

**No. X. 11035/374/2016-DFQC
GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE**

**Nirman Bhavan, New Delhi 110008
Dated: 12.07.2016**

SUBJECT: MEDICAL DEVICE RULES, 2016

The Government of India has, after extensive consultations with all stakeholders prepared a draft notification v/z. Medical Device Rules, 2016 for regulating manufacturing/import/sale/clinical investigation and other related matters concerning medical devices. A copy of the draft Rules is annexed.

2. Comments, objections and suggestions, if any on these Rules, may be addressed to Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414 A, D-Wing, Nirman Bhavan, New Delhi - 110011, e-mail: rg.singh72@nic.in.


(K.L. SHARMA)

JOINT SECRETARY TO THE GOVERNMENT OF INDIA

(To be published in Part II, Section 3, Sub-section (i) of the Gazette of India,
Extraordinary, dated the, 2016)

Government of India
Ministry of Health and Family Welfare
(Department of Health and Family Welfare)

New Delhi, the, 2016

Notification.

G.S.R. _____ (E).- The following draft of the medical devices rules, which the Central Government proposes to make, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public.

The objections and suggestions which may be received from any person with respect to the said draft rules within the period specified above will be considered by the Central Government.

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414-A, D-Wing, Nirman Bhawan, New Delhi- 110011.

Draft rules

	PART I PRELIMINARY	
Short title	1. These rules may be called the Medical Device Rules, 2016.	
Application and commencement	2. (1) These rules shall be applicable in respect of,- (i) substances covered under sub-clause (i) of clause (b) of section 3 used for <i>in vitro</i> diagnosis; (ii) substances that are in the nature of mechanical devices covered under sub-clause (ii) of clause (b) of section 3; and (iii) devices specified from time to time by the Central Government by notification in the Official Gazette under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940). (2) These rules shall come in to force from such dates as may be notified by the Central Government after their final publication in the Official Gazette: Provided that the Central Government may notify different dates in respect of different class or category of medical devices.	

	<p>(3) Medical device already marketed in India prior to the commencement of these rules shall continue to be marketed as hitherto before subject to the condition that the manufacturer shall provide evidence of previous sale in India and apply for licence within a period of one hundred and eighty days from the date the device is notified under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940).</p> <p>(4) The Central Government shall, by notification, specify the date from which medical device referred in clause (2) shall be regulated in accordance with these rules.</p>	
	<p>(5) Medical device already notified under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 and marketed in India prior to the commencement of these rules shall continue to be marketed as hitherto before till the expiry of eighteen months or the current validity of the licence, whichever is later, from the commencement of these rules.</p>	
	<p><i>Explanation:</i> For the purposes of these rules, the <i>in vitro</i> diagnostic medical devices which are already marketed in India and governed under sub-clause (i) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 shall be deemed to be medical devices and shall also continue to be marketed as hitherto before till the expiry of eighteen months or the current validity of the licence, whichever is later, from the commencement of these rules.</p>	
Definitions.	<p>3. In these rules, unless the context otherwise require,-</p>	
	<p>(i) “academic clinical study” means a clinical study conducted on registered or approved medical device for any new intended use, new material of construction, new design or new population for academic purpose;</p>	
	<p>(ii) “accessory” means an article, which whilst not being a device, is intended specifically by the manufacturer to be used together with a specific medical device, to enable the medical device to be used in accordance with its intended use by the manufacturer of the device;</p>	
	<p>(iii) “Act” means the Drugs and Cosmetics Act, 1940 (23 of 1940);</p>	
	<p>(iv) “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;</p>	
	<p>(v) “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;</p>	
	<p>(vi) “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</p>	

	the treatment or alleviation of any illness, injury or handicap;	
	(vii) “authorised agent” means a person including any firm, organisation who has been appointed by the overseas manufacturer through a power of attorney authenticated in India either by a Magistrate of First Class or by Indian Embassy in the said country of origin or by an analogous authority through apostille to undertake import for sale or distribution of medical device in India;	
	(viii) “body orifice” means any natural opening in a human body, the external surface of any eyeball, or any permanent artificial opening, such as a stoma or permanent tracheotomy;	
	(ix) “Central Licensing Authority” means the Drugs Controller General of India appointed by the Central Government;	
	(x) “central medical devices testing centres” means a medical devices testing centre established or designated by Central Government under sub-rule (1) of rule 14;	
	(xi) “change in the constitution” in respect of,- (i) a firm means to change in proprietorship to 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 in the body corporate or in the 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 clause (a) or clause (b);	
	(xii) “clinical investigation” means the systematic study of an investigational medical device in or on human participants to assess its safety, performance or effectiveness;	
	(xiii) “clinical investigation plan” means a document containing background, objective, rationale, design, methodology including performance, management, adverse event, withdrawal and statistical consideration pertaining to clinical investigation;	
	(xiv) “clinical performance evaluation” means the systematic performance study of a new <i>in vitro</i> diagnostic medical device on a specimen collected from human participants to assess its safety and performance;	
	(xv) “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;	
	(xvi) “conformity assessment” means the systematic examination of evidence	

	generated and procedures undertaken, by the manufacturer, under the provisions of these rules, 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;	
	(xvii) “custom made medical device” means a medical device made specifically in accordance with a written prescription of a registered medical practitioner, specialized 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;	
	(xviii) “Ethics Committee” means committee referred under rule 44;	
	(xix) “Form” means forms specified in Appendix to these rules.	
	(xx) “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.	
	(xxi) “intended use” means use for which a medical device is intended according to the specifications laid down by its manufacturer as stated on any or all of the following: (i) the label of medical device; (ii) the instructions for use of medical device; (iii) promotional materials in relation to medical device;	
	(xxii) “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;	
	(xxiii) “investigational medical device” means a device which does not has a predicate device approved by the Central Licensing Authority being assessed for safety or performance in a clinical investigation including medical devices already in the market that are being evaluated for new intended uses, new populations, new materials or major design changes;	
	(xxiv) “licence” means a licence granted by the State Licensing Authority or Central Licensing Authority in Form MD7, Form MD11, Form MD13, Form MD15 or Form MD17, as the case may be;	
	(xxv) “loan licence” for manufacture means a licence, which a State Licensing Authority or Central Licensing Authority, as the case may be, may issue to an applicant who intends to utilize the manufacturing facility of another licence holder to manufacture medical device;	
	(xxvi) “long term use” means intended continuous use of a medical device for more than thirty days;	
	(xxvii) “manufacture” in relation to,- (i) medical device includes any process for designing, making, assembling, configuring, finishing, packing, sterilizing, labelling or adapting with a	

	<p>view to sell or distribute or stock but does not include a custom made device;</p> <p>(ii) <i>in vitro</i> diagnostic medical device includes any process for designing, making, assembling, configuring, labeling or packing with a view to sell or distribute or stock.</p>	
	<p>(xxviii) “manufacturer” means a person who himself manufactures a medical device and includes any other person who undertakes such manufacturing activity on his behalf;</p> <p><i>Explanation:</i> for the purpose of these rules, the person who has marketed or promoted any medical device or used any other similar expression printed, written, embossed or put in any manner on the medical device, shall be construed as the manufacturer.</p>	
	<p>(xxix) “medical device” means,-</p> <p>(a) any instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including the software, intended by its manufacturer to be used specially for human beings or animals for one or more of the specific purposes of,-</p> <ul style="list-style-type: none"> (i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder; (ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability; (iii) investigation, replacement or modification or support of the anatomy or of a physiological process; (iv) supporting or sustaining life; (v) disinfection of medical devices; (vi) control of conception; <p>which does not achieve the primary intended action in or on the human body or animals by any pharmacological or immunological or metabolic means, but which may be assisted in its intended function by such means, and covered under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940);</p> <p>(b) an accessory to such an instrument, apparatus, appliance, material or other article;</p> <p>(c) substances covered under sub-clause (i) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) used for <i>in vitro</i> diagnosis which is a reagent, calibrator, control material, kit, instrument, apparatus, equipment or system, specimen receptacle, whether used alone or in combination with any other reagent, calibrator, control material, kit, instrument, apparatus, equipment or system, that is intended by its manufacturer to be used <i>in vitro</i> for examination of any specimen, including any blood or tissue donation, derived</p>	

	<p>from the human body, solely or principally for the purpose of providing information,-</p> <ul style="list-style-type: none"> (i) concerning a physiological or pathological state or a congenital abnormality; (ii) to determine the safety and compatibility of any blood or tissue donation with a potential recipient thereof; or (iii) to monitor therapeutic measures; (d) substances in the nature of medical devices covered by sub-clause (ii) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940). 	
	(xxx) “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;	
	(xxxi) “medical device officer” means an officer appointed or designated by the Central Government or State Government, as the case may be, under rule 13;	
	(xxxii) “medical device testing officer” means an officer appointed or designated by the Central Government or State Government, as the case may be, under rule 13;	
	(xxxiii) “near-patient testing” means as 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 perhaps rapidly enough to affect immediate patient management;	
	<p>(xxxiv) “new <i>in vitro</i> diagnostic medical device” means an <i>in vitro</i> diagnostic medical device if:</p> <ul style="list-style-type: none"> (a) there has been no such device continuously available on the market in India during previous four years for the relevant analyte or other parameter related to such device; or (b) the procedure involves analytical technology not continuously used in connection with a given analyte or other parameter related to such device on the market in India during previous four years; 	
	(xxxv) “Notified Body” means a body corporate or other legal entity, notified by the Central Government, as competent body to carry out the audit of manufacturing site, assessment, and verification of specified category of medical devices for establishing conformity with standards and other requirements under these rules;	
	(xxxvi) “performance evaluation” in relation to <i>in vitro</i> diagnostic medical device means any systematic investigation by which data is assessed and analyzed to establish or verify the performance of the <i>in vitro</i> diagnostic medical device for its intended use.	
	(xxxvii) “Post Marketing Surveillance” means systematic process to collect and analyze information gained from medical device that have been placed in the	

	market;	
	(xxxviii) “predicate device” means a device, first time and first of its kind, approved by the Central Licensing Authority;	
	(xxxix) “reagent” means a chemical, biological or immunological component, solution or preparation intended by the manufacturer to be used as <i>in vitro</i> diagnostic medical device;	
	(xl) “serious adverse event” means an untoward medical occurrence that led to,- (i) a death; (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 hospitalization 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; (iii) foetal distress, foetal death or a congenital abnormality or birth defect.	
	(xli) “short term use” means intended continuous use of a medical device for not less than sixty minutes but not more than thirty days;	
	(xlii) “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;	
	(xliii) “sponsor” includes a person, 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.	
	(xliv) “State Licensing Authority” means the authority designated by the State Government under sub-rule (2) of rule 8;	
	(xlv) “state medical devices testing centre” means a medical devices testing centre established by State Government under sub-rule (2) of rule 14;	

	(xlvii) “transient use” means a device intended for continuous use for less than sixty minutes; means intended continuous use of a medical device for less than sixty minutes;	
	(xlviii) “transmissible agent”, for the purpose of classification of <i>in vitro</i> diagnostic medical device, means an agent capable of being transmitted to a person, which causes communicable, infectious or contagious disease.	
	Part II Regulation of Medical Device.	
Criteria for classification of medical devices.	4. Medical devices shall be classified, based on the severity of risk associated with a medical device, as specified in rule 5.	
Classification of medical devices.	5. (1) Medical devices other than <i>in vitro</i> diagnostic devices shall be classified on the basis of parameters specified in Part I of the <i>First Schedule</i> in to following classes, by the Central Government by notification in the Official Gazette- (i) low risk - Class A; (ii) low moderate risk- Class B; (iii) moderate high risk- Class C; (iv) high risk- Class D.	
	(2) <i>In vitro</i> diagnostic medical devices shall be classified and notified by the Central Government on the basis of parameters specified in Part II of the <i>First Schedule</i> in to the following classes,- (i) low risk - Class A; (ii) low moderate risk- Class B; (iii) moderate high risk- Class C; (iv) high risk- Class D.	
	(3) Manufacture of Class A medical devices referred in sub-rule (1) shall not be required to be licensed and such devices shall be self-regulated in accordance with the applicable standards. (4) Where the manufacturer of Class A medical device referred in sub-rule (3) voluntarily applies for licence for conformance with the regulatory requirements under these rules, the same shall be assessed by the Notified Body for conformance with the relevant part of the Quality Management System in accordance with the procedure specified in the rules.	
Medical device grouping.	6. Any person may, while applying for grant of licence for,- (i) import for sale or for distribution; (ii) manufacture for sale or for distribution; (iii) sale, stock, exhibit or offer for sale; group medical devices in the manner in accordance with the guidelines to be issued from time to time by the Central Licensing Authority by taking into consideration the technological changes or development in the field of medical devices and <i>in</i>	

	<i>vitro</i> diagnostic devices.	
Essential principles for manufacturing medical devices.	7. 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 Central Government from time to time keeping in view the contemporary scientific and technological knowledge and development.	
	Part III Authorities, Officers and Bodies.	
Central Licensing Authority, State Licensing Authority and Notified Body.	<p>8. (1) The Drugs Controller General of India shall be the Central Licensing Authority and shall be the competent authority for enforcement of these rules in matters relating to import, manufacture of Class C and Class D medical devices, clinical investigation and clinical performance evaluation of medical devices and other related functions:</p> <p style="padding-left: 40px;">Provided that where any manufacturer intends to manufacture Class C or Class D medical device along with Class A or Class B medical device, the Central Licensing Authority shall be the competent for enforcement of these rules and no separate licence from the State Licensing Authorities shall be required in respect of devices of Class A or Class B.</p>	
	<p>(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 manufacture of Class A or Class B medical devices, sale, stock, exhibit or offer for sale of medical devices and other related functions:</p> <p style="padding-left: 40px;">Provided that where any person intends to manufacture predicate medical device, prior approval from the Central Licensing Authority shall be necessary before applying to the State Licensing Authority.</p>	
	(3) Subject to the supervision by the State Licensing Authority, the Notified Body shall carry out audit of manufacturing sites of Class A or Class B medical devices to verify conformance with the Quality Management System and other applicable standards in respect of such devices.	
Delegation of power of Central Licensing Authority and State Licensing Authority.	9. (1) The Central Licensing Authority may, with the approval of the Central Government, by an order in writing, delegate all or any of its powers, to any other officer under its control.	
	(2) The officer to whom the powers have been delegated under sub-rule (1) shall exercise all its powers in the name and seal of the Central Licensing Authority.	
	(3) The State Licensing Authority, by whatever name called, may, with the approval of the State Government, by an order in writing, delegate all or any of its powers to any other officer under its control.	
	(4) The officer to whom the powers have been delegated under sub-rule (3) shall exercise all its powers in the name and seal of the State Licensing Authority.	
Designation of National Accreditation Body.	10. (1) The Central Government shall, by notification, designate any institute, firm or a Government aided or Government organisation as the National Accreditation	

	<p>Body.</p> <p>(2) The designated National Accreditation Body shall be responsible for carrying out the assessment of such entities who may apply for accreditation as the Notified Body for the purpose of these rules.</p> <p>(3) The National Accreditation Body referred in sub-rule (1), shall, after carrying out the assessment of the entity which applied for being accredited as a Notified Body under rule 12, issue a certificate to such entity in respect of specified medical devices.</p>	
Terms and conditions for National Accreditation Body.	11. The National Accreditation Body shall not act as a Notified Body, and shall,-	
	(1) identify the conformity assessment activities for accreditation of Notified Bodies and lay down standards for such accreditation;	
	(2) have a number of competent persons for proper performance of its functions;	
	(3) prepare norms and procedures for accreditation of Notified Body with the prior approval of the Central Government;	
	(4) audit the Notified Body periodically for assessing conformance with these rules and the norms laid down by the National Accreditation Body.	
Registration process for Notified Body.	12. (1) Any accredited Notified Body shall be required to be registered with the Central Licensing Authority before carrying out the audit of manufacturing site, assessment, and verification of specified category of medical devices for establishing conformity with standards and other requirements under these rules.	
	(2) An application for registration shall be made to the Central Licensing Authority in Form MD1 by the accredited Notified Body referred in sub-rule (1), accompanied with a fee specified in the <i>Second Schedule</i> along with the documents specified in Part I of the <i>Third Schedule</i> .	
	<p>(3) The Central Licensing Authority, on being satisfied, shall register the entity as a Notified Body and issue a certificate in Form MD2 which shall be valid till it is suspended or cancelled or the Notified Body on its own decides not to work as a Notified Body and notifies the Central Licensing Authority of the decision.</p> <p>(4) The Central Licensing Authority may, give a direction to the Notified Body to improve conditions in accordance with requirements of registration of the registration or suspend or cancel the registration of a Notified Body for reasons to be recorded in writing.</p> <p>(5) The accredited Notified Body shall perform the functions as specified in Part II of the <i>Third Schedule</i>.</p>	
	(6) The Central Licensing Authority may, in cases where the conditions for registration of Notified Body have not been complied with, reject the application and shall inform the applicant of the reasons for such rejection.	
	(7) An applicant who is aggrieved by the refusal of registration under sub-rule (5), may within thirty days from the date of receipt of such order, appeal to the Central Government, and the Central Government may, after such enquiry into the matter, as considered necessary and after giving the said body an opportunity of being heard, pass such order in relation thereto as it thinks fit.	
Medical Device Testing Officer or Medical Device	13. (1) The Central Government, or the State Government, may designate a	

