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GOVERNMENT OF PAKISTAN
DRUGS REGULATORY AUTHORITY OF PAKISTAN
MINISTRY OF NATIONAL HEALTH SERVICES, REGULATION AND COORDINATION
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Islamabad, the 9th March, 2015

NOTIFICATION

S.R.O. 204(I)/2015.— In exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012(XXI of 2012), the Drug Regulatory Authority of Pakistan, with approval of the Federal Government, is pleased to make the following rules, being made on the first occasion, namely:-

CHAPTER I
PRELIMINARY

1. Short title and commencement.— (1) These rules may be called the Medical Devices Rules, 2015.

(2) They shall come into force at once.

2. Definitions.— (1) In these rules, unless there is anything repugnant in the subject or context,—

(i) "accessory" means an article that is intended specifically by its manufacturer to—

(a) be used together with a medical device to enable that device to be used in accordance with its intended purpose as a medical device; or

(b) augment or extend the capabilities of that medical device in fulfillment of its intended purpose as a medical device,

and therefore should be considered as a medical device;

(ii) "active device intended for diagnosis" means any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing or monitoring or to support the treatment of treating physiological conditions, states of health, illnesses or congenital deformities;

(iii) "active medical device" means any medical device, the operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy but does not include medical devices intended to transmit energy, substances or other elements between an active medical device and the patient without any significant change;

(iv) "active therapeutic device" means any active medical device, whether used alone or in combination with other medical devices, to support,

modify, replace or restore biological functions or structures with a view to treat or alleviate an illness, injury or handicapness;

(v) "adulterated medical device" means a medical device. —

(a) which consists in whole or in part of any filthy, putrid or decomposed substance or which contains any foreign matter, vermin, worm, rodent or insect;

(b) which has been manufactured, packed or held under unsanitary conditions whereby it has been contaminated with dirt, filth or any other foreign matter or whereby it may have been rendered injurious to health;

(c) which releases any poisonous or deleterious substance which may render it injurious to health; or

(d) which has been mixed or packed with other substance or article so as to reduce its quality or performance or for which any substance or an article has been substituted wholly or in part;

(vi) "Asian Harmonization Working Party (AHWP)" means an affiliated organization of International Medical Device Regulators Forum (IMDRF) working for harmonization of medical devices' regulations in Asian and other regions;

(vii) "auditor" means the person employed by the conformity assessment body for the purpose of conducting conformity assessment in pursuance of these rules;

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

(ix) "central circulatory system" means the major internal blood vessels including pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, carotid arteries (common, internal and external), cerebral arteries, brachiocephalic artery, aorta (includes all segments of the aorta), inferior and superior vena cava and common iliac arteries;

(x) "central nervous system" means brain, meninges and spinal cord;

(xi) "client" of a conformity assessment body means any establishment responsible to appoint conformity assessment body to carry out conformity assessment under these rules;

(xii) "clinical evaluation" means review of relevant scientific literature or the review and assessment of data collected through clinical investigation;

(xiii) "clinical investigation" means any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and performance of a medical device;

(xiv) "component" means one of several possibly unequal subdivisions which together constitute the whole medical device to achieve the latter's intended purpose, which may also be known as a part but not a medical device in its own;

(xv) "conformity assessment" means systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the MDB, 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;

(xvi) "conformity assessment body" or "CAB" means a body that has been registered by the MDB under these rules based on designated requirements, such as knowledge, experience, independence and resources to conduct the conformity assessments to determine whether the relevant requirements in technical regulations or standards are fulfilled;

(xvii) "continuous use" means. —

(a) the entire duration of use of the device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device; or

(b) the accumulated use of a medical device that is intended by the manufacturer to be replaced immediately with another of the same type;

(xviii) "counterfeit medical device" means a medical device the label or outer packing of which is an imitation of or resembles or so nearly resembles as to be calculated to deceive for believing that it is the label or outer-packing of a medical device of another manufacturer;

(xix) "court" means the Drug Court established under the Act.

