you this receipt as the fair price tendered for the samples of the medical devices taken by me.

Date:..... Medical Device Officer
Seal or Stamp

Form MD-38

[See sub-rule (1) rule 78]

Memorandum to Medical Device Testing Officer

Serial No. of Memorandum …….
From
To
The Medical Device Testing Officer

The sample of medical device described below is enclosed for test or evaluation under the provisions of clause (i) of sub-section (4) of section 23 of the Drugs and Cosmetics Act, 1940 (23 of 1940).
The sample of medical device has been marked by me with following mark.
……
Details of sample of medical device with name of medical device which is purports to contain-
……..

Date: _____ Medical Device Officer
Seal or Stamp

Form MD-39

[See sub-rule (1) of rule 81]

Application for grant of registration to Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf of manufacturer

1. Name of Applicant:
2. Nature and constitution of applicant:
   (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
3. (i) Corporate/ registered office address including telephone number, mobile number, fax number and e-mail id:
   (ii) Testing laboratory address including telephone number, mobile number, fax number and e-mail id:
   (iii) Address for correspondence:
   [corporate office/ testing laboratory]
4. Details of medical device(s) to be tested or evaluated [Annexed].
5. Fee paid on _____ Rs_____ receipt/challan/transaction id_____.
6. I have enclosed the documents as specified in the sub-rule (2) of rule 82 of Medical Devices Rules, 2017.
7. I hereby state and undertake that:
   (i) the testing laboratory is ready for inspection or shall be ready for inspection on ……... in accordance with the requirements of Medical Devices Rules, 2017.

   (ii) I shall comply with the applicable provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940), and the Medical Devices Rules, 2017.

Place: _____ Signature
Date: _____ (Name and designation)
[To be signed digitally]

Annexure:

S.N.	Generic name	Class of medical devices

Form MD-40

[See sub-rule (3) of rule 83]

Certificate of registration to Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf of manufacturer

Registration No.: …….

1. M/s, ……(Name of the firm) situated at ……(full address with telephone and e-mail) has been registered as a Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf of manufacturer under the Medical Devices Rules, 2017.

2. Details of medical device(s) to be tested or evaluated [Annexed].

3. This Registration is subject to the conditions as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: _____
Date: _____

Central Licensing Authority
[To be signed digitally]

Annexure:

S.N.	Generic name	Class of medical devices

[F. No. X. 11035/374/2016-DFQC]

K. L. SHARMA, Jt. Secy.

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