Officer.	Government Analyst appointed under section 20 of the Act as Medical Device Testing Officer and an Inspector appointed under section 21 of the Act as Medical Device Officer.	
	(2) The Medical Device Testing Officer and Medical Device Officer designated under sub-rule (1), while exercising the powers and duties under these rules, shall be deemed to have been appointed as the Government Analyst and Inspector, respectively.	
Medical device testing centre.	14. (1) The Central Government may, by notification, establish or designate Central medical devices testing centre or laboratory or any other centre for,- (a) testing and evaluation of medical devices; (b) functioning as an appellate centre or laboratory; (c) carrying out any other function as may be specifically assigned.	
	(2) The State Government may, by notification, establish State medical devices testing centre or laboratory for test or evaluation of medical devices and carrying out any other function as may be specifically assigned.	
	(3) Medical Device Testing Centre involved for test or evaluation of medical devices other than <i>in vitro</i> diagnostic medical devices on behalf of the manufacturer shall be accredited by the National Accreditation Body designated under rule 10.	
	(4) Medical Device Testing Centre involved for test or evaluation, of <i>in vitro</i> diagnostic medical devices specified time to time by the Central Government, on behalf of the manufacturer shall be accredited by National Accreditation Board for Testing and Calibration Laboratories or any other similar body as may be notified by the Central Government for such accreditation.	
	Part IV Manufacture of Medical Devices for sale or for distribution	
Application for manufacture for sale and distribution of medical device.	15. (1) Save as provided in sub-rule (4) of rule 5, an application shall be made to the State Licensing Authority through an identified online portal of the Central Government for licence to manufacture for sale or for distribution of Class A or Class B medical devices in Form MD3. (2) An application shall be made by the applicant to the Central Licensing Authority through an identified online portal of the Central Government for licence to manufacture for sale or for distribution of Class C or Class D medical device in Form MD4. (3) Where any manufacturer intends to manufacture Class C or Class D medical device along with Class A or Class B medical device, an application shall be made to the Central Licensing Authority through an identified online portal of the Central Government for licence to manufacture for sale or for distribution in Form MD4.	
	(4) The application in Form MD4 referred in sub-rule (2), relating to Class A medical devices referred under sub-rule (4) of rule 5, shall be accompanied with a	

	<p>fee as specified in the <i>Second Schedule</i> along with documents specified in clause (i) of Part II of the <i>Fourth Schedule</i>.</p> <p>(5) The application in Form MD3 or Form MD4 referred in sub-rule (1), (2) and (3), relating to Class B, Class C or Class D medical device, as the case may be, shall be accompanied with a fee as specified in the <i>Second Schedule</i> along with documents as specified in clause (ii) of Part II of the <i>Fourth Schedule</i>.</p>	
	<p>(6) The Central Licensing Authority may, wherever required, in case of Class C or Class D medical device, use the services of experts for matters relating to inspection or review of the documents:</p> <p style="text-align: center;">Provided that the powers and functions under this rule shall be exercised by the Central Licensing Authority till such time the Central Government is satisfied that the requisite technical competence has been acquired by the State Licensing Authority.</p>	
Loan licence to manufacture for sale and distribution.	<p>16. (1) An application for grant of loan licence to manufacture for sale or distribution of Class A medical device referred under sub-rule (4) of rule 5, or Class B medical devices, as the case may be, shall be made to the State Licensing Authority in Form MD5 accompanied with fee as specified in the <i>Second Schedule</i> along with documents as specified in clause (i) of Part II or clause (ii) of Part II of the <i>Fourth Schedule</i>, as the case may be.</p>	
	<p>(2) An application for grant of loan licence to manufacture for sale or for distribution of Class C or Class D medical devices, as the case may be, shall be accompanied with a fee as specified in the <i>Second Schedule</i> along with documents as specified in clause (ii) of Part II of the <i>Fourth Schedule</i> including details of the constitution of the firm, manufacturing premises plan or layout, full particulars of competent and regular technical staff, artwork of product literature, package insert or instruction for use, proposed device labels, shall be made to the Central Licensing Authority in Form MD6.</p>	
	<p>(3) Where any manufacturer intends to manufacture Class C or Class D medical device along with Class A or Class B medical device, an application for grant of loan licence shall be made as per sub-rule (3) of rule 15 to the Central Licensing Authority in Form MD6.</p>	
	<p>(4) The Central Licensing Authority may, wherever required, in case of Class A, Class B, Class C or Class D medical device, use the services of external agencies or bodies for matters relating to inspection or review of documents.</p>	
Conditions to be complied before grant of manufacturing licence or loan licence.	<p>17. Before grant of licence or loan licence, the following conditions shall be complied with by the applicant,-</p>	
	<p>(i) Manufacturing activity of medical device shall be undertaken only under the direction and supervision of competent technical staff and who has,-</p>	

	<p>(a) degree in engineering (in appropriate branch) or in pharmacy or in science in appropriate subject and shall have experience of not less than two years; or</p> <p>(b) diploma in engineering (in appropriate branch) or in pharmacy and shall have the experience of not less than four years in manufacturing of medical devices.</p>	
	(ii) The testing shall be conducted under the direction and supervision of the competent technical staff having degree or diploma in engineering in appropriate branch or in pharmacy or in science in appropriate subject and shall have the experience of not less than two years in testing of medical devices.	
	(iii) The manufacturing site shall comply with the requirements of the <i>Fifth Schedule</i> .	
Audit or inspection before grant of licence for manufacture.	<p>18. Before grant of licence under this part,-</p> <p>(i) in respect of Class A medical device referred under sub-rule (4) of rule 5 or Class B medical devices, the establishment where manufacture of such device is proposed to be undertaken shall be audited by the Notified Body;</p> <p>(ii) in respect of Class C or Class D medical devices, the establishment in which the manufacture is or proposed to be undertaken shall be inspected by the Medical Device Officer with or without an expert in the concerned field for adequacy and suitability;</p>	
Report by Medical Device Officer or Notified Body.	<p>19. (1) The Notified Body shall forward a detailed descriptive report giving findings on each aspect of audit along with recommendations after completion of audit in accordance with the provisions of rule 18, to the State Licensing Authority or Central Licensing Authority, as the case may be, through online portal of the Government referred in rule 15, with a copy to the manufacturer.</p> <p>(2) The Medical Device Officer shall forward a detailed descriptive report giving findings on each aspect of inspection along with recommendations after completion of inspection in accordance with the provisions of rule 18, to the Central Licensing Authority, through online portal of the Central Government referred in rule 15, with a copy to the manufacturer.</p>	
Grant of licence to manufacture for sale and distribution of medical device.	<p>20. (1) If the State Licensing Authority or the Central Licensing Authority, as the case may be, after such further enquiry, if any, as may be considered necessary, is satisfied that the requirements of these rules have been complied with, it shall issue a licence in Form MD7, or loan licence in Form MD8, as the case may be:</p> <p>Provided that where a manufacturing licence has been granted to any manufacturer under Drugs and Cosmetics Rules, 1945, before the date of commencement of these rules, such manufacturing licence shall be deemed to have been granted as licence under the provision of these rules for the remaining period of the said licence.</p>	
	(2) If the State Licensing Authority or the Central Licensing Authority, as the case may be, is not satisfied, it may reject the application and shall inform the applicant	

	of the reasons in writing for such rejection.	
Conditions for manufacturing licence or loan licence.	<p>21. After the grant of licence or loan licence, the licence holder shall comply with the following conditions, namely:-</p> <ul style="list-style-type: none"> (i) licence shall be kept on the approved premises and shall be produced when requested by the Medical Device Officer; (ii) the licence holder shall inform about the occurrence of any suspected unexpected serious adverse event and action taken thereon including any recall to the State Licensing Authority or Central Licensing Authority, as the case may be, within 15 days of such event being brought to the notice of licence holder; (iii) the licence holder shall inform forthwith any major change as specified in the <i>Sixth Schedule</i> to the State Licensing Authority or Central Licensing Authority, as the case may be, for its approval; (iv) the licence holder shall inform forthwith any minor change as specified in the <i>Sixth Schedule</i> to the State Licensing Authority or Central Licensing Authority, as the case may be; (v) the licence holder shall inform the State Licensing Authority or the Central Licensing Authority, as the case may be, in writing within a period of thirty days in the event of change other than change of constitution of the manufacturer or change referred in condition (iii) above. The manufacturer shall submit the confirmation that no changes in specification, labelling or technical staff has been made; (vi) the licence holder shall carry out test of each batch of final product prior to its release for compliance to specification either in his own testing centre or in any accredited testing centre and shall maintain records of such tests for a period of one year after expiry of the medical device; (vii) 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 by the licensing authority not conforming with the provisions specified under the rules and on being directed so to do, 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; (viii) the licence holder shall maintain an audit or inspection book in Form MD9 to enable notified body or medical device officer to record his impressions and the defects noticed; (ix) the licence holder shall maintain at least two units of samples from each batch of the invasive medical device manufactured by him for reference purpose. (x) the license holder shall maintain records of manufacturing and sales which shall be open to inspection by a medical device officer. 	

	<p>(xi) the licence holder shall supply the medical device for sale, offer for sale along with its package insert.</p> <p>(xii) in case if the manufacturer has closed down the manufacturing site, the same shall be intimated to the Central Licensing Authority or State Licensing Authority, as the case may be.</p>	
Fresh Application in case of change in constitution.	<p>22. In case of change in constitution after grant of licence under rule 20, the manufacturer shall make an application under rule 15 for grant of licence within a period of ninety days from the date of such change in constitution:</p> <p>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.</p>	
Unannounced audit by State Licensing Authority.	<p>23. The State Licensing Authority shall have at least two per cent. of the cases of licence recommended by every Notified Body annually, audited by its officers, and such cases shall be selected on a random basis.</p>	
Duration of licence.	<p>24. (1) A licence or loan licence shall remain valid, unless, it is suspended or cancelled, provided the licence holder deposits a licence retention fee as specified in the <i>Second Schedule</i> in every five years from the date of its issue.</p>	
	<p>(2) If the licence holder fails to pay licence retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent. of the licence fee for every month or part thereof up to six months, in the event of non-payment of such fee, the licence shall be deemed to have been cancelled.</p>	
Suspension and cancellation of manufacturing licence.	<p>25. (1) Where the licence holder contravenes any provision of these rules, the State Licensing Authority or the Central Licensing Authority, as the case may be, may, after giving the licence holder an opportunity to show cause why such an order should not be passed, shall by an order in writing including the reasons thereof suspend it for such period as it thinks fit either wholly or in respect of any of the medical device or cancel the licence or loan licence.</p>	
	<p>(2) A licence holder whose licence or loan licence has been suspended or cancelled by the State Licensing Authority or Central Licensing Authority, as the case may be, under sub-rule (1), may within sixty days of the receipt of a copy of the order by him, prefer an appeal to the State Government or Central Government, as the case may be, and State Government or the Central Government, as the case may be, may after giving the licence holder an opportunity of being heard, confirm, reverse or modify such order.</p>	
	<p>(3) Any licence suspended in accordance with these rules shall not be revoked by the State Licensing Authority or the Central Licensing Authority without a detailed written order indicating the reasons for such suspension and the extent of compliance vis-à-vis the deficiencies that led to suspension and publishing the order on its website.</p>	

	(4) All orders of suspension issued or revoked or cancellation of licence shall be duly published on the websites of the State Licensing Authority concerned and the Central Licensing Authority.	
	(5) The State Licensing Authority or the Central Licensing Authority, as the case may be, may order destruction of such stock of medical device in the presence of a Medical Device Officer, if in its opinion, the licence holder has failed to comply with any of the conditions of the licence or loan licence or with any provisions of the Act or rules made thereunder.	
Product Standards for medical device.	<p>26. The medical devices shall conform to the standards,-</p> <p>(1) laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or the Central Government from time to time;</p> <p>(2) If there is no relevant Standard laid down by the Bureau of Indian Standard or the Central Government, then it shall conform to the standard laid down by International Organisation for Standards (ISO) or other Pharmacopeial standard;</p> <p>(3) In case, national or international standards are not available, the device shall conform to the manufacturer's standards which are validated.</p>	
Manufacturing of medical devices for clinical investigation, test, evaluation, examination and demonstration.	27. (1) Small quantity of any class of medical device may be manufactured for the purpose of clinical investigations, test, evaluation, examination, demonstration or training for which an application shall be made in Form MD10 to the Central Licensing Authority and shall be accompanied with a fee as specified in the <i>Second Schedule</i> .	
	(2) On receipt of an application for test licence in the form and manner specified in sub-rule (1) and (2), the Central Licensing Authority shall, on being satisfied, grant the test licence in Form MD11.	
	(3) The licensee shall keep a record of, and shall report to the Central Licensing Authority, the date and quantity of product manufactured under test licence.	
Duration of licence for clinical investigations, test, analysis, demonstration and training.	28. A licence in Form MD11 shall, unless cancelled earlier, be in force for a period of three years from the date of issue.	
Cancellation of licence for clinical investigations, test, analysis, demonstration and training	29. (1) Where the licensee contravenes any provision of these rules, the Central Licensing Authority may, after giving him an opportunity in writing, to show cause as to why such an order should not be made, by an order stating the reasons therefor, suspend for such period as he may be deemed proper, or cancel the test licence.	
	(2) Where the licensee is aggrieved by an order made by the Central Licensing Authority under sub-rule (1), he may, within thirty days of the receipt of the order, prefer an appeal to the Central Government and that the Central Government may, after such enquiry as it considers necessary and after affording an opportunity of	

	being heard, issue such order as it may deem proper.	
	Part V Import of Medical Devices	
Application for issue of licence of overseas manufacturing site and import of medical device.	<p>30. (1) The Central Licensing Authority shall have the powers to grant licence and perform other related functions for import of medical devices specified in sub-rule (1) and (2) of rule 5.</p> <p>(2) An authorised agent having, licence to manufacture for sale or licence to sale by way of wholesale under these rules, shall make an application for import of such medical device to the Central Licensing Authority in Form MD12 for obtain a licence.</p>	
	<p>(3) The application under sub-rule (2) shall be accompanied with fee as specified in the <i>Second Schedule</i> along with documents as specified in the Part I, II, and III of the <i>Fourth Schedule</i>:</p> <p style="padding-left: 40px;">Provided that any change in the documents submitted at the time of application and prior to grant of licence shall be notified to the Central Licensing Authority.</p>	
	<p>(4) (i) Any subsequent application for grant of licence of additional manufacturing site made by the same authorised agent shall be accompanied with a fee as referred in sub-rule (3);</p> <p>(ii) Any subsequent application for licence of additional medical device made by the same authorised agent shall be accompanied with the fee as specified in the <i>Second Schedule</i> for each medical device;</p> <p>(iii) In case of any subsequent application for grant of licence of different variants of already registered family is made by the same authorised agent, the additional fee as specified in the <i>Second Schedule</i> shall be paid for each variant.</p>	
	(5) A single licence may be granted to an authorised agent in India in respect of one or more medical devices manufactured at one or more manufacturing sites.	
	(6) Where the Central Licensing Authority has a reasonable doubt about the quality of the medical device and decides to subject it to evaluation, test or examination, the fee as charged by concerned testing Centre shall be paid by the authorised agent for such evaluation, test or examination directly to the testing laboratory as specified by the Central Licensing Authority.	
	(7) Where the original licence is defaced, damaged or lost, the authorised agent may make an application accompanied with fee as specified under the <i>Second Schedule</i> for duplicate copy of such licence.	
Inspection of overseas manufacturing site.	31. The Central Licensing Authority may cause an inspection of the overseas manufacturing site either by itself or by any other person to whom the power has been delegated for the purpose and the applicant shall be liable to pay a fee as specified under the <i>Second Schedule</i> in respect of expenditure required in connection with the visit to the overseas manufacturing site.	