(xx) "custom-made medical device" means a medical device, other than a mass produced medical device , that is.—

(i) assembled or adapted in the manner that is intended for individual patient; or

(ii) specially fabricated or imported for the sole use of a particular person, in accordance with the specifications of a qualified practitioner;

(xxi) "DRAP Act" means the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012);

(xxii) "duration of use" means use as classified into—

(a) transient use which is normally intended for continuous use for less than sixty minutes;

(b) short term use which is normally intended for continuous use between sixty minutes and thirty days both inclusive;

(c) long term use which is normally intended for continuous use for more than thirty days;

(xxiii) "essential principles" means essential principles of safety and performance of medical device as described in these rules;

(xxiv) "establishment" means any legal entity involved in manufacturing, import, export, storage, distribution or sale of medical devices;

(xxv) "field corrective action" means an action taken by the manufacturer or his authorized agent to reduce a risk of death or serious deterioration in the state of health associated with the use of medical device that is already placed on the market;

(xxvi) "Form" means a form annexed to these rules;

(xxvii) "generic proprietary name" means a unique name given by the manufacturer to identify a medical device as a whole product, also known as the trade name or brand name;

(xxviii) "Global Medical Device Nomenclature (GMDN)" means a comprehensive system of internationally recognized coded descriptors in the format of preferred terms with definitions used to generically identify medical devices and related health care products;

(xxix) "harm" means physical injury or damage to the health of people or damage to property or the environment;

(xxx) "hazard" means potential source of harm;

(xxxi) "healthcare facility" means.—

(a) a hospital, medical clinic, dental clinic, laboratory or health clinic under the Federal or a Provincial Government; or

(b) a private hospital, medical clinic, dental clinic or healthcare institution established by qualified health care professionals recognized by Pakistan Medical and Dental Council (PMDC) or any other body established for this purpose by the Federal or a Provincial Government or a recognized group of healthcare providers or individuals in healthcare sector;

(xxxii) "immediate danger" means a situation where the patient is at risk of either losing his life or an important physiological function if no immediate preventive measure is taken;

(xxxiii) "implantable medical device" means any medical device, including one that is partially or wholly absorbed or which is intended to be totally administered into the human body or to replace an epithelial surface or the surface of the eye, by surgical intervention and which is intended to remain in place after the procedure or any medical device intended to be partially administered into the human body through surgical intervention and intended to remain in place after the procedure for at least thirty days;

(xxxiv) "intended purpose" means the use for which the medical device is intended according to the specifications of its manufacturer as stated on any or all of the following: —

(a) the label of the medical device;

(b) the instructions for use of the medical device;

(c) the promotional materials in relation to the medical device;

(xxxv) "intended use" means the objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer;

(xxxvi) "International Medical Device Regulators Forum (IMDRF)" means a forum working for global harmonization of medical devices regulations, previously known as Global Harmonization Task Force (GHTF);

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

(xxxviii) "in-vitro diagnostic medical device(IVD)" means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes including reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles and are used, for example, for the test purposes of diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction and determination of physiological status;

(xxxix) "labelling" means a term used to cover all written, printed or graphic matter presented by a manufacturer, for the purposes of providing information concerning a medical device to the users and others, which may be attached to the medical device itself, on its packaging or as a packaging insert or may be made available by other means, such as by electronic means, when appropriate for the purpose as an additional or alternative way of transmitting certain information regarding the medical device;

(xl) "life supporting or life sustaining medical device" means a medical device that is essential to or that yields information that is essential to the restoration or continuation of a body function important to the continuation of human life;

(xli) "manufacturer" means any establishment which designs, manufactures, fabricates, assembles, processes, labels, packs, sterilizes and other like processes of a finished medical device and includes but is not limited to those which perform the functions of contract sterilization, relabelling, remanufacturing, repacking or specification development and initial distributors of foreign entities performing these functions;

(xlii) "Medical Device Board" or "MDB" means a body responsible for registration of conformity assessment bodies and medical devices, licensing of establishments and issuance of permits for export and import of medical devices, their components and raw materials and for the matters ancillary thereto;

(xliii) "medical device for self-testing or self-administration" means a medical device intended by the manufacturer to be able to be used by lay persons in a non-clinical environment;

(xliv) "medical device service provider" means a person domiciled or resident in Pakistan or a firm or company, whose business or practice in Pakistan is principally to install, test, commission or maintain a medical device but does not include manufacturing, importing and placing in the market of a medical device;

(xlv) "misbranded medical device" means a medical device —

(a) which is not labelled in the prescribed manner;

(b) on the label or labelling of which any word, statement or other matter or information required by these rules to appear is not prominently placed with such conspicuousness as compared with other words, statements, designs or devices on the label or labelling and in such terms as may render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(c) which is not labelled with such directions for use and such warnings against use in indications where its use may be

dangerous to health, or against unsafe administration or application in such manner and form as are necessary for the protection of users or as may be prescribed;

(d) the label or container of which or anything accompanying which, bears any statement, design or device which makes any false claim for the medical device or which is false or misleading in any particular; or

(e) which is so coloured, coated or polished or treated that damage is concealed or which is made to appear of better or of greater performance than it really is;

(xlvi) "notified body" means a conformity assessment body

(xlvii) "objective evidence" means verifiable information or records pertaining to the quality of an item or service or to the existence and implementation of a quality management system requirements, which is based on visual observation, measurement, testing or other means;