Grant of licence of medical device and manufacturing site for import.	32. (1) On receipt of an application under sub-rule (2) of rule 30, the Central Licensing Authority shall, on being satisfied about the information and the documents enclosed with the application, grant the licence in Form MD13:	
	Provided that where licence has been granted to the authorised agent before the date of commencement of these rules, such licence certificate shall be deemed to have been granted under the provisions of these rules for the remaining period of the said licence.	
	(2) A licence shall be granted under sub-rule (1) if the medical device is having free sale certificate from the national regulatory authority or competent authority of the United States of America, European Union countries, Canada, Australia and Japan.	
	(3) Where the medical device is proposed to be imported from countries other than those referred to in sub-rule (2), the licence in case of Class C and Class D medical devices may be granted after its safety and effectiveness has been proved or established through clinical investigation in India as specified under Part VII of these rules.	
Duration of licence.	33. (1) A licence shall remain valid, unless, it is suspended or cancelled, provided the authorised agent deposits a licence retention fee as specified in the <i>Second Schedule</i> for each overseas manufacturing site and for each device in every five years from the date of its issue	
	(2) If the authorised agent fails to pay licence retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent. of the licence retention fee for every month or part thereof up to six months and thereafter the licence shall be deemed to have been cancelled.	
Conditions to be complied with by authorised agent.	34. The licence holder shall comply with the following conditions, namely:- (i) The licence shall be kept and made available in the licensed premises; (ii) The authorised agent shall inform the licensing authority forthwith in the event of any administrative action taken due to adverse reaction, viz. Market withdrawal, regulatory restrictions, cancellation of authorisation or not of standards quality report of any medical device pertaining to this licence declared 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) The authorised agent in cases referred in condition (ii), shall stop immediately the dispatch and marketing of the medical device; (iv) The Central Licensing Authority after due consideration may issue directions in respect of marketing, sale or distribution of the medical device referred in condition (iii) including withdrawal of medical device from Indian market within a specified time period; (v) The authorised agent shall obtain prior approval from the Central Licensing Authority in case of any change in the intended use or any major change as	

	<p>specified in the <i>Sixth Schedule</i> of medical devices classified under Class B, Class C or Class D;</p> <p>(vi) the authorised shall inform forthwith any minor change as specified in the Sixth Schedule to the State Licensing Authority or Central Licensing Authority, as the case may be;</p> <p>(vii) The 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 authorized agent;</p>	
	<p>(viii) Where the Central Licensing Authority is satisfied that the sample of any medical device is not in conformity with the provisions of these rules, it may issue direction for not to sell or offer for sale, or to recall or withdraw, such medical device;</p>	
	<p>(ix) the consignment of medical device shall be accompanied by an invoice or statement showing the name and address of the manufacturer and the name and quantity of medical device.</p> <p>(x) the licence holder shall supply the medical device for sale, offer for sale along with its package insert.</p>	
Fresh Application in case of change in constitution.	<p>35. In case of change in constitution after grant of licence under rule 32, the importer shall make an application under rule 30 for grant of licence within a period of ninety days from the date of such change in constitution:</p> <p style="padding-left: 40px;">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.</p>	
Test licence for import for the purpose of clinical investigations, test, evaluation, demonstration or training	<p>36. (1) Medical device or <i>in vitro</i> diagnostic medical device, the import of which is otherwise not approved, may be allowed by the Central Licensing Authority to be imported in such quantities as may be necessary for the purpose of clinical investigations, test, evaluation, and demonstration or training.</p> <p>(2) The quantity considered necessary shall be determined by the Central Licensing Authority after taking into account the clinical investigation or approved clinical investigation plan or information and documents submitted by the applicant.</p>	
	<p>(3) An application for an import licence for test, evaluation or demonstration or training shall be made to the Central Licensing Authority in Form MD14 and shall be accompanied by the fee as specified in the <i>Second Schedule</i>.</p>	
	<p>(4) On receipt of an application under sub-rule (2), the Central Licensing Authority shall, on being satisfied about the contents and the documents enclosed with the application, grant the test licence in Form MD15.</p>	
	<p>(5) The medical device for which the test licence is granted under sub-rule (4), shall, be used exclusively for purposes of clinical investigation, test, evaluation, demonstration or training, as the case may be, and such clinical investigations, test, evaluation, demonstration or training, shall be conducted in the place specified in</p>	

	such test licence.	
	(6) The holder of test licence shall maintain record of the activities undertaken including the name of manufacturer, quantity imported and date of import.	
	(7) The consignment of medical device shall be accompanied by an invoice or statement showing the name and address of the manufacturer and the name and quantity of medical device.	
	(8) A licence in Form MD15 shall, unless cancelled earlier, be in force for a period of three years from the date of issue.	
	(9) The medical devices including <i>in vitro</i> diagnostic medical device referred in sub-rule (5) that are not used may be permitted to be exported or destroyed under intimation to the Central Licensing Authority.	
Import of investigational medical device by Government hospital or statutory medical institution for treatment of patient.	37. (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 the Medical Officer through the medical superintendent of a Government hospital or a statutory medical institution in Form MD16 and such application shall be accompanied by documents required and the fee as specified in the <i>Second Schedule</i> .	
	(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 the import licence for treatment of patient in Form MD17.	
	(3) The medical device for which the licence is granted under sub-rule (2), shall, be used exclusively for the purpose of treatment of patient declared in the application.	
	(4) The holder of licence shall maintain record of activities undertaken including the name of the manufacturer, quantity imported and used, date of import, name and address of the patient and diagnosis.	
	(5) The holder of 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 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 the 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 address of the manufacturer and the name and quantity of medical device.	
Import of medical device for personal use.	38. (1) Small quantity of medical device, the import of which is not allowed, may be imported for personal use, on an application made by applicant in Form MD18 which shall be accompanied by documents confirming that the device is for legitimate personal use.	
	(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 permission in Form MD19.	
	(3) The medical device shall be imported subject to the following conditions, namely:- (i) the medical device shall be deemed to be part of the baggage of a passenger or patient and be intended for, the exclusive use of the patient; (ii) the medical device shall be declared as the personal property to the Customs Authorities if they so direct ; (iii) the quantity to be imported is reasonable in the opinion of the Central Licensing Authority; (iv) the medical device is prescribed by a registered medical practitioner; and (v) the consignment of medical device shall be accompanied by an invoice or statement showing the name and address of the manufacturer and the name and quantity of medical device.	
	(4) Where the Central Licensing Authority is satisfied, it may, in exceptional and special circumstances, allow the import of larger quantity of medical devices for use by the patient.	
	Part VI Labelling of Medical Devices	
Labelling of medical devices.	39. 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 such medical device and on every outer covering in which the medical device is packed, namely:- (a) proper name of medical device; (b) the details necessary for the user to identify the device and its use; (c) the name of the manufacturer and address of the manufacturing premises where the device has been manufactured; (d) the correct statement of the net quantity in terms of weight, measure, volume, number of units, as the case may be, and the number of devices contained in the package, shall be expressed in metric system; and (e) the date of manufacture and date of expiry; alternately the label shall bear the shelf life of the product: Provided that in case of sterile devices, the date of sterilization may	

	<p>be given as the date of the manufacture of the device:</p> <p>Provided further that when the device is made up of materials such as stainless steel or titanium and supplied non-sterile, date of expiry may not be necessary;</p> <p><i>Explanation:</i> For the purpose of this rule, the date of expiry shall be in terms of month and year and it shall mean the medical device is recommended till the last day of the month. The date of expiry shall be preceded by the words 'Expiry date'.</p> <p>(f) to provide, wherever required, an indication that the device contains medicinal or biological substance;</p> <p>(g) to provide, a distinctive batch number or lot number preceded by the word "Lot No." or "Lot" or "Batch No." or "B. No.";</p> <p>(h) to indicate, wherever required, any special storage or handling conditions applicable to the device;</p> <p>(i) to indicate, if the device is supplied as a sterile product, its sterile state and the sterilisation method;</p> <p>(j) to give, if considered relevant, warnings or precautions for the attention of the user of the medical device;</p> <p>(k) to label the device, if the device is intended for single use;</p> <p>(l) to overprint on the label of the container, the words "FOR CLINICAL INVESTIGATION ONLY", if the device is intended for clinical investigation;</p> <p>(m) 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;</p> <p>(n) to provide, except for imported devices, the manufacturing licence number by preceding the words "Manufacturing Licence Number" or "Mfg. Lic. No." or "M. L.";</p> <p>(o) devices or In-vitro diagnostics which are not sold to customer or patient directly and are sold for use by hospitals or diagnostic labs shall provide the information affixing additional label or sticker on outer shelf pack;</p> <p>(p) to provide unique device identification of the medical device which shall contain device identifier and production identifier.</p> <p><i>Explanation:</i> for the purpose of this rule,-</p> <p>(i) "device identifier" means global trade item number.</p> <p>(ii) "production identifier" means serial number, lot or batch number, software as a medical device version, manufacturing and or expiration date.</p> <p>(q) to provide on the label, in case of imported devices, with the approval of the Central Licensing Authority, the import licence number, name and address of the importer and address of the actual manufacturing premises, date of manufacture, (if not already printed at the time of import) may be stickered or overprinted on outer shelf pack:</p>	
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	<p>Provided that the label may bear symbols recognised by the Bureau of Indian Standards or International Organisation for Standardization (ISO) in lieu of 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.</p> <p>Provided that all such medical devices on which the information cannot be printed legibly due to the small size constraints, shall include the information necessary for product identification and safety viz. information covered by clauses (a), (b), (c), (g) and (k) above.</p>	
Exemption of certain labelling requirements for medical devices for export from India.	<p>40. 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 of the medical device in which the device is packed and every other outer covering in which the container is packed:-</p> <p>(a) name of the Device;</p> <p>(b) the distinctive batch number or lot number preceded by the word “Lot No.” or “Lot” or “Batch No.” or “B.No.”;</p> <p>(c) date of expiry, if any;</p> <p>(d) the name and address of the manufacturer and address of actual premises where the device has been manufactured;</p> <p>(e) licence No. preceded by the letters “Licence No. or Lic. No.”.</p> <p>(f) internationally recognised symbols in lieu of text, wherever required:</p> <p>Provided that where a device is required by the consignee not to be labeled with the name and address of the manufacturer, the label on the packages 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”.</p> <p>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 licensing authority.</p>	
Shelf life of the medical devices.	<p>41. The shelf life of the medical devices shall not exceed sixty months from the date of manufacture:</p> <p>Provided that this period may be extended by the Central Licensing Authority, in respect of any specified medical device, if satisfactory evidence is produced by the manufacturer to justify such extension:</p>	
	<p>Provided that the licensing authority shall not allow the import of any medical device, whose total shelf life claim is less than three months, having less than forty per cent. residual shelf-life period as on the date of import.</p>	

	Provided further that the licensing authority shall not allow the import of any medical device, whose total shelf life claim is between three months and one year, having less than fifty per cent. residual shelf-life period as on the date of import.	
	Provided also that the licensing authority shall not allow the import of any medical device, whose total shelf life claim is more than one year, having less than sixty per cent. residual shelf-life period as on the date of import.	
Labelling of medical device import or manufactured for purpose of clinical investigations, test, analysis, demonstration and training.	42. Any medical device imported or manufactured, for the purpose of clinical investigations, test, evaluation, demonstration and training, shall be kept in containers bearing labels, indicating name of the product or code number, batch or lot number, date of manufacture, use before date, storage conditions, name and address of the manufacturer, and the purpose for which it has been manufactured.	
	PART VII CLINICAL INVESTIGATION OF MEDICAL DEVICE AND CLINICAL PERFORMANCE EVALUATION OF NEW <i>INVITRO</i> DIAGNOSTIC MEDICAL DEVICE	
Conduct of clinical investigation.	43. 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.	
Application of Rule 122DD of Drugs and Cosmetics Rules, 1945 with regard of Ethics Committee.	44. (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 other provisions of Ethics Committee provided in rule 122DD of the Drugs and Cosmetics Rules, 1945 shall be applicable <i>mutatis mutandis</i> , for the purpose of clinical investigation and clinical performance evaluation under this part.	
Application for grant of permission to conduct and carry out clinical investigation.	45. (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 MD20 by a sponsor and shall be accompanied with information specified in the <i>Seventh Schedule</i> : Provided, that the investigational medical devices approved for marketing by <i>United States Food and Drug Administration</i> shall be waived off from the requirements of the clinical investigation under this Part.	
	(2) An application for grant of permission to conduct,- (a) a pilot clinical investigation or first in human study, on an investigational medical device in India shall be made as referred to in sub-rule (1) accompanied with fee as specified in the <i>Second Schedule</i> along with the information as specified in the <i>Seventh Schedule</i> . (b) a pivotal clinical investigation on an investigational medical device shall be made on the basis of data emerging from pilot clinical investigation, as referred in	

	sub-rule (1), accompanied with a fee as specified in the <i>Second Schedule</i> :	
	Provided that no fee shall be paid by any institute, organization, hospital run or funded by the Central Government or State Government, as the case may be, for conduct of clinical investigation.	
	(3) No permission for conduct of academic clinical study on registered or approved medical device shall be required, where,- (a) the investigation is approved by the Ethics Committee; and (b) the data generated shall not be used to furnish it to the Central Licensing Authority for manufacture or import to market investigational medical device in the country.	
	(4) The Central Licensing Authority may, in public interest, abbreviate, defer, or waive the requirement of conducting clinical investigation for reasons to be recorded in writing before granting permission to import or manufacture investigational medical device in the country.	
	(5) Medical device requiring clinical investigation but claiming substantial equivalence to a predicate device shall not be marketed unless the Central Licensing Authority has approved it.	
	<i>Explanation</i> -. 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;	
	(6) The Central Licensing Authority, after being satisfied with the information furnished along with application under sub-rule (1), may grant permission to conduct clinical investigation for an investigational medical device in Form MD21:	
	Provided that the Central Licensing Authority shall, where the information including clinical investigation is inadequate as per the <i>Seventh Schedule</i> , intimate the applicant in writing, within ninety days from the date of application or such extended period, not exceeding a further period of thirty days, as the Central Licensing Authority may, for reasons to be recorded in writing, permit, the conditions which shall be satisfied before permission could be considered: Provided that if the applicant has not furnished the required information sought by the Central Licensing Authority, within ninety days from the date of intimation, it may reject the application for reasons to be recorded in writing.	
Condition for permission.	46. After grant of permission referred in rule 45 the following conditions shall be complied with by the applicant,-	
	(i) clinical investigation shall be initiated under the supervision of an approved Ethics Committee;	
	(ii) clinical investigation shall be conducted in compliance with the approved clinical investigation plan, Good Clinical Practices Guidelines and provisions	

	of the <i>Seventh Schedule</i> ;	
	(iii) clinical investigation shall be registered with the Clinical Trial Registry of India before enrolling the first patient 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 also 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 to the Central Licensing Authority within fifteen days of the sponsor coming to know about its occurrence as specified in the <i>Seventh Schedule</i> and in compliance with the procedure specified in these rules.	
	(vi) in case of an injury or death during clinical investigation of the subject of a clinical investigation, the applicant shall provide complete medical management and compensation in case of clinical investigation related injury or death 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 to inspection by officers of Central Licensing Authority or authorised personnel of Notified Bodies under these rules, to verify compliance of the requirements of these rules for conduct of clinical investigation.	
	(viii) the clinical investigation shall be initiated by enrolling first patient within the period of one year from the date of grant of permission, failing which prior permission from the Central Licensing Authority is required.	
	(ix) the Central Licensing Authority may impose any other 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.	
Suspension or cancellation of permission.	<p>47. (1) If any person to whom permission is granted under this part fails to comply with any of conditions of permission, the Central Licensing Authority may,-</p> <ul style="list-style-type: none"> (a) issue warning letter giving details of deficiency found; or (b) debar the investigator, sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors to conduct any clinical investigation in future; or (c) suspend the permission for such period as it thinks fit or cancel either wholly or partly to which it relates; 	

	(2) Any person who is aggrieved by the order passed under sub-rule (1), may, within thirty days from the date of receipt of such order, prefer an appeal to the Central Government, and the Central Government may, after such enquiry into the matter, as is considered necessary and after giving an opportunity of being heard, pass such order in relation thereto as, it thinks fit.	
Medical management and compensation for injury or death related to clinical investigation.	48. (1) Where any participant is injured on account of his participation in the clinical investigation, the sponsor permitted under rule 45 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 45 shall provide to that participant, medical management and such compensation in such manner as specified under rule 122DAB of the Drugs and Cosmetics Rules, 1945 and shall be applicable <i>mutatis mutandis</i> , for the purpose of medical management and such compensation in case of clinical investigation and clinical performance evaluation under this part.	
	(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 45 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 and shall be applicable <i>mutatis mutandis</i> , for the purpose of such compensation in case of clinical investigation and clinical performance evaluation under this part.	
Power of Medical Devices Officer in respect of clinical investigation or clinical performance evaluation.	49. The Medical Devices Officer, with or without expert, with the prior approval of the Central Licensing Authority may, with or without prior notice, enter into any premises related to clinical investigation or clinical performance evaluation to inspect the facilities, search and seize, record, data, documents, books, and medical devices including investigational medical devices.	
Maintenance of record and furnishing information.	50. Every person, sponsor, clinical research organisation, any other organisation or investigator conducting a clinical investigation or clinical performance evaluation or his agent holding a permission under this part shall keep and maintain such data, record, registers and other documents for a period of twenty years 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 49.	
Disclosure of name, address, etc. of persons involved in clinical investigation or clinical performance evaluation.	51. Every person, sponsor, clinical research organisation, any other organisation or investigator conducting a clinical investigation or clinical performance evaluation or his agent, 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 conducting clinical investigation or clinical performance evaluation and similar	

	details in respect of participants in such clinical investigation or clinical performance evaluation.	
Permission to Conduct of clinical performance evaluation for new <i>in vitro</i> diagnostic medical device	52. (1) No person or sponsor shall conduct any clinical performance evaluation in respect of a new <i>in vitro</i> diagnostic device on specimen, including any blood or tissue donation, derived from the 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.	
	<p>(2) An application for grant of permission to conduct, clinical performance evaluation of new <i>in vitro</i> diagnostic device shall be made to the Central Licensing Authority in Form MD22 by the sponsor and shall be accompanied with a fee as specified in the <i>Second Schedule</i> and along with information specified in sub-rule (3) duly signed by the sponsor in India:</p> <p>Provided that no fee shall be required to be paid by the institutes, organizations, hospitals run by the Central Government or State Government, involved in conduct of clinical performance evaluation of new <i>in vitro</i> diagnostic medical devices.</p>	
	<p>(3) The information specified under sub-rule (2) shall contain the following information, namely,-</p> <ul style="list-style-type: none"> (i) approval from an Ethics Committee, which is registered with the Central Licensing Authority, as prescribed in Appendix VII of the <i>Seventh Schedule</i>; (ii) source and quantity of all types 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, scope of evaluation and number of devices concerned; (vi) Case Report Form as prescribed in Appendix IV of the <i>Seventh Schedule</i>; (vii) Undertaking by investigators as prescribed in Appendix VI of the <i>Seventh Schedule</i>; (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 the evaluation and apart from 	

	those specifically itemized in the undertaking, and that every precaution has been taken to protect the health and safety of the patient, user and other persons.	
	(4) The Central Licensing Authority may, in public interest, abbreviate, defer, or waive the requirement of conducting clinical performance evaluation for reasons to be recorded in writing for grant of permission to import or manufacture new <i>in vitro</i> diagnostic medical device for marketing.	
	<p>(5) The Central Licensing Authority after being satisfied with the information furnished along with application under sub-rule (1) may grant permission to conduct clinical performance evaluation for anew <i>in vitro</i> diagnostic medical device in Form MD23:</p> <p>Provided where information, as referred to in sub-rule (3) is inadequate, the Central Licensing Authority shall inform the applicant in writing, within ninety days from the date of application or such extended period, not exceeding a further period of thirty days, as the Central Licensing Authority may, for reasons to be recorded in writing, permit, the requirements to be complied with as before permission may be granted:</p> <p>Provided further, if the applicant has not furnished the required information sought by the Central Licensing Authority within ninety days from the date of intimation, it may reject the application for reasons to be recorded in writing.</p>	
Conditions for permission to conduct of clinical performance evaluation.	53. After grant of permission referred in rule 52, the following conditions shall be complied with by the applicant,-	
	(i) clinical performance evaluation shall be conducted in compliance with the approved clinical performance evaluation plan, Good Clinical Practices Guidelines;	
	(ii) clinical performance evaluation shall be initiated under the supervision of an approved Ethics Committee;	
	(iii) clinical performance evaluation shall be registered with the Clinical Trial Registry of India before enrolling the first patient 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 30 days of 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 to inspection by officers of the Central Licensing Authority authorised 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 the period of one year from the date of grant of permission, failing which prior permission from the Central Licensing Authority shall be required.	
	(vii) the Central Licensing Authority may impose any other 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.	
Suspension or cancellation of permission.	54. (1) If any person to whom permission is granted under sub-rule (5) of rule 52 fails to comply with any of conditions of permission, the Central Licensing Authority may suspend the permission for such period as it thinks fit or cancel either wholly or partly to which it relates.	
	(2) Any person who is aggrieved by the order passed under sub-rule (1), may within thirty days from the date of receipt of such order, appeal to the Central Government, and the Central Government may, after such enquiry into the matter, as is considered necessary and after giving an opportunity of being heard, pass such order in relation thereto as, it thinks fit.	
Medical management and compensation for injury related to clinical performance evaluation.	55. Where any participant is injured on account of his participation in the clinical performance evaluation, the sponsor permitted under rule 52 shall provide medical management to that participant.	
Performance evaluation of <i>in vitro</i> medical devices.	56. (1) The Central Government shall, by notification, designate the Central Government Laboratories or Central medical device testing centres, as the case may be, to carry out performance evaluation in respect of specified <i>in vitro</i> diagnostic medical devices.	
	(2) Performance evaluation prior to grant registration, in respect of <i>in vitro</i> diagnostic medical devices, shall be carried out at the designated laboratories or medical device testing centres under sub-rule (1).	
	(3) Performance evaluation of <i>in vitro</i> diagnostic medical devices shall be carried out as specified by the concerned laboratory or medical device testing centre notified under sub-rule (1).	
	Part VIII Permission to import or manufacture medical device which does not have predicate medical device	
Permission to import or manufacture medical device of clinical investigation.	57. (1) Save as otherwise provided in these rules for import or manufacture of medical device which does not have predicate medical device or has undergone clinical investigation, an application for grant of permission for such medical device after completion of its clinical investigation or clinical performance evaluation, as the case may be, under Part VII shall be made to the Central Licensing Authority in Form MD24 either by an authorised agent or a manufacturer	

	himself, as the case may be, and shall be accompanied with fee as specified in the <i>Second Schedule</i> along with information specified in Part IV of the <i>Fourth Schedule</i> :	
	<p>Provided 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:</p> <p>Provided further 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 the safety of the drug.</p>	
	(3) The Central Licensing Authority, after being satisfied, may grant permission to import or manufacture medical device which does not have predicate medical device or has undergone clinical investigation in Form MD25.	
Permission to import or manufacture new <i>in vitro</i> diagnostic medical device.	58. (1) An application for grant of permission to import or manufacture new <i>in vitro</i> diagnostic medical device shall be made to the Central Licensing Authority in Form MD26 either by an authorised agent or a manufacturer himself, as the case may be, and shall be accompanied with fee as specified in the <i>Second Schedule</i> along with information specified in Part IV of the <i>Fourth Schedule</i> :	
	<p>Provided new <i>in vitro</i> diagnostic 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 clinical data requirements may be abbreviated, deferred or omitted, as deemed appropriate by the Central Licensing Authority.</p>	
	(3) The Central Licensing Authority, after being satisfied, may grant permission to import or manufacture new <i>in vitro</i> diagnostic medical device in Form MD27.	
Condition of permission to import or manufacture investigational medical device and new <i>in vitro</i> diagnostic medical device.	59. A permission in Form MD25 or Form MD27 shall be subject to the following conditions, namely:-	

	(1) The medical device shall conform to the specification submitted along with the application;	
	(2) The permission holder 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 month for the first two years, followed annually two years submission.	
	(3) The permission holder shall inform the date of launch of medical device in the market to the Central Licensing Authority.	
	(4) The permission holder shall submit the suspected unexpected serious adverse event within fifteen days of the awareness of the event to the Central Licensing Authority.	
	(5) The label, prescribing information or package insert to be adopted for marketing medical device in the country, shall be got approved from the Central Licensing Authority before the medical device is marketed.	
	PART IX Duties and Powers of Medical Device Officer, Medical Device Testing Officer and Notified Body	
Duties of medical device testing officer.	60. 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 persons under provisions of Part IV, V and VII of these rules and shall furnish the report of the result of the test or evaluation in accordance with these rules.	
Procedure to be adopted by medical device testing officer on receipt of sample.	61. (1) On receipt of the sealed package of medical device or portion thereof, from a Medical Device Officer or any other persons 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 MD28 of the result of the test or evaluation along with full protocols of the test or evaluation applied.	
Application for test or evaluation of medical device.	62. 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 MD29 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 MD28.	
Duties of medical device officer.	63. Subject to the instructions of the Central Licensing Authority or State Licensing Authority, as the case may be, it shall be duty of Medical Device Officer to,-	
	(i) inspect not less than once in a year all establishments licensed by the Central Licensing Authority as the case may be, for manufacturing of medical device	

	or State Licensing Authority for sale, distribution, exhibit or offer for sale of medical device, as the case may be, within the area assigned to him;	
	(ii) conform that the conditions of licence are being observed;	
	<p>(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:</p> <p>Provided that in case of large sized medical device, where in the opinion of the Medical Device Officer, drawing samples of such a device may not be physically practical, shall be inspected at the same place 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 State Licensing Authority, as the case may be;</p>	
	(iv) maintain a record of all inspections undertaken, drawing of samples and 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 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 relating to medical device in writing which may be made to the Medical Device 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.	
Prohibition of disclosure of information.	64. Except for the purpose of official business or when required by a Court, a Medical Device Officer shall not, without the sanction in writing of his official superior, disclose to any person any information acquired while exercising such official duties.	
Form of order not to dispose of stock.	65. 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 MD30.	
Prohibition of sale.	66. 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.	

Form of receipt for seized medical devices, record, register, documents or any other material objects.	67. 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 MD31.	
Manner of certifying copies of seized documents.	68. 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.	
Form of intimation of purpose of taking samples.	69. When a Medical Device Officer takes a sample of a medical device other than medical device specified in proviso to sub-rule (iii) of rule 63 for the purpose of test or evaluation, Medical Device Officer shall inform such purpose in writing in Form MD32 to the person from whom it takes and shall tender the fair price thereof under a written acknowledgement.	
Form of receipt for samples of medical devices where fair price tendered is refused.	70. 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 MD33.	
Procedure for dispatch of sample to medical device testing officer.	71. (1) The sample of medical device or portion thereof sent by 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 hand in a sealed packet, enclosed together with a memorandum in Form MD34, 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.	
Confiscation of medical devices, implements, machinery, etc.	72. (1) Where any person has been convicted for contravening any of the provisions of the Act or any rule made thereunder, 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 notified under sub clause (iv) of clause (b) of section 3 of the Act, which is deemed to be misbranded, adulterated or spurious, for sale, stocking or exhibiting for sale or distribution without a valid licence or 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.	
Procedure for disposal of confiscated medical device.	73. (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, 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. The Court shall thereupon order destruction of such medical devices. The destruction 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.	
	(3) If the Medical Devices 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, Medical Devices Officer shall, after keeping the Central Licensing Authority or the State Licensing Authority, informed, as the case may be, report to the Court accordingly. 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 the hospital or dispensary maintained or supported by the Government or to a charitable institution.	
Duties of Notified Body	74. A Notified Body, referred in rule 12, shall carry out its duties and functions, in respect of Class A or Class B medical devices as specified in the Part II of <i>Third Schedule</i> .	
Procedure to be adopted by Notified Body.	75. A 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 referred to in Part II of the <i>Third Schedule</i> .	
Fees to be charged by Notified Body.	76. Notified Body may charge fee for the services rendered by it as may be determined by the Central Government.	
Monitoring of Notified Bodies	77. (1) Every Notified Body shall be subjected to assessment and audit to ensure compliance of the provisions of Part II of the <i>Third Schedule</i> in respect of its duties, functions and requirements by the Central Licensing Authority.	
	(2) The Central Licensing Authority shall audit the Notified bodies at least once in two years or as may be considered necessary, by the Central Licensing Authority.	
Suspension and Cancellation of Notified Body.	78. (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 he thinks fit, if in its opinion, the Notified Body has failed to comply with any of the conditions of registration.	
	(2) A 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 date the validity of its accreditation by a National Accreditation Body expires.	
	PART X SALE OF MEDICAL DEVICES	
Provisions for sale of medical devices.	79. (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 <i>mutatis mutandis</i> in respect of sale of medical devices.	
	(2) The licences granted or renewed under Part VI of the Drugs and Cosmetics Rules, 1945 for sale of drugs prior to the commencement of these rules, shall be deemed to continue to be valid for the purpose of sale in relation to medical devices.	
Supply of medical device to the hospitals against delivery challan	80. (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 licensee 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 preserved by the licensee as per condition of licence.	
Recall of device.	81. (1) If a manufacturer or authorised agent, as the case may be, considers or has reasons to believe that a medical device which he has imported, manufactured, sold or distributed is not in compliance with the Act, or these rules, he 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 authorities details thereof to. (2) A manufacturer or authorised agent, as the case may be, shall immediately inform the competent authorities and co-operate with them, if he considers or has reasons to believe that a medical device which he has 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 authorities of the action taken to prevent risks to the patient and shall not prevent or discourage any person from cooperating, in accordance with the Act and these rules, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a medical device.	
	Part XI Miscellaneous	
Exemption from the provisions related to medical devices.	82. The medical devices specified in the <i>Eighth Schedule</i> shall be exempted from	

	the provisions of these rules to the extent and subject to the conditions specified in that Schedule.	
Rejection of application of licence.	83. If any document submitted by the applicant for grant of licence for import or manufacture, test licence, permit for personal use, permission to import or manufacture investigational medical device, permission to conduct of clinical investigation, is found to be misleading, or fake, or fabricated, the application shall be summarily rejected.	
Debarment of applicant.	84. (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 why such an order should not be made in writing stating the reasons thereof, be debarred by the Central Licensing Authority or 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 State Licensing Authority, as the case may be, under sub-rule (1), he may within thirty days of the receipt of the order, make an appeal to the Central Government or State Government, as the case may be, and the 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.	
Mode of payment of fee.	85. (1) The fees prescribed under these rules shall be paid through challan or by electronic mode, in case of applications made to the Central Licensing Authority, in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110001 or any other branch or branches of Bank of Baroda, or any other bank, notified by 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 prescribed 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.	
Repeal and saving.	86. The Drugs and Cosmetics Rules, 1945, to the extent inconsistent with the provisions of these rules, are hereby repealed:	
	Provided that such repeal shall not affect:- (i) the previous operations of the permission, licence, registration certificate, no objection certificate under so repealed rules or anything duly done or suffered there under; or (ii) any right, privilege, obligation or liability acquired, accrued or incurred under any of the rules under repeal; or (iii) any penalty, forfeiture or punishment incurred in respect of any offences committed against rules under repeal:	

First Schedule
[See rule 5(1) and 5(2)]

Classification of medical devices and *in vitro* diagnostic medical devices.

Part I

Classification of Medical Devices other than *in vitro* diagnostic medical devices.

1. General parameters for classification of 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) 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.
 - (e) 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.
2. The parameters for classification of medical devices as follows:-
 - (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; or
 - (b) subject to sub-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; or
 - (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 sub-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; or
 - (b) a non-invasive medical device referred to in sub-paragraph (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 sub-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 sub-clause (b), a non-invasive medical device shall be assigned to Class C, if it is intended for modifying the biological or 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 sub-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) a non-invasive medical device to which clauses (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 sub-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 sub-clause (a) shall be assigned to Class B, if,-
 - (1) it is intended for use on the external surface of any 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 sub-clause (2), 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 sub-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 sub-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 sub-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 sub-clauses (b) to (g), a surgically invasive medical device intended for transient use (referred to in this clause as a transient use surgically invasive medical device) shall be assigned to Class B.
- (b) subject to sub-clause (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 sub-clauses (b), (d) and (e), a surgically invasive medical device intended for short term use (referred to in this clause as a short term use surgically invasive medical device) shall be assigned to Class B.
- (b) subject to sub-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 sub-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 sub-clauses (b), (c) and (d), an implantable medical device or a surgically invasive medical device intended for long term use (referred to in this clause as a long term use medical device) 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 sub-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 sub-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 sub-clause (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 sub-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 (a)(1) 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 sub-clause (a) shall be assigned to Class C, if it is intended by its product owner 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 sub-clause (d).
- (f) subject to sub-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 sub-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 (xii) and (xiii) do not apply shall be assigned to Class A.

(xv) Medical devices incorporating medicinal products,

- (a) subject to sub-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 sub-clause (a) shall be assigned to Class B, if the incorporated substance is a medicinal product exempted from the licensing requirements of the Act and rules made thereunder.

(xvi) Medical devices incorporating animal or human cells, tissues or derivatives,

- (a) Subject to sub-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 sub-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 sub-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 sub-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 sub-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

Risk classification provisions for *in vitro* diagnostic medical devices.

1. General parameters 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 clause 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 strictest rules resulting in the higher classification shall apply.

2. The parameters for classification of medical devices as follows:-

(i) *In vitro* diagnostic products 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 staging, 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 syndrome or spina bifida.

(ii) *In vitro* diagnostic products for blood grouping or tissue typing,

- (a) subject to sub-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 sub-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 products for self-testing,

- (a) Subject to sub-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 sub-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 products 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 products used in *in vitro* diagnostic procedures,

- (a) 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 products,

- (a) an *in vitro* diagnostic medical device shall be assigned to Class B, if clauses (2)(i) to (2)(v) 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 rule 12(2), 15(4), 15(5), 15(6), 16(1), 16(2), 24(1), 27(1), 30(3), 30(4), 30(7),
31, 33(1), 36(3), 37(1), 45(2), 52(2), 57(1), 58(1)]

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.	12(2)	Registration of notified body.	50000
2.	15(4)	Manufacturing licence of Class A medical device for one site.	5000
3.	15(5)	Manufacturing licence of Class B medical device for one site.	5000
4.	15(5)	Manufacturing licence of Class C or Class D medical device,-	----
5.		(a) one site;	50000
6.		(b) each distinct medical device.	1000
7.	15(5)	Manufacturing licence of Class C or Class D along with class A or class B medical device,-	----
8.		(a) one site;	50000
9.		(b) each distinct medical device of Class C or Class D;	1000
10.		(c) each distinct medical device of Class A or Class B.	200
11.	16(1)	Loan licence to manufacture of Class A or Class B medical device for one site.	5000
12.	16(2)	Loan licence to manufacture of Class C or Class D medical devices,-	
13.		(a) one site;	50000
14.		(b) each distinct medical device.	1000
15.	24(1)	Manufacturing licence or loan licence retention fee of Class A or Class B or Class C or Class D.	50000
16.	27(1)	Test licence to manufacture for clinical investigations, test, evaluation, examination, demonstration or training,-	
17.		(a) each distinct medical device:	500
18.	30(3)	Import licence for Class A medical Device,-	
19.		(a) one site:	\$1000
20.		(b) each distinct medical device:	\$50
21.	30(3)	Import licence for Class B medical Device,-	
22.		(a) one site:	\$1000
23.		(b) each distinct medical device:	\$50
24.	30(3)	Import licence for Class C and Class D medical Device,-	
25.		(a) one site:	\$3000
26.		(b) each distinct medical device:	\$1500
27.	30(7)	Licence is defaced, damaged or lost	\$300
28.	31	inspection of the overseas manufacturing site	\$6000
29.	33(1)	Import licence retention fee of Class A or Class B or Class C or Class D	\$3000
30.	36(3)	Import licence for test, evaluation or demonstration or training,-	
31.		(a) each distinct medical device:	500
32.	37(1)	Import of investigational medical device by Government hospital or statutory medical institution for treatment of patient,-	
33.		(a) each distinct medical device:	500

34.	45(2)(a)	Permission to conduct pilot clinical investigation	100000
35.	45(2)(b)	Permission to conduct pivotal clinical investigation	100000
36.	52(2)	Permission to conduct clinical performance evaluation	25000
37.	57(1)	Permission to import or manufacture an investigational medical device	50000
38.	58(1)	Permission to import or manufacture new in vitro diagnostic medical device	25000

Third Schedule

[See rule 12(2), 12(4), 74, 75, 77(1)]

Documents to be submitted for registration of Notified Body, its duties and functions.