(xlviii) "performance evaluation" means a review of the performance of a medical device based upon data already available, scientific literature and where appropriate, laboratory, animal or clinical investigations;

(xlix) "performance test" means testing of a medical device using testing methods and equipment as recommended by the manufacturer or standard practices, to yield qualitative test results;

(l) "permit holder" means a holder of any permit issued under the rules;

(li) "qualified practitioner" means a person registered with PMDC under the Medical and Dental Council Ordinance, 1962 (XXXII) or under any other law provided for this purpose, when acting in the course of providing medical treatment to a patient under his care;

(lii) "recognized standards" means standards deemed to offer the presumption of conformity to specific essential principles of safety and performance;

(liii) "registration holder" in relation to a registered medical device or a registered conformity assessment body, means a person or an organization who obtained the registration of a medical device or conformity assessment body, as the case may be, under these rules;

(liv) "regulatory authority of a foreign jurisdiction" means an organization which—

(a) exercises a regulatory right to control the manufacture, use or sale of medical devices within a country or territory outside Pakistan;

(b) may take enforcement action to ensure that medical devices placed in the market within that country or territory outside Pakistan comply with the legal requirements applicable in that country or territory;

(lv) "reusable surgical instrument" means instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or other surgical procedures, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures for cleaning, disinfection or sterilization;

(lvi) “risk” means combination of the probability of occurrence of harm and the severity of that harm;

(lvii) “self-testing medical device” means any device intended by the manufacturer to be able to be used by lay persons in a home environment;

(lviii) “special access medical device” means a medical device that is intended to be used by a qualified practitioner in an emergency or in a case where all conventional remedies have failed or unavailable or unsuitable to meet any special needs arising in the course of his practice;

(lix) "specifications" means the specifications approved for the purpose of registration under these rules;

(lx) “specimen” means the discrete portion of a body fluid or tissue or other sample associated with the body taken for examination, study or analysis of one or more quantity or characteristic to determine the character of the whole;

(lxi) "spurious medical device" means a medical device.—

(a) which purports to be the product of a manufacturer, place or country of whom or of which it is not truly a product;

(b) which is imported or exported or sold or offered or exposed for sale under a particular name while actually it is another medical device;

(c) the label of which bears the name of an individual or company purporting to be its manufacturer or producer which individual or company is fictitious or does not exist; or

(d) which purports to contain a drug but does not contain that drug;

(lxii) "sub-standard medical device" means a medical device which is not of specifications;

(lxiii) “surgically invasive medical device” means an invasive medical device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation; and

(lxiv) “technical documentation” means the documented evidence, normally an output of the quality management system that demonstrates conformity of a medical device to the essential principles of safety and performance as described in these rules

(2) The words and phrases used but not defined herein shall have the same meanings as are assigned to them in the DRAP Act and the Act.

CHAPTER II
PART I
CONFORMITY ASSESSMENT PROCEDURE

3. Requirements and procedures for conformity assessment for the purpose of medical device registration.—(1) For the purpose of registration, each medical device shall be subjected to conformity assessment to demonstrate its conformity to the requirements as specified in these rules.

(2) The manufacturer shall collect and compile all the evidences of conformity and depending upon the class of medical device, shall appoint a conformity assessment body registered by the MDB to conduct the assessment on the conformity to the requirements as specified in these rules.

(3) Where the conformity assessment body is satisfied that all the applicable requirements for conformity assessment have been fulfilled, it shall issue a report and certificate of the conformity assessment to the establishment as specified in these rules.

(4) Copy of the report and certificate of conformity assessment issued by the conformity assessment body under sub-rule (3) shall be submitted to the MDB when applying for medical device registration.

(5) If the medical device manufacturer is not present in Pakistan, it shall—

(a) authorize a representative to act on its behalf with regard to the conduct of the conformity assessment; and

(b) provide all the evidence of conformity and necessary support to the authorized representative for the purpose of the conformity assessment.

(6) The conformity assessment body shall conduct the conformity assessment in accordance with the requirements specified in these rules.

PART II
ELEMENTS OF CONFORMITY ASSESSMENT

4. Elements of conformity assessment for the purpose of medical device registration.— (1) Conformity assessment for the purpose of registration of a medical device shall comprise the following elements, namely: —

(a) conformity assessment of quality management system;

(b) conformity assessment of post-market surveillance system;

(c) conformity assessment of technical documentation; and

(d) declaration of conformity.

(2) The level of evidence under sub-rule (1) to be collected by the manufacturer shall be in accordance with the requirements as prescribed in rules 5, 6, 7 and 8 respectively.