Part I

[See rule 12(2)]

Documents to be furnished along with application in Form MD1.

1. An accredited Notified Body shall furnish duly signed copy of the following documents to the Central Licensing Authority.
 - (i) Constitution;
 - (ii) Accreditation Certificate issued by the National Accreditation Body as referred to in the rule 10.
 - (iii) Responsibilities of individuals within, and the reporting structure of the notified body;
2. Undertaking to be submitted stating that the,-
 - (i) Notified body including its directors, executives and personnel responsible for carrying out the 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 the 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 the devices in question, their manufacturing control or test procedures, or their manufacturer.

Part II

[See rule 12(4), 74, 75, 77(1)]

Duties and functions of Notified Body

A. Duties:

1. Notified body shall perform the audit of manufacturer who applied under sub-rule (1) of rule 15. The specific application shall be allotted to the notified body by the portal of the Central Government. The audit shall relate 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.

B. Functions:

A notified body,-

- (a) to impart training to staff covering all the evaluation and verification operations for which the notified body has been designated;
- (b) staff shall have adequate knowledge and experience of the requirement of the control;
- (c) shall carry out the evaluation and verification operations with the highest degree of professional integrity independently with technical competence;

- (d) ensure that the manufacturing site and products comply with the prescribed standards referred in rule 26;
- (e) shall not provide training or consultancy to the manufacturers whose site is being audited;
- (f) ensure that their auditors possess required qualification and expertise in the relevant field for carried out assessments of manufacturing site and medical device that they are undertaking;
- (g) establish and maintain procedure and record which demonstrate its compliance with quality management system.

C. Procedure for audit:

The notified body shall perform the audit in the following manner,-

- (i) on-site audit of the manufacturer's quality management system to establish conformity by the examination and provision of objective evidence, and that of sub-contractor wherever applicable, the requirements of the *Fifth Schedule*;
- (ii) technical review of documents as per prescribed in the *Fourth Schedule*;
- (iii) establish conformity by the 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) conformity to the product and process standards as per the provisions of these rules;
- (vii) inform the manufacturer about the observed noncompliance to during audit, if any and provide a copy of the audit report to the manufacturer;
- (viii) 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 the audit to the State Licensing Authority and a copy of the same to the manufacturer.

Fourth Schedule

[See rule 15(4), 15(5), 16(2), 30(3), 57(1), 58(1)]

Documents required for grant of manufacturing and import licence

**Part I
(Only for import)**

POWER OF ATTORNEY

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

Whereas, _____ (Name of authorized person) of M/s _____ (Name, full address, as per wholesale licence or manufacturing licence, with telephone, fax and E-mail address) herein after to be known as authorized agent for the M/s _____ (Name of the Manufacturer) intends to apply for an import licence of manufacturer, manufacturing site and medical device in India under the Medical Device Rules, 2016 for the import, use and marketing into India, of the Medical Devices listed below. We M/s _____ (Name of the Manufacturer with complete address) hereby delegate Power of Attorney for our below listed premise and medical device.

Sr. No.	Name & address of manufacturer (full address with telephone, fax and E-mail address of the manufacturer)	Name & address of manufacturing facility (full address with telephone, fax and E-mail address of the manufacturing site)	Name of medical device

- (1) The _____ (Name) shall be our Authorized Agent for the import licence for manufacturer of medical device under rule 30 of Medical Devices Rules 2016 and shall act in the following respects:-
- (a) to act as the official representative for the product registration for and on behalf of _____ (Name and complete address of the manufacturer) in India
- (b) to submit all necessary documents in the name of _____ (Name and complete address of the manufacturer) for the licence of manufacturer of medical device as defined in the *Fourth Schedule*.
- (2) We shall comply with all the conditions imposed on the import licence and with provisions of the Medical Device Rules, 2016.
- (3) We declare that we are carrying on the manufacture of the medical device mentioned in this *Schedule* at the premise specified above, and we shall from time to time report any change of premise on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories.
- (4) We shall allow the Central Licensing Authority or any person authorized by it in that behalf to enter and inspect the manufacturing premise and to examine the process, procedure and documents in respect of any manufacturing facility for which the application for import licence has been made.
- (5) We shall allow the Central Licensing Authority or any person authorized by him in that behalf to take samples of the Medical Devices concerned for test, evaluation or examination, if considered necessary by the Central Licensing Authority.
- (6) We do hereby state and declare that all the photocopies or scanned copies in the application are true copies of the original documents.
- (7) We do hereby state and declare that all the documents submitted by the undersigned are true and correct.

S. No	Name of Medical Devices (Including model No's, if applicable)		Indication and/or Intended Use	Shelf Life
	Generic Name	Model Name, if any		

Place:

Date:

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

Place:

Date:

**Signature of the Indian Agent
(Name and Designation)
Seal/Stamp**

Part II

(i) Information to be submitted with the application for grant of licence to manufacture or import of a Class A medical device,-

The manufacturer or authorised agent shall submit the duly signed and notarized (in case of import) information pertaining to Manufacturing premises in the following format.

(a) General Information including,-

- (i) Name and complete address of the Manufacturer in India or overseas manufacturer (Telephone No., E-mail address) to be registered.
- (ii) Name(s) and complete address of the manufacturing site in India or at overseas (Telephone No., E-mail address) to be registered.
- (iii) In case of import, Name and complete address of the authorized agent in India, responsible for the business of the overseas manufacturer (Telephone No., E-mail address).
- (iv) A brief profile of the manufacturer's business activity in domestic as well as global market.
- (v) A brief profile of the manufacturer's research activity.
- (vi) Regulatory status of the similar device in India (approved or not approved in India), reference to predicate or previous generations of the device to prove substantial equivalence.
- (vii) Summary of any reported Serious Adverse Event in any of the countries where device is marketed and action taken by the manufacturer and National Regulatory Authority concerned.
- (viii) In case of import,-
 1. Plant registration or approval or renewed certificate issued by the Ministry of Health or National Regulatory Authority of the country concerned.
 2. Duly notarized copy of Certificate, issued by the competent authority of the country concerned, in respect of the manufacturer and manufacturing site's Quality Management System, Full Quality Assurance or Production Quality Assurance.

3. Duly notarized copy of latest inspections or audit reports carried out by Notified bodies or National Regulatory Authority or Competent Authority within last 3 years, if any.

(b) Summary Technical Document including,-

- (i) Device description, Specification including variants and accessories,
- (ii) intended use of the device,
- (iii) In case of *in vitro* medical devices, a summary of analytical technology, relevant analytes and test procedure,
- (iv) material of construction (except *in vitro* diagnostic medical device),
- (v) Working principle and use of a Novel technology(if any),
- (vi) Labels and Package inserts (IFU, etc.,).
- (vii) Analytical Performance Summary (only in case of *in vitro* diagnostic medical device)

(c) Site or Plant Master File as specified in Appendix I of this Schedule.

(d) Essential Principles checklist for demonstrating conformity to the Essential Principles of Safety and Performance of the Medical Device.

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

The manufacturer or authorised agent shall submit the duly signed and notarized (in case of import) information pertaining to Manufacturing premises in the following format.

- (a)** General Information as specified in clause (i)(a).
- (b)** Site or plant Master File as specified in Appendix I of this Schedule.
- (c)** Device master file as specified in Appendix II or Appendix III, as the case may be, of this Schedule.
- (d)** Essential Principles checklist for demonstrating conformity to the Essential Principles of Safety and Performance of the Medical Device.

Appendix I

CONTENTS OF A SITE OR PLANT MASTER FILE

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

1. General Information:

- (i) brief information on the site (including name and address), relation to other sites;
- (ii) manufacturing activities;
- (iii) any other operations carried out on the site
- (iv) name and exact address of the site, including telephone, fax numbers, web site URL and e-mail address;
- (v) type of medical devices handled on the site and information about specifically toxic or hazardous substances handled, mentioning the way they are handled and precautions taken;
- (vi) short description of the site (size, location and immediate environment and other activities on the site);
- (vii) number of employees engaged in Production, Quality Control, warehousing, and distribution;
- (viii) use of outside scientific, analytical or other technical assistance in relation to the design, manufacture and testing;
- (ix) short description of the quality management system of the company;
- (x) devices details registered with foreign countries;

2. Personnel

- (i) organisation chart showing the arrangements for key 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 equipments.

6. Production:

- (i) Brief description of production operations using, wherever possible, flow sheets and charts specifying important parameters ;
- (ii) arrangements for the handling of starting materials, packaging materials, bulk and finished products, including sampling, quarantine, release and storage;
- (iii) arrangements for reprocessing or rework;
- (iv) arrangements for the handling of rejected materials and products;
- (v) brief description of general policy for process validation.

7. Quality Assurance:

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

8. Storage :

Policy on the storage of medical device.

9. Documentation :

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

10. Medical Device Complaints and Field Safety Corrective Action:

- (i) Arrangements for the handling of complaints ;
- (ii) Arrangements for the handling of field safety corrective action

11. Internal Audit:

Short Description of the internal audit system.

12. Contract Activities:

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

Appendix II

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

EXECUTIVE SUMMARY:

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 and Control.
- 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)
- 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
- 1.7 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

1.8 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

Serious Adverse Event	Frequency of event 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

- b. If the device contains any of the following 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

2.0 DEVICE DESCRIPTION AND PRODUCT SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

2.1 Device Description

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, accompanied by animation or videos (if available)
- d) Risk class and the applicable classification rule according to principles of medical device classification as specified in the *First Schedule*;
- e) An explanation of any novel features;
- f) 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. It should also be clarified whether these accessories or device are supplied as a kit or separate components.
- g) A description or complete list of the various configurations or variants of the device that will be made available;
- h) A general description of the key functional elements, e.g. its parts or components (including software if appropriate), its formulation, its composition, its functionality. 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.
- i) 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.
- j) 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; and
- b) predicate devices available on the local and international markets.

3.0 LABELLING

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

- a) 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.

4.0 DESIGN AND MANUFACTURING INFORMATION

4.1 Device Design

The dossier should contain information to allow a 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 a 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 & 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.

5.0 ESSENTIAL PRINCIPLES CHECKLIST

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.

Methods used to demonstrate conformity may include one or more of the following:

- a) conformity with recognised or other standards
- b) conformity with a commonly accepted industry test method;
- c) conformity with an in-house test method;
- d) the evaluation of pre-clinical and clinical evidence
- e) comparison to a similar device already available on the market.

The EP 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

6.0 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.

7.0 PRODUCT VERIFICATION AND VALIDATION

7.1 General

The dossier should contain product verification and validation documentation.

As a general rule, 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.

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 are 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.

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.

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

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

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.

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

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.

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

7.5 Sterilization

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.

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

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.

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 Shelf Life or Stability Data

The dossier should contain both Accelerated Stability Data as well as Real time Stability data to ensure the quality and effectiveness of the device during assigned shelf life period. The protocol to carry out stability studies should be submitted.

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 Schedule IV. If a predicate device is available nationally, the manufacturer needs to submit the substantial equivalence evaluation along with relevant published literature.

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.

The information submitted above is true to the best of my knowledge and belief.

Place:

Date:

Signature

Name:

Designation:

Seal/Stamp of manufacturer or his authorized agent in India

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 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.
5. The above information should be submitted in the form of one or more bounded form (like spiral binding or hard binding).

Appendix III

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

1.0 EXECUTIVE SUMMARY:

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

- 1.1 Introductory descriptive information on the Diagnostics Kits, the intended use and Class of Kit, novel features of the Kit (if any), Shelf Life of the Kit and a synopsis on the content of the dossier.
- 1.2 Regulatory status of the similar device in India (Approved or New Kit)
- 1.3 Domestic Price of the device in the currency followed in the Country of origin
- 1.4 Marketing History of the Kit from the date of introducing the Kit in the market
- 1.5 List of regulatory approvals or marketing clearance obtained (Submit respective copies of Approval Certificates)

Countries	Approved Indication	Approved Shelf life	Composition and/or Material of Construction	Class of Kit	Date of First Approval
USA					
Australia					
Japan					
Canada					
European Union					
Others (Specify all countries)					

- 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 kit:

- a. Summary of reportable events and field safety corrective action from the date of introduction
For Adverse event

Adverse Event	Frequency of Occurrence during the period (Number of Report/Total Units sold)

--	--

For Field Safety Corrective Action (FSCA)

Date of FSCA	Reason for FSCA

- b. If the kit 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.

2.0 KIT DESCRIPTION AND PRODUCT SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

2.1 Device Description

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

- a) the intended use of the Diagnostics kits. This 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 classification 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) and where applicable;
- f) a description of the specimen collection and transport materials provided with the Diagnostics kits 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 Diagnostics kits;
- j) a description or complete list of the various configurations/variants of the Diagnostics kits that will be made available;
- k) a description of the accessories, other Diagnostics kits and other products that are not Diagnostics kits, which are intended to be used in combination with the Diagnostics kits.

Reference to the Manufacturer's Previous Device Generation(s) and/or Similar Devices or Device History

2.2 For an IVD medical device not yet available on any market

Where relevant to demonstrating conformity to the Essential Principles, and to provide general background information, the Device master file may provide a summary of:

- a) the manufacturer's previous generation of the IVD medical device, if such exist; and/or
- b) the manufacturer's similar IVD medical devices available on the market.

2.3 For an IVD medical device already available on the market in any jurisdiction

This information may include a summary of the number of adverse event reports related to the safety and performance of this IVD medical device in relation to the number of IVD medical devices placed on the market.

External certificates and documents which give written evidence of conformity with the Essential Principles may be annexed to the Device master file.

3. Essential Principles (EP) Checklist

The Device master file should include an EP checklist that identifies:

- a) the Essential Principles of Safety and Performance;

- b) whether each Essential Principle applies to the IVD 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.

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 IVD medical device already available on the market.

The EP 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 IVD medical device such as the risk from false positive or false negative results, indirect risks which may result from IVD 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 IVD 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 IVD 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 IVD 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 QMS 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

As a general rule, the Device master file should summarize the results of validation and verification studies undertaken to demonstrate conformity of the IVD 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:

1. **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 IVD medical devices.

2. **Detailed Information**

Detailed information should include:

- a) the complete study protocol,
- b) the method of data analysis,
- c) the complete study report,
- d) the 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/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 IVD 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**

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.

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.

Note: 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 IVD medical devices, detailed information would be provided.

11. Analytical specificity

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.

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.

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. haemoglobin, 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).

Typically, 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

Note: 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 and/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 IVD 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 IVD medical device as described in Rule 96 of Drugs and Cosmetics Rules on labelling should include the following:

- a) Labels on the IVD medical device (immediate and outer container)
- b) Instructions for use.
- c) The label should bear name of the product, batch/Lot number, date of expiry or use before date, storage conditions, name and address of the actual and Legal manufacturer(if any), and Name and address of Importer, Import licence number etc

21. Post Marketing Surveillance Data (Vigilance Reporting)

The dossier should contain the Post Marketing Surveillance/ 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 Diagnostic kits

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

2. Test protocol of the kit 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 kits, the report of evaluation in details conducted by the National Control Authority of country of origin.

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

4. The detailed test report of all the components used/packed in the finished kit.
5. Pack size and labeling.
6. Product inserts.

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

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

The information submitted above is true to the best of my knowledge and belief.

Place:

Date:

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 batches should be submitted.
3. All certificates submitted must be within the validity period.
4. Any information which is not relevant for the subject kits may be stated as 'Not Applicable' in the relevant Sections/Columns of the above format, and reasons for non-applicability should be provided.

Note: The above information should be submitted in bounded form (like spiral binding or hard binding).

Part IV

Information required to be submitted with the Application Form for import or manufacture of medical devices which does not has 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) *ex vivo* tests, and
2. Bio-compatibility tests data, Report of biocompatibility 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 and Pivotal Clinical Investigation data including that, if any, carried out in other countries.
6. Regulatory status and Restriction on use in other countries (if any) where marketed or approved.
7. 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)-
 - (a) design input and design output documents
 - (b) device specification including specificity, sensitivity, reproducibility and reputability.
 - (c) validation of software relating to the function of the device,
 - (d) any performance tests,
 - (e) *ex vivo* tests, and
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 17(iii)]

Quality Management System for notified medical devices and *in vitro* diagnostics

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* diagnostics. If the manufacturer does not carry out design and development activity, the same shall be recorded in the quality management system. The manufacturer shall maintain conformity with this Schedule to reflect the exclusions.
- 1.2. If any requirement in clause 7 (product realisation) of this Schedule is not applicable due to the nature of the medical device and *in vitro* diagnostics for which the quality management system is applied, the manufacturer does not need to include such a requirement in its quality management system.
- 1.3. The processes required by this Schedule, which are applicable to the medical device and in-vitro diagnostics, 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* diagnostics 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* diagnostics, 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* diagnostics, 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* diagnostics;

- b. the modification of a medical device and *in vitro* diagnostics;
- c. the return of the medical device and *in vitro* diagnostics to the organization that supplied it; or
- d. the destruction of a medical device and *in vitro* diagnostics.

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* diagnostics 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 *In vitro* Diagnostics means *in vitro* Diagnostics referred in to in rule 3 of these rules.

3.12 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.

3.13 Medical device referred in this rule 3 of these rules.

3.14 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.

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

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

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

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

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

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

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

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

4 Quality management system.-

4.1 General:

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

The manufacturer shall;-

- (a) identify the processes needed for the quality management system and their application throughout the organization;
- (b) determine the sequence and interaction of these processes;
- (c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective;
- (d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes;
- (e) monitor, measure and analyse these processes; and
- (f) implement actions necessary to achieve planned results and maintain the effectiveness of these processes.

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

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

4.2 Documentation requirements.-

4.2.1 General

The quality management system documentation shall include;-

- (a) documented statements of a quality policy and quality objectives;
- (b) a quality manual;
- (c) documented procedures required by this schedule;
- (d) documents needed by the manufacturer to ensure the effective planning, operation and control of its processes;
- (e) records required by this schedule, and

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

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

The manufacture shall prepare documentation for device or *in vitro* diagnostics in a form of a Device Master File containing specific information as referred to in 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* diagnostics have been manufactured and tested are retained for at least one year after the date of expiry of the medical device or *in vitro* diagnostics as defined by the manufacturer.

4.2.4 Control of records.-

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

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

5 Management responsibility.-

5.1 Management commitment:

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

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

5.2 Customer focus:

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

5.3 Quality policy:

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

- (a) is appropriate to the purpose of the manufacturing facility;
- (b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system;
- (c) provides a framework for establishing and reviewing quality objectives;
- (d) is communicated and understood within the manufacturer's organization; and
- (e) is reviewed for continuing suitability.

5.4 Planning.-

5.4.1 Quality objectives:

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

5.4.2 Quality management system planning:

Top management of the manufacturer shall ensure that.-

- (a) the planning of the quality management system is carried out in order to meet the specified requirements, as well as the quality objectives; and
- (b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, authority and communication.-

5.5.1 Responsibility and authority:

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

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

5.5.2 Management representative:

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

- (a) ensuring that processes needed for the quality management system are established, implemented and maintained;
- (b) reporting to top management on the performance of the quality management system and any need for improvement; and
- (c) ensuring the promotion of awareness of regulatory and customer requirements throughout the manufacturing organization.

5.5.3 Internal communication:

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

5.6 Management review.-

5.6.1 General:

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

5.6.2 Review input:

The input to management review shall include information on:-

- (a) results of audits,
- (b) customer feedback,
- (c) process performance and product conformity,
- (d) status of preventive and corrective actions,
- (e) follow-up actions from previous management reviews,
- (f) changes that could affect the quality management system,
- (g) recommendations for improvement, and
- (h) new or revised regulatory requirements as and when issued.

5.6.3 Review output:

The output from the management review shall include any decisions and actions related to:-

- (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* diagnostics.

NOTE 1.-If a medical device or *in vitro* diagnostics 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* diagnostics devices that provides traceability and identifies the amount manufactured and amount approved for distribution.

The batch record shall be verified and approved.

7.5.1.2 Control of production and service provision — Specific requirements

7.5.1.2.1 Cleanliness of product and contamination control:

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

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

- (b) product is supplied non-sterile to be subjected to a cleaning process prior to sterilisation or its use; or
- (c) product is supplied to be used non-sterile and its cleanliness is of significance in use; or
- (d) process agents are to be removed from product during manufacture.

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

7.5.1.2.2 Installation activities:

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

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* diagnostics returned to the manufacturer are identified and distinguished from conforming product.

7.5.3.2 Traceability.-

7.5.3.2.1 General:

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

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

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

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

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

The manufacturer shall require that its agents or distributors maintain records of the distribution of active implantable medical devices and implantable medical devices to allow traceability and that such 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 dispatched, used or installed.

7.5.4 Customer property:

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

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

7.5.5 Preservation of product:

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

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

7.6 Control of monitoring and measuring devices:

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

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

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

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

- (c) identified to enable the calibration status to be determined;
- (d) safeguarded from adjustments that would invalidate the measurement result;
- (e) protected from damage and deterioration during handling, maintenance and storage.

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

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

8 Measurement, analysis and improvement.-

8.1 General:

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

- (a) to demonstrate conformity of the product;
- (b) to ensure conformity of the quality management system; and
- (c) to maintain the effectiveness of the quality management system.

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

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

8.2 Monitoring and measurement.-

8.2.1 Feedback:

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

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

8.2.2 Internal audit:

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

- a) conforms to the planned arrangements, to the requirements of this schedule and to the quality management system requirements established by the manufacturer, and
- b) is effectively implemented and maintained.

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

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

8.2.3 Monitoring and measurement of processes:

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

8.2.4 Monitoring and measurement of product.-

8.2.4.1 General requirements:

The manufacturer shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product 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 determine that the activities outside the manufacturer's organisation contributed to the customer complaint, relevant information shall be exchanged between the organisations involved.

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

8.5.2 Corrective action:

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

- (a) reviewing nonconformities (including customer complaints);
- (b) determining the causes of nonconformities;
- (c) evaluating the need for action to ensure that nonconformities do not recur
- (d) determining and implementing action needed, including, if appropriate, updating documentation;
- (e) recording of the results of any investigation and of action taken; and
- (f) reviewing the corrective action taken and its effectiveness.

8.5.3 Preventive action:

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

- (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 para 6.4 (b)) Environmental requirement for medical devices and <i>in vitro</i> diagnostics		
Name of Device	Type of Operation	ISO Class (At rest)
Cardiac stent/Drug Eluting Stent	Primary Packing and Crimping	5
	Washing, Ultrasonic cleaning & Drug coating	7
	Assembly, Wrapping & Packaging	8
	Laser cutting, Descaling, Annealing & Electro polishing	9
Heart Valves	Valve Packing	5
	Ultrasonic Cleaning & Visual Inspection	7
	Frame & Disc Assembly	7
Intra Ocular Lenses	Packing & Sealing	5
	Final Inspection	7
	Power Checking & Final Cleaning	8
	Tumble Polishing & Lathe Cutting	9
Bone Cements	Final Product Filling	5
	Sieving & Calcinations	7
	Powder Preparation, Granulation & Drying	8
Internal Prosthetic Replacement	Packing	5
	Product Preparation	7
	Component Preparation	8
Orthopaedic Implants	Cleaning & packaging (to be sterilized in factory premises)	7
	Cleaning & 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 & Packing	7
	Component Preparation & Cleaning	8
	Moulding	9
Condom	Compounding	Well ventilated Area with minimum 5 micron filter
	Moulding	Well ventilated Area with minimum 5 micron filter
	Vulcanising	Normal Air
	Packing	Air conditioned
Intra Uterine Devices	Moulding	Well ventilated Area with minimum 5 micron filter
	Assembling	7
	Packaging	7
Tubal ring	Extrusion	7
	Cutting and Assembly	7
	Packaging	7
Blood bags	Moulding/Extrusion of components	8
	Assembly	7
	Filing	5
Suture	Extrusion	9
	Assembly	8
	Packing	8
Staplers	Staple formation	9
	Staple assembly	8
	Staple final pack	8
Ligatures	Extrusion	9
	Cutting and assembly	8
	Final Pack	8
Surgical dressings	Weaving	9
	Assembly and Gauzing	9
	Final pack	9
<i>In vitro</i> diagnostics Kit/Reagents	Dry, Liquid Reagent Preparation	Well Lighted and Ventilated controlled temperature & humidity as per process or product requirement
	Coating of sheets etc.	
	Assembly and primary packing	
	Filling	Well Lighted and Ventilated controlled temperature and humidity as per process or product requirement. Provision of Laminar hood if required, Clean Room class 8 or class 9 as per product/process requirement
	Secondary Packing	Well Lighted and Ventilated controlled temperature if required
	Storage	As per recommended storage condition of the product

Sixth Schedule
[See rule 21(iii) (iv), 34(v) (vi)]

Post approval Major and Minor changes

(A) Major Changes:

1. If there is change in material of construction or design;
2. If there is change in intended use;
3. If there is change in facility for sterilization;
4. Extension of Shelf life;
5. Change in the address of manufacturing site;
6. Existing competent technical staff
7. Name of the manufacturer or authorised agent, for which applicant shall intimate to obtain approval from concerned Licensing Authority.
8. Labels
9. Storage condition of medical device

(B) Minor Changes:

10. Update of information for use or prescribing information;
11. Minor modification in shape of medical device;
12. Change in manufacturing process, testing or validation and verification.

Seventh Schedule

[See rule 45(1), 45(6), 46(ii), 46(v), 48(2), 48(3), 52(2), 52(3), 55(2)]

Requirements for permission to conduct clinical investigation of medical devices other than in vitro diagnostics medical device which does not has a predicate device

1. Application for permission.-

(1) an application in Form MD20 shall be made to the Central Licensing Authority along with following data in accordance with appendices namely:-

- (i) Design Analysis data as per Table 1.
- (ii) Biocompatibility data as per Table 2.
- (iii) In case of application for clinical investigation, documents 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, Informed Consent Form as prescribed in Table 8, investigator's undertaking as prescribed in Table 9 and Ethics Committee clearance, if available, as prescribed in Appendix VII of Drugs and Cosmetics Rule, 1945.
- (iv) Regulatory status in other countries as prescribed Table 3, including information in respect of restrictions imposed, if any, on the use of the investigational medical device in other countries, including 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 the reasons and its relevance, if any, to the Country. This information must continue to be submitted by the sponsor to the Central Licensing Authority during the course 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 application for manufacture/Import for marketing of the medical device. The drafts of label shall comply with provisions of labeling rules specified in Medical Device Rules, 2016:

Provided after submission and approval by the Central Licensing Authority, no change in the Instructions for Use shall be effected without such changes being approved by the Central Licensing Authority;
- (vi) 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 as specified in Table 3.
- (vii) 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 the 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 is granted.
- (viii) Report of clinical investigation should be in consonance with the format as prescribed in

Table 10, such reports shall be certified by Principal Investigator.

- (ix) Clinical Investigation data required shall depend on the purpose of the application (Clinical Investigation/Import/Manufacture). 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 study.
- (2) If the investigational medical device is intended to be imported or manufactured for the purposes of Clinical Investigation, the application or the required quantities of an investigational medical device for such purpose shall be made in respective Form MD14 or Form MD10, as the case may be, supported by scientific rationale.
- (3) For 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 clinical data requirements may be abbreviated, deferred or omitted, as deemed appropriate by the Central Licensing Authority.

2. CLINICAL INVESTIGATION:

(1) Approval for clinical investigation

- (i) Clinical investigation on an investigational medical device shall be initiated only after the approval obtained from the institutional ethics committee(s), registered under rule 122DD of Drugs and Cosmetics Rules, 1945, and the permission granted by Central Licensing Authority. The investigation shall be initiated at each respective site only after obtaining such an approval from Central Licensing authority for that site.
- (ii) Clinical Investigation shall be registered with Clinical Trial Registry of India (CTRI) before enrollment of first patient.
- (iii) All investigational 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 investigational plan. A qualified physician (or dentist, when appropriate) who is an investigator or a sub-investigator for the investigation, should be responsible for all investigation related medical (or dental) decisions. Laboratories used for generating data for clinical investigation should be compliant with Good Laboratory Practices. If services of a laboratory or a facility outside the country are to be availed, its name, address and specific services to be used should be stated in the clinical investigational plan to avail Central Licensing Authority's permission to send clinical investigation related samples to such laboratory or facility. 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.
- (iv) Clinical investigational plan amendments, if become necessary before initiation or during the course of a clinical investigation, all such amendments should be notified to the Central Licensing Authority in writing along with the approval by the ethics committee which has granted the approval for the study. No deviations from or changes to the clinical investigational plan should 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 investigational subject or when change involve only logistic or administrative aspects of the investigation. All such exceptions must 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 medical devices by 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 of occurrence of the serious adverse event as prescribed in Table 7.
- (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 prescribed in the Medical Device Rules, 2016.
- (v) The sponsor or his representative, whosoever, had obtained permission from the Central Licensing Authority for conduct of clinical investigation shall submit the detail of compensation provided or 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) 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 of investigation need to be prematurely discontinued for any reason including lack of commercial interest, the sponsor shall need to inform to the Central Licensing Authority and also shall submit summary report within a period of three months having a description of the investigation, the number of patients exposed to the investigational medical device, details of adverse device affect, compensation paid, if any, and the reason for discontinuation of the investigation or non-pursuit of the an investigational medical device application;

(3) Responsibilities of the Investigator:

- (i) The investigator shall be responsible for the conduct of the investigation according to the clinical investigation plan, GCP guidelines and also for compliance as per the undertaking given in Table 9. 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 twenty four 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 satisfaction of 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 the 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 Appendix V 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 the purpose of making claims in the 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 wellbeing of all investigational subjects. The ethics committee should exercise particular care to protect the rights, safety and wellbeing 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 academicians institutions), patients with incurable diseases, unemployed or impoverished persons, patients in emergency situation, ethnic minority groups, homeless persons, nomads, refugees, minors or others in capable of personally giving consent. Ethics committee(s) should get document 'standard operating procedures' and should maintain a record of its proceedings.
- (ii) Ethics Committee(s) should make, at appropriate intervals, an ongoing review of the investigation for which they review the Clinical Investigation Plan. Such view may be based on the periodic study progress reports furnished by the investigators and/or monitoring and internal audit reports furnished by the Sponsor and/or by visiting the investigational sites.
- (iii) In case an ethics committee revoke sites approval accorded to a Clinical Investigation Plan it must 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 or serious adverse event occurring during clinical investigation after due analysis shall be forwarded by Chairman of Ethics Committee to the Central Licensing Authority, and the Head of institution where the clinical investigation has been conducted within 14 calendar days 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 investigational subject. The investigator must provide information about the study verbally as well as using a 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'. Both the patient information sheet as well as the Informed Consent Form should have been 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 for or authorize an intervention in the patient as provided by the law of 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.
- (iv) An audio-video recording of inform consent process in case of vulnerable subjects in clinical investigation of an innovative medical device which is not approved anywhere across the globe.

(6) Pilot Clinical Investigation

- (i) Pilot clinical investigation is defined as those clinical investigation used to acquire specific essential information about a device before beginning the pivotal clinical investigation. Pilot clinical investigation is exploratory study may be conducted in 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 clinical pilot investigation typically include assessing feasibility (eg, preliminary device performance), exploring eligibility criteria and their practical application for the pivotal randomized 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 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 for undertaking 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 may be conducted in large number of patients with the disease or condition being studied and scope to provide the effectiveness and adverse effects.
- (ii) For medical device which does not have a predicate medical device but approved outside in India, pivotal studies need to be carried out primarily to generate evidence of safety and effectiveness of medical device in Indian patients when used as recommended in the prescribing information. Prior to conduct of pivotal clinical investigation in Indian subjects, the Central Licensing Authority may require pilot study data generated in Indian population 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 a part of multi-national clinical development of medical device, the number of sites and the 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 the medical device approval and related 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. They may be of any type but should have valid scientific objectives. Post Marketing Clinical investigation includes additional drug-device interaction, safety studies, investigation designed to support use under the approved indication e.g. mortality/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.

(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) when there is specific reason to expect that conditions common in the elderly are likely to be encountered; or
- (d) when the investigational medical device is likely 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 will 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 should be made in the appropriate age group. When clinical investigation is required to be conduct 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 use 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 medical device, paediatric population should 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 should be justified in detail.
 - (e) If the medical device has a potential for use in paediatric patient, paediatric studies should be conducted. These studies may be initiated at various phases 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 should be obtained from parent or legal guardian. However, all the paediatric participants should 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 must 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 should be sufficient to allow participation in the study.
 - (g) For clinical investigations conducted in the paediatric population, the reviewing ethics committee should include members who are knowledgeable about pediatric, ethical, clinical and psychosocial issues.
- (iii) Pregnant or nursing women-
- (a) Pregnant or nursing women should 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, is not 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, medical device should 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) summarize the market authorization status in different countries and any significant variations related to safety; and
 - (d) indicate whether changes should 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 presentations of data for different indications or separate population need to be given.
 - (iii) All relevant clinical and non-clinical safety data should cover only the period of the report (interval data). The PSURs shall be submitted every six months for the first two years after approval of the medical device is granted to the applicant. For subsequent two years, the PSURs need to be submitted annually. Central Licensing Authority may extend the total duration of 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 must be reported to the licensing authority within fifteen days of initial receipt of the 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 should capture the name of 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 should capture the reporting interval; medical device mode of action, therapeutic class, dose, route of administration, formulation; a brief description of the approved indication and population.

(c) Current Worldwide Marketing Authorization Status:

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

(d) Actions Taken in Reporting Interval for Safety Reasons

This section of PSUR should 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 committees, or ethics committees.

(e) Changes to Reference Safety Information:

This section of PSUR should capture any significant changes to the reference safety information within the reporting interval. Such changes might include information relating to contraindications,

warnings, precautions, adverse device event (ADCs), and important findings from ongoing and completed clinical investigations and significant non-clinical findings.

(f) Estimated Patient Exposure:

This section of PSUR should provide the estimates of the size and nature of the population exposed to the medical device. Brief descriptions of the method(s) used to estimate the subject/patient exposure should be provided.

- (i) Cumulative and interval subject exposure in Clinical investigation.
- (ii) Cumulative and interval patient exposure from Marketing Experience from India.
- (iii) Cumulative and interval patient exposure from Marketing Experience from rest of the world.

(g) Presentation of Individual Case Histories:

This section of PSUR should provide the individual case information available to a licence holder provide brief case narrative, medical history indication treated with suspect medical device, causality assessment. 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 should capture the brief summary of clinically important emerging efficacy/effectiveness and safety findings obtained from the licence holder sponsored clinical investigation and published safety studies that became available during the reporting interval of the report which has potential impact on 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 should include the details about signals and Risk Management Plan in place by licence holder (if any).

- a) Signal and risk evaluation: In this section licence holder will provide the details of signal and risk identified during the reporting period and evaluation of signals identified during the reporting period.
- b) Risk Management Plan: In this section licence holder will provide the brief details of safety concern and necessary action taken by him to mitigate these safety concerns.

(j) Overall Safety Evaluation:

This section of PSUR should capture the overall safety evaluation of the medical device based upon 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 should provide the 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).

3. Table means “Table” given below this Schedule.

Table 1
Design Analysis Data

The Design Analysis for a medical device includes, its Physical and Metrological Standardization and testing. 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 established National Standards or in case of unavailability of national standards International standards may be followed (e.g. ISO standards) and a comprehensive report 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. If available international standards are not followed for a device, then an explanation must be included for justifying deviation from those standards.

Table 2
Bio compatibility Study and other animal testing of Medical Device

1. Bio-compatibility study for invasive medical devices should be carried out as per the international Organization Standard, ISO-10993, Biological Evaluation of Medical Devices, latest version.
2. Animal Performance Study
 - (a) Device performance for its actions (including mechanical, electrical, thermal, radiation and any other of this type) and safety data in healthy and with pathology animal model (intended to be treated by such medical device) demonstrating absolute tissue reaction to active and basic parts of the devices, on local tissue and on whole organism, clearly recording local, general and systemic adverse events, risks or potential risks and performance of device in line with intended use, and conclusion whether safe or unsafe for human use. Wherever possible, histopathology, pathophysiology and path anatomy should be carried out.
 - (b) If the active component of device is defined as drug, data for its animal studies as per schedule Y should be submitted.
 - (c) Characteristics of good animal study
 1. Powered high
 2. Staged randomization
 3. Defined Methodology for induction or selection
 4. Live and killed studies
 5. Defined measurement

Table 3
Data 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, and
2. Bio-compatibility tests data, Report of biocompatibility 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. Clinical Investigational Plan, Investigator's Brochure as prescribed, , Case Report Form as prescribed, Informed Consent Form as prescribed, investigator's undertaking and Ethics Committee clearance.
6. Pilot and Pivotal Clinical Investigation data including that, if any, carried out in other countries.
7. Regulatory status and Restriction on use in other countries (if any) where marketed or approved.
8. Proposed Instruction for use and labels

Table 4
Investigator's Brochure (IB)

1 General

1.1 Introduction

The content of the Information Brochure shall contain, as a minimum, all topics listed in this annex.

1.2 Identification of the IB

- a) Name of the investigational 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 the case of amendments, if appropriate.
- f) A version or issue number and reference number, if any, with the 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 device.

2. Investigational device information

- a) Summary of the literature and evaluation supporting the rationale for the design and intended use of the investigational device.
- b) Statement concerning the regulatory classification of the investigational device, if relevant.
- c) General description of the investigational 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 the investigational device, along with supporting scientific literature.
- f) Manufacturer's instructions for installation and use of the investigational 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 the preclinical testing that has been performed on the investigational medical device, together with an evaluation of the 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 device and with medical devices that have similar characteristics, including such characteristics that relate to other indications for use of the investigational 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 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 and address of the sponsor of the clinical investigation.

1.1.4 Principal investigator, coordinating investigator and investigation site

- a) Name, address, and professional position of
 - a. Principal Investigator,
 - b. 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 the clinical investigation design such as inclusion or exclusion criteria, number of subjects, duration of the clinical investigation, follow-up, objective and endpoint.

1.2 Identification and description of the investigational medical device

- a) Summary description of the investigational device and its intended purpose.
- b) Details concerning the manufacturer of the investigational 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 the clinical investigation, for example by assignment of lot numbers, batch numbers or serial numbers.
- e) Intended purpose of the investigational device in the proposed clinical investigation.
- f) The populations and indications for which the investigational device is intended.
- g) Description of the 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 device.
- i) Description of the specific medical or surgical procedures involved in the use of the investigational device.

1.3 Justification for the design of the clinical investigation

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

- a) an evaluation of the results of the relevant pre-clinical testing or assessment carried out to justify the use of the 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 the 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 the investigational 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 the 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 the clinical investigation.
- d) Number of investigational 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 the 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 the 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 the clinical investigation or the interpretation of results. The follow-up period during the clinical investigation shall permit the demonstration of performance over a period of time sufficient to represent a realistic test of the performance of the investigational device and allow any risks associated with adverse device effects over that period to be identified and assessed.

The CIP shall specifically address what medical care, if any, will be provided for 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 CIP.

1.10 Deviations from clinical investigation plan

- a) Statement specifying that the investigator is not allowed to deviate from the CIP, 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 CIP 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.

- a) 1.12 Statements of compliance [TBD]
- b) Statement specifying that the clinical investigation shall be conducted in accordance with the ethical principles that have their origin in the Good Clinical Practices.
- c) Statement specifying that the clinical investigation shall not begin until the required approval from the Ethics Committee.
- d) Statement specifying that any additional requirements imposed by the Ethics Committee or Central Licensing Authority shall be followed, if appropriate.
- e) Statement specifying the type of insurance that shall be provided for subjects, if appropriate.
- f)
- g) 1.13 Informed consent process
- h) Description of the general process for obtaining informed consent, including the process for providing subjects with new information, as needed.
- i) 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.
- j)

- k) 1.14 Adverse events, adverse device effects and device deficiencies
- l) Definitions of adverse events and adverse device effects.
- m) Definition of device deficiencies.
- n) Definitions of serious adverse events and serious adverse device effects and, where appropriate, unanticipated serious adverse device effects.
- o) 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.
- p) 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 device).
- q) Details of the process for reporting device deficiencies.
- r) List of foreseeable adverse events and anticipated adverse device effects, together with their likely incidence, mitigation or treatment.
- s) Emergency contact details for reporting serious adverse events and serious adverse device effects.
- t) Information regarding the DMC, if established.

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 the 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 Forms

1 General

Case Report Forms (herein after to be referred as CRFs) are established to implement the Clinical Investigation Plan, to facilitate subject observation and to record subject and investigational 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.

The CRFs should reflect the CIP and take account of the nature of the investigational device.

2 Content and format

2.1 Overall considerations

The CRFs 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.

The format of CRFs should be such as to minimize errors that can be made by those who enter data and those who transcribe the data into other systems.

The data categories and format listed in this annex can be considered when designing CRFs.

2.2 Cover page/login screen

- a) Name of sponsor or sponsor logo.
- b) CIP version and date (if required).

- c) Version number of CRFs.
- d) Name of clinical investigation or reference number (if applicable).

2.3 Header or footer/e-CRF identifier

- a) Name of the clinical investigation or reference number.
- b) Version number of CRFs.
- 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) CRF 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 CRF

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:
 - a. demographics;
 - b. medical diagnosis;
 - c. relevant previous medications or procedures;
 - d. date of enrolment;
 - e. 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 authorized designee.
- o) CIP deviation(s).

3 Procedural issues

A system should 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

- Initials & other relevant identifier (hospital/OPD record number etc.)*
- Gender
- Age and/or date of birth
- Weight
- Height

2. Suspected Device(s)

- Name of the Device*.
- Indication(s) for which suspect device was prescribed
- Device details including model number/size/lot number, if applicable
- Starting date and time of day.
- Stopping date and time, or duration of treatment

3. Other Treatment(s)

- Provide the same information for concomitant devices as for the suspected Devices(s).

4. Details of Suspected Adverse Device Reaction(s)

- 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.*
- Start date (and time) of onset of reaction.
- Stop date (and time) or duration of reaction.
- Setting (e.g., hospital, out-patient clinic, home, nursing home).

5. Outcome

- Information on recovery and any sequel; results of specific tests and/or treatment that may have been conducted.
- For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.
- 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*

- Name
- Address
- Telephone number
- Profession (specialty)
- Date of reporting the event to Central Licensing Authority:
- Date of reporting the event to Ethics Committee overseeing the site:
- Signature of the Investigator

Note: Information marked * must be provided.”

Table 8
Informed Consent Form

Checklist for study 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 randomized 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 a 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 study 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 product to provide intended therapeutic effect.
15. Statement that in the case of placebo controlled clinical investigation, the placebo administered to the subjects shall not have any therapeutic effect.
16. 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 study.
- (c) The consequences of a Subject's decision to withdraw from the research 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 develop during the course of the research 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 study

2. Format of informed consent form for Subjects participating in a clinical investigation -

Informed Consent form to participate in a clinical investigation

Study Title:

Study Number:

Subject's Initials: _____

Subject's Name: _____

Date of Birth / Age: _____

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 study and have had the opportunity to ask questions. []

(ii) I understand that my participation in the study 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 study 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 study provided such a use is only for scientific purpose(s). []

(v) I agree to take part in the above study. []

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative: _____

Date: ____/____/____

Signatory's Name: _____

Signature of the Investigator: _____

Date: ____/____/____

Study Investigator's Name: _____

Signature of the Witness _____ Date: ____/____/____

Name 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, and / or any other statement(s) of qualification(s))
3. Name and address of all clinical facilities to be used in the study.
4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.
5. Names of the other members of the research team (Co- or sub-Investigators) who will be assisting the Investigator in the conduct of the investigation (s).
6. Clinical Investigation Plan (CIP) Title and Study 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 study until all necessary Ethics Committee and regulatory approvals have been obtained.
 - ii) I agree to conduct the investigation in accordance with the current CIP. I will not implement any deviation from or changes of the CIP 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 Investigation Subjects 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 study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the study.
 - 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 study 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 days of their occurrence. In case of failure, I will submit the justification to the satisfaction of the Central Licensing Authority.
 - xi) I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study 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 should contain the following information:

- a) title of the clinical investigation;
- b) identification of the investigational 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 and provisions and this *Schedule*.
- 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 should 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 should 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 should contain a brief statement placing the clinical investigation in the context of the development of the investigational 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 device and methods

6.1 Investigational device description

The description of the investigational device should contain the following points:

- a) a description of the investigational device;
- b) the intended use of the investigational device(s);
- c) previous intended uses or indications for use, if relevant;
- d) any changes to the investigational device during the clinical investigation or any changes from the IB, including
 - a. raw materials,
 - b. software,
 - c. components,
 - d. shelf-life,
 - e. storage conditions,

- f. instructions for use, and
- g. other changes.

6.2 Clinical investigation plan (CIP)

A summary of the CIP, including any subsequent amendment(s) with a rationale for each amendment, should be provided. The summary should include a brief description of the following points:

- a) the clinical investigation objectives;
- b) the clinical investigation design including
 - a. the type of clinical investigation, and
 - b. the clinical investigation endpoints,
 - c. the ethical considerations;
 - d. the data quality assurance;
 - e. the subject population for the clinical investigation, with the
 - i. inclusion/exclusion criteria, and
 - ii. sample size:

A clear accounting of all investigation subjects who entered the study 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;

- f. the treatment and treatment allocation schedule;
- g. any concomitant medications/treatments;
- h. the duration of follow-up;
- i. the statistical analysis including
 - i. the clinical investigation hypothesis or pass/fail criteria,
 - ii. a sample size calculation, and
 - iii. statistical analysis methods.

6.3 Ethics Committee (EC)

This section should document that the study 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 should 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 should 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 Study team

Briefly describe the administrative structure of the study (Investigators, site staff, Sponsor/ designates, Central laboratory etc.).

7 Results

The results report 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 devices;
- d) the subject demographics;
- e) CIP compliance;
- f) an analysis, which includes
 - a. a performance analysis provided for in the CIP,
 - b. 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 devices or procedure,
 - c. 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,
 - d. any needed subgroup analysis for special populations (i.e. gender, racial/cultural/ethnic subgroups), as appropriate,
 - e. an accountability of all subjects with a description of how missing data or deviation(s) were dealt within the analysis, including subjects
 - i. not passing screening tests,

- ii. lost to follow-up,
- iii. withdrawn or discontinued from the clinical investigation and the reason.

8 Discussion and overall conclusions

The conclusions should 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 investigation 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 study
- j. Audit certificate, if available
- k. Investigator's certificate that he/she has read the report and that the report accurately describes the conduct and the results of the study.

Eighth Schedule
(See rule 82)

Exemptions

S.N.	Class of medical devices	Extent and Conditions of Exemption
1	Class A medical devices (only voluntarily)	The provisions of Part X of these rules which required them to be covered by a licence for sale provided that the medical devices have been manufactured by registered manufacturers.
2	Custom made device.	All provisions of Part IV and Part X 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 contain the words 'custom made device'. <i>Explanation.-</i> 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.
3	Medicated dressings and Bandages for First Aid.	The provisions of Part X of these rules which require them to be covered by a sale licence, subject to conditions that such products have been manufactured by registered manufacturers.
4	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 India to a degree which render him liable to the provisions of Chapter IV of the Act and the rules made thereunder.	All provisions of Part X of these rules which requires them to be covered by a sale licence subject to the following conditions:- (a) The medical devices shall be purchased only from a dealer or a manufacturer licensed 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 purchases of the medical devices and may also take samples for test. (b) The medical devices will be stored under proper storage conditions as directed on the label. (c) No medical device shall be supplied or dispensed after the date of expiration recorded on its container, label or wrapper or in violation of any statement or direction recorded on such container, label or wrapper.
5	Medical devices supplied by a hospital or dispensary maintained or supported by Government or local body.	All provisions of Part X 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 dealer licensed 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 supplied or dispensed after the date of expiration recorded on its container, label or wrapper or in violation of any statement or direction recorded on such container, label or wrapper.
6	Mechanical contraceptives	The provisions of Part X of these rules which require them to be covered by a sale licence subject to condition that the provisions of condition (17) of rule 65 of Drugs and Cosmetics Rules, 1945 are complied with by the person stocking or selling mechanical contraceptives.

Appendix

Form MD1

[See sub-rule (2) of rule 12]

Application for grant of Certificate of Registration of a Notified Body

To

The Central Licensing Authority,

Sir/Madam,

I/We, _____ (Name of the firm) hereby apply for the grant of registration certificate to be a Notified Body situated at _____ (full address with telephone and e-mail ID) for below listed medical device(s), as per the classification specified in the Medical Devices Rules, 2016.

1. Medical device(s):

S.N.	Generic name	Class of medical devices

2. I enclose herewith the documents as specified in the Part I of the *Third Schedule* duly signed by me for grant of registration to be a Notified Body.

3. I shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2016.

4. A fee of Rs. _____ has been credited to the Government under the Head through Challan No. _____ dated _____ (attached in original).

I undertake to comply with all conditions provided under Part II of the *Third Schedule* of the Medical Devices Rules, 2016.

Place _____

Date _____

Signature
(Name and designation)
Seal or Stamp of designated
person in India

Form MD2

[See sub-rule (3) of rule 12]

Certificate of Registration for a Notified Body under the Medical Devices Rules, 2016

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. Medical device(s):

S.N.	Generic name	Class of medical devices

2. This Registration shall be in force from _____ to _____ unless it is sooner suspended or cancelled under the Medical Devices Rules, 2016.

3. This Registration is subject to the conditions as specified in the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2016.

Place _____
Date _____

Central Licensing Authority
Seal or Stamp

Form MD3

[See rule 15(1)]

Application for Grant of Licence to Manufacture for Sale and Distribution of Class A or Class B medical device

To

The State Licensing Authority,

Sir/Madam,

I/We, M/s _____ (Name and address of administrative office of the manufacturer) situated at _____ (full address of manufacturing site with telephone and e-mail) hereby apply for the grant of licence to manufacture for Sale and Distribution of Class A or Class B medical device on the premises below listed medical device.

1. Details of medical device(s):

S.N.	Generic name	Brand name	Model No.	Dimension	Intended use	Shelf life	Sterile or Non sterile	Class of medical device

2. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s):

- (a) Details of staff responsible for manufacture.....
(b) Details of staff responsible for testing.....

3. The manufacturing site is ready for audit or shall be ready for audit on

4. I shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2016.

5. A fee of Rs. _____ has been credited to the Government under Head of account through Challan No. _____ dated _____ (attached in original).

Place _____
Date _____Signature
(Name and designation)
Seal or Stamp

Form MD4

[See rule 15(2) and 15(3)]

Application for Grant of Licence to Manufacture for Sale or for Distribution of (i) Class C or Class D or (ii) Class A or Class B, and Class C or Class D Medical Devices.

To

The Central Licensing Authority,

Sir/Madam,

I/We, M/s _____ (Name and address of administrative office of the manufacturer) situated at _____ (full address of manufacturing site with telephone and e-mail) hereby apply for the grant of licence to manufacture for sale and distribution of medical device as listed below.

1. Details of medical device(s):

S.N.	Generic name	Brand name	Model No.	Dimension	Intended use	Shelf life	Sterile or Non sterile	Class of medical device

2. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device:

(a) Details of staff responsible for manufacture.....

(b) Details of staff responsible for testing.....

3. The manufacturing site is ready for inspection or audit or shall be ready for inspection or audit on

4. I shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2016.

5. A fee of Rs. _____ has been credited to the Government under Head through Challan No. _____ dated _____ (attached in original).

Place _____

Date _____

Signature
(Name and designation)
Seal or Stamp

Form MD5

[See rule 16(1)]

Application for Grant of Loan Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

To

The State Licensing Authority,

Sir/Madam,

I/We, M/s _____ (Name and full address of administrative office with telephone and e-mail) hereby apply for the grant of loan licence to manufacture for sale and distribution of Class A or Class B medical device on 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) for below listed medical device(s).

1. Details of medical device(s):

S.N.	Generic name	Brand name	Model No.	Dimension	Intended use	Shelf life	Sterile or Non sterile	Class of medical device

2. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device:

(a) Details of staff responsible for manufacture.....

(b) Details of staff responsible for testing.....

3. The manufacturing site is ready for inspection or shall be ready for inspection on

4. I shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2016.

5. A fee of Rs _____ has been credited to the Government under Head through Challan No. _____ dated _____ (attached in original).

Place _____
Date _____Signature of manufacturer
(Name and designation)
Seal or Stamp

Form MD6
[See rule 16(2) and 16(3)]

Application for Grant of Loan Licence to Manufacture for Sale and Distribution of (i) Class C or Class D or (ii) Class A or Class B, and Class C or Class D Medical Devices.

To
The Central Licensing Authority,

Sir/Madam,

I/We, M/s _____ (Name and full address of administrative office with telephone and e-mail) hereby apply for the grant of loan licence to manufacture for Sale and Distribution of medical device on 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) for below listed medical device(s).

1. Details of medical device:

S.N.	Generic name	Brand name	Model No.	Dimension	Intended use	Shelf life	Sterile or Non sterile	Class of medical device

2. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device:

- (a) Details of staff responsible for manufacture.....
(b) Details of staff responsible for testing.....

3. The manufacturing site is ready for inspection or shall be ready for inspection on

4. I shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and Medical Devices Rules, 2016.

5. A fee of Rs _____ has been credited to the Government under Head through Challan No. _____ dated _____ (attached in original).

Place _____
Date _____

Signature of manufacturer
(Name and designation)
Seal or Stamp

Form MD7

[See rule 20(1)]

Licence to Manufacture for Sale and Distribution of (i) Class C or Class D or (ii) Class A or Class B, and Class C or Class D Medical Devices.

Licence Number:

M/s _____ (Name and full address of manufacturer with telephone, fax and e-mail) is hereby licensed to Manufacture for Sale and Distribution of below listed medical device(s) on the premises situated at _____ (address of manufacturing facility where the manufacturing will be carried out).

1. Details of medical device:

S.N.	Generic Name	Brand name	Model No.	Dimension	Intended Use	Shelf life	Sterile/ Non Sterile	Class of medical device

2. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s):

(a) Details of staff responsible for manufacture.....

(b) Details of staff responsible for testing.....

3. Any other medical device(s) manufactured by the said manufacturer as may from time to time be endorsed on this licence.

4. This licence is subject to the conditions as specified in the Drugs and Cosmetics Act 1940 and the Medical Devices Rules, 2016.

Place: _____

Date: _____

*Central Licensing Authority/*State
Licensing Authority
Seal or Stamp

*Delete whichever is not applicable.

Form MD8

[See rule 20(1)]

Loan Licence to Manufacture for Sale and Distribution of Class A or Class B or Class C or Class D medical device

Loan Licence Number:

M/s _____ (Name and full address of manufacturer with telephone, fax and e-mail) is hereby licensed to Manufacture for Sale and Distribution of below listed medical device(s) on 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).

1. Details of medical device:

S.N.	Generic name	Brand name	Model No.	Dimension	Intended use	Shelf life	Sterile or Non sterile	Class of medical device

2. The names, qualifications and experience of competent technical staff responsible for the manufacture and testing of the above mentioned medical device:

(a) Details of staff responsible for manufacture.....

(b) Details of staff responsible for testing.....

3. Any other medical devices manufactured by the said manufacturer as may from time to time be endorsed on this licence.

4. This licence is subject to the conditions as specified in the Drugs and Cosmetics Act 1940 and the Medical Devices Rules, 2016.

Place _____

Date _____

*Central Licensing Authority/*State
Licensing Authority
Seal or Stamp

*Delete whichever is not applicable.

Form MD9

[See rule 21(vi)]

Form in which the Audit or Inspection Book shall be maintained.

- (A) The cover of the audit or inspection book contain the following particulars, namely:-
1. The name and address of the licensee _____
 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 audit or inspects the premises of the licensee:

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 Device Rules, 2016.

*Central Licensing Authority/

*State Licensing Authority

Seal or Stamp.

*Delete whichever is not applicable.

Notes:

- (i) Printed copy of the Inspection Book may be obtained by the licensee from the Licensing Authority on payment as may be specified by concerned Licensing Authority from time to time.
- (ii) The audit or inspection book shall be maintained at the premises of the licensee.
- (iii) The original copy of observations made by the auditor or medical device officer shall be maintained in the premises of the licensee 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 MD10

[See rule 27(1)]

Application for licence to manufacture medical device for purpose of clinical investigations, test, evaluation, examination, demonstration or training

To

The Central Licensing Authority,

Sir/Madam,

I/We,, of hereby apply for a licence to manufacture the medical device specified below for the purpose of clinical investigations, test, evaluation, examination, demonstration or training at(Name and address, where clinical investigations or test or evaluation or demonstration or training is to be carried out).

2. Details medical device to be manufactured

S.N.	Generic name	Class of medical device	Quantity proposed to be manufactured

3. A fee of Rs _____ has been credited to the Government under Head through Challan No. _____ dated _____ (attached in original).

Place _____
Date _____

Signature of manufacturer
(Name and designation)
Seal or Stamp

Form MD11

[See rule 27(2)]

Licence to Manufacture Medical Devices for the Purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training

....., of....., is hereby licensed 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 proposed to be manufactured

2. This licence is subject to the conditions prescribed under the Medical devices rules, 2016.
3. This licence shall, unless previously suspended or revoked, be in force for a period of three year from the date specified below.

Place _____
Date _____

Central Licensing Authority
Seal or Stamp

Form MD12

[See rule 30(2)]

Application for issue of import licence to import medical device

To

The Central Licensing Authority,

Sir/Madam,

I/We, _____, (Name, full address, as per wholesale licence or manufacturing licence, of authorised agent with telephone, fax and e-mail address) hereby apply for grant of licence to import medical device(s) manufactured at the manufacturing site(s) mentioned below.

2. 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)

3. Particulars of Medical Device(s):

S.N.	Generic name	Brand name	Model No.	Dimension	Intended use	Shelf life	Sterile or Non sterile	Class of medical device

4. I enclose the documents as specified in the *Fourth Schedule* for grant of licence to import medical device(s) for manufacturer and manufacturing site stated above.

5. A fee of Rs _____ has been credited to the Government under Head through Challan No. _____ dated _____ (attached in original).

I undertake to comply with all conditions as specified in Medical Device Rules, 2016 required to obtain licence to import medical device(s) for manufacturer and manufacturing site(s).

Place _____

Date _____

Signature
(Name and designation)
Seal or Stamp of authorized
agent in India

Form MD13

[See rule 32(1)]

Licence to Import Medical Device

Licence No.: _____

M/s _____ (Name, full address, as per wholesale licence/ manufacturing licence, of authorised agent with telephone and e-mail address) is hereby licensed to import the medical device(s) manufactured by overseas manufacturer having manufacturing site as specified below.

2. Details of manufacturer and manufacturing site under this licence.

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

3. Details of medical device(s) under this licence.

S.N.	Generic Name	Brand name	Model No.	Dimension	Intended use	Shelf life	Sterile/Non sterile	Class of medical device

4. The authorised agent M/s. _____ will be responsible for the business activities of the manufacturer, in India in all respects.

5. This licence is subject to the conditions prescribed under the Medical devices rules, 2016.

6. This licence shall be in force, unless previously suspended or revoked, from the date of issue.

Place _____
Date _____

Central Licensing Authority
Seal or Stamp

Form MD14

[See rule 36(3)]

Application for Licence to Import Medical Devices for the Purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training

To

The Central Licensing Authority,

Sir/Madam,

I/We,, of hereby apply for a licence to import the medical device specified below from M/s. (Name and full address of overseas manufacturer) for the purpose of clinical investigations, test, evaluation, examination, demonstration or training at (Name and address, where clinical investigations or test or evaluation or demonstration or training is to be carried out).

S.N.	GenericName	Class of medical device	Quantity proposed to be manufactured

2. I shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2016.

3. A fee of Rs. _____ has been credited to the Government under Head through Challan No. _____ dated _____ (attached in original).

Place _____

Date _____

Signature of applicant

Seal or Stamp

Form MD15

[See rule 36(4)]

Licence to Import Medical Devices for the Purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training

..... is hereby licensed 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 demonstration or training is to be carried out).

S.N.	Generic name	Class of medical device	Quantity proposed to be manufactured

2. This licence is subject to conditions prescribed under the Medical devices rules, 2016.
3. This licence shall, unless previously suspended or revoked, be in force for a period of three year from the date specified below:-

Place _____
Date _____

Central Licensing Authority
Seal or Stamp

Form MD16

[See rule 37(1)]

Application for Licence to Import Medical Devices for the Purposes by a Government Hospital or Statutory Medical Institution for the treatment of patients

To

The Central Licensing Authority,

Sir/Madam,

I (Name and designation) of
..... (Name of the Government Hospital or Statutory Medical
Institution) hereby apply for a licence to import small quantities of 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 Medical devices	Quantities which may be imported

3. I shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and Medical Devices Rules, 2016.

4. A fee of Rs. _____ has been credited to the Government under Head through Challan No. _____ dated _____ (attached in original).

Place

Date

Signature.....

Name.....

Seal or Stamp.....

Certificate

Certified that the 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

Date

Signature.....

Medical Superintendent of the Government Hospital /
Head of Statutory Medical Institution Seal or Stamp

Form MD17

[See rule 37(2)]

**Licence to Import Medical Device by a Government Hospital or Statutory
Medical Institution for the treatment of patients**

Licence No. _____

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 _____
Date _____

Central Licensing Authority
Seal or Stamp

Form MD18

[See rule 38(1)]

Application for Licence to Import Small Quantity of Medical Devices for Personal Use

To

The Central Licensing Authority,

Sir/Madam,

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

- The prescription from a registered medical practitioner prescribing the need for the said medical device is attached.
- The particular of the patients is specified below.

Name	Age	Gender	Complete Address

Place _____

Date _____

Signature of applicant

Form MD19
[See rule 38(2)]

Permission to Import of Small Quantities of Medical Devices for Personal Use

Permit No. _____

Date _____

.....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 Device Rules, 2016.
3. This licence shall, unless previously suspended or revoked, be in force for a period of six months from the date of issue specified above.

Central Licensing Authority
Seal or Stamp

Form MD20

[See rule 45(1)]

Application for Grant of permission to conduct Clinical Investigation

To

The Central Licensing Authority,

Sir/Madam,

I/We, _____, of M/s. _____ (Name and full address) hereby apply for the grant of permission to conduct clinical investigation for investigational medical device as per clinical investigation plan _____ dated _____ on the below mentioned clinical investigation sites and investigational medical device(s).

2. Details of medical device(s):

S. N.	Generic name	Intended use	Class of medical device

3. Details of clinical investigation site(s):

S. N.	Name and address of site(s)	Ethics Committee details	Name of Principle Investigator

4. The documents as specified in the *Seventh Schedule* are enclosed.

5. I shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and Medical Devices Rules, 2016.

6. A fee of Rs _____ has been credited to the Government under Head through Challan No. _____ dated _____ (attached in original).

Place _____
Date _____Signature of sponsor
(Name and designation)
Seal or Stamp

Form MD21

[See rule 45(6)]

Grant of permission to conduct Clinical Investigation

Permission No. _____

I/We, _____, of M/s. _____ (Name and full address) hereby apply for the grant of permission to conduct clinical investigation for investigational medical device as per clinical investigation plan _____ dated _____ on the below mentioned clinical investigation sites and investigational medical device(s).

2. Details of medical device(s):

S. N.	Generic name	Intended use	Class of medical device

3. Details of clinical investigation site(s):

S. N.	Name and address of site(s)	Ethics Committee details	Name of Principle Investigator

4. This permission is subject to conditions as specified in the Act and Medical Device Rules, 2016.

Place _____
Date _____

Central Licensing Authority
Seal or Stamp

Form MD22

[See rule 52(2)]

Application for Grant of permission to conduct Clinical Performance Evaluation

To

The Central Licensing Authority,

Sir/Madam,

M/s _____ (Name and full address of manufacturer with telephone and e-mail) hereby apply for the grant of permission to conduct clinical performance evaluation of 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:

S. N.	Name	Intended use	Class of new <i>in vitro</i> diagnostic device

3. Details of laboratory(s) or institution(s) involved.

S. N.	Name and address of site(s)	Ethics Committee details	Name of the Investigator(s)

4. The documents as specified in sub-rule (3) of rule 52 of Medical Device Rules, 2016 are enclosed.

5. I shall comply with the provisions of the Drugs and Cosmetics Act, 1940 and Medical Devices Rules, 2016.

6. A fee of Rs _____ has been credited to the Government under Head through Challan No. _____ dated _____ (attached in original).

Place: _____
Date: _____

Signature of sponsor
(Name and designation)
Seal or Stamp

Form MD23

[See rule 52(5)]

Grant of permission to conduct clinical performance evaluation

Permission No. _____

M/s _____ (Name and full address of manufacturer with telephone and e-mail) is hereby granted permission to conduct clinical performance **evaluation of 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:

S. N.	Name	Intended use	Class of new <i>in vitro</i> diagnostic device

3. Details of laboratory(s)/institution(s) involved.

S. N.	Name and address of site(s)	Ethics Committee details	Name of the Investigator(s)

4. This permission is subject to conditions as specified in the Act and Medical Device Rules, 2016.

Place _____

Date _____

Central Licensing Authority
Seal or Stamp

Form MD24

[See rule 57(1)]

Application for grant of permission to import or manufacture medical device does not have predicate medical device

To

The Central Licensing Authority,

Sir/Madam,

I/We,, of (Name and address of applicant) hereby apply for grant of permission to import or manufacture medical device(s), manufactured at (address of manufacturing site), does not have predicate medical device and has undergone clinical investigation.

4. Details of medical device:

S.N.	Generic name	Brand name	Model No.	Dimension	Intended use	Shelf life	Class of medical device

4. The documents as specified in part IV of the *Fourth Schedule* Medical Device Rules, 2016 are enclosed.

3. A fee of Rs _____ has been credited to the Government under Head through Challan No. _____ dated _____ (attached in original).

Place _____
Date _____

Signature of manufacturer
(Name and Designation)
Seal or Stamp

Form MD25

[See rule 57(3)]

**Permission to import or manufacture medical device does not have
predicate medical device**

Permission No. _____

The 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 medical device(s):

S.N.	Generic name	Brand name	Model No.	Dimension	Intended use	Shelf life	Class of medical device

3. This permission is subject to conditions as specified in the Act and Medical Device Rules, 2016.

Place _____
Date _____

Central Licensing Authority
Seal or Stamp

Form MD26

[See rule 58(1)]

Application for grant of permission to Import or Manufacture of New *In Vitro* Diagnostic Medical Device

To

The Central Licensing Authority,

Sir/Madam,

I/We,, of (Name and address of applicant) hereby apply for grant of permission to import or manufacture new *in vitro* diagnostic medical device(s), manufactured at (address of manufacturing site), does not have predicate medical device and has undergone clinical performance evaluation.

4. Details of new *in vitro* diagnostic medical device(s):

S.N.	Name	Brand name	Model No.	Intended use	Shelf life	Class of medical device

5. The documents as specified in part IV of the *Fourth Schedule* Medical Device Rules, 2016 are enclosed.

5. A fee of Rs. _____ has been credited to the Government under Head through Challan No. _____ dated _____ (attached in original).

Place _____
Date _____Signature of manufacturer
(Name and designation)
Seal or Stamp

Form MD27

[See rule 58(3)]

Permission to Import or Manufacturer New *In Vitro* Diagnostic Medical Device

Permission No. _____

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 medical device(s):

S.N.	Name	Brand name	Model No.	Intended use	Shelf life	Class of medical device

3. This permission is subject to conditions as specified in the Act and the rules.

Place _____
Date _____

Central Licensing Authority
Seal or Stamp

Form MD28

[See rule 61(2)]

Report of Test or Evaluation of Medical Devices by Medical Device Testing Officer

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
.....
3. Based upon the test or evaluation and in the opinion of undersigned the sample is, not of standard
quality/ adulterated/misbranded/spurious, as defined in the Drugs and Cosmetics Act, 1940 for the
reasons given below:-

Dated

Medical Device Testing Officer
Seal or Stamp

Form MD29

(See rule 62)

**Application from a purchaser for test or evaluation of a Medical Device under Section 26 of the
Drugs and Cosmetics Act, 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 rupeesas charged by medical device testing centre
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.

Dated

Signature
Seal or Stamp

Form MD30

(See rule 65)

**Order Under Section 22(1)(c) of the Drugs and Cosmetics Act, 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;

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 MD31

(See rule 67)

Receipt for stock of medical devices for record, register, document or material object seized under Section 22(1) (c) or (cc) of the Drugs and Cosmetics Act, 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 MD32

(See rule 69)

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 MD33

(See rule 70)

**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 MD34

[See rule 71(1)]

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.

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

[F. No. X.....]

K. L. SHARMA,

Joint Secretary to the Government of India