5. Conformity assessment of quality management system.—(1) The medical device manufacturer shall establish, maintain and implement an appropriate quality management system in accordance with these rules to ensure good manufacturing practices of its medical device.

(2) The extent of the quality management system to be established, maintained and implemented as required in sub-rule (1) shall be determined by the class of the medical device as follows: —

(A) for Class A medical device or *in-vitro* diagnostic medical device, the manufacturer shall.—

(a) establish, maintain and implement a quality management system and may exclude design and development control and process control; and

(b) appoint a conformity assessment body to verify evidence on the aspects of manufacture concerned with—

(i) securing and maintaining sterile conditions if the medical device is to be supplied sterile; and

(ii) conformity of the medical device with the metrological requirements if the medical device has a measuring function;

(B) for Class B medical device or *in-vitro* diagnostic medical device, the manufacturer shall.—

(a) establish and maintain a quality management system and may exclude design and development control and process control; and

(b) appoint a conformity assessment body which may review and conduct on-site audit, as it thinks fit, to verify evidence of compliance to the requirements of these rules; and

(C) for Class C or Class D medical device or *in-vitro* diagnostic medical device, the manufacturer shall —

(a) establish, maintain and implement a full quality management system; and

(b) appoint a conformity assessment body to review and conduct on-site audit to verify evidence of compliance to the requirements of these rules.

6. Conformity assessment of post-market surveillance system.—(1) The manufacturer shall establish, maintain and implement a post-market surveillance system as part of the quality management system to ensure continued conformity of its medical device to essential principles of safety and performance throughout the post-market stage.

(2) During the conduct of the conformity assessment by the conformity assessment body.—

(a) for Class A medical device or *in-vitro* diagnostic medical device, the conformity assessment body may audit post-market surveillance system to investigate specific safety or regulatory concerns; and

(b) for Class B, Class C or Class D medical device or *in-vitro* diagnostic medical device, the conformity assessment body shall conduct an audit to ensure that an appropriate post-market surveillance system is established, maintained and implemented by the manufacturer.

7. Conformity assessment of technical documentation.—(1) The manufacturer shall.—

(a) collect and examine evidence and undertake procedures to determine conformity of a medical device to essential principles of safety and performance as specified in these rules; and

(b) compile these evidences in a technical documentation.

(2) The manufacturer shall establish a summary of the technical documentation in the format which shall be mandatory for Classes C and D medical devices as specified in these rules, for the purpose of the conformity assessment procedure.

(3) The extent of information to be included in the summary of the technical documentation as required in sub-rule (2) shall be determined by the class of the medical device as follows:—

(a) for Class A or Class B medical device or *in-vitro* diagnostic medical device,—

(i) the manufacturer shall prepare summary of technical documentation and shall make it available upon request by the conformity assessment body;

(ii) the manufacturer shall submit summary of technical documentation and other document or information to the conformity assessment body; and

(iii) if the submission of the summary of technical documentation or other document or information is required, the conformity assessment body shall review the summary of technical documentation or other document or information;

(b) for Class C or Class D medical device or *in-vitro* diagnostic medical device.—

(i) the manufacturer shall prepare and submit the summary of technical documentation in the format as specified in these rules for review by the conformity assessment body; and

(ii) the conformity assessment body shall review the summary of technical documentation to determine and verify conformity to the requirements.

8. Declaration of conformity.—(1) The manufacturer shall be required to certify that its medical device complies fully with all essential principles for safety and performance and shall draw up a declaration of conformity in the format as specified in these rules.

(2) The conformity assessment body shall review and confirm the adequacy of the declaration of conformity by examining the supporting documents or other evidence.

9. Evidence of conformity for an imported medical device.— (1) For an imported medical device, the authorized representative shall obtain the evidence of conformity from its foreign manufacturer.

(2) Upon receipt of evidence of conformity under sub-rule (1) from the foreign manufacturer, the authorized representative shall be responsible to appoint a registered conformity assessment body to conduct conformity assessment procedure as required under these rules.

10. Quality management system requirement for a manufacturer, an importer or authorized representative of a foreign manufacturer and distributor of medical device.—(1) For the purpose of placing a medical device in the market.—

(a) a manufacturer;

(b) an importer or authorized representative of foreign manufacturer; and

(c) a distributor

shall establish, maintain and implement an appropriate quality management system that is commensurate with the role and function of the establishment and in compliance with the requirements in the Table 1 below.

TABLE 1
REQUIREMENT ON QUALITY MANAGEMENT SYSTEM

S.No	Type of establishment	Quality management system
(1)	**(2)**	**(3)**
1.	Manufacturer	ISO 13485-Medical devices-quality management systems-Requirements for regulatory purposes.
2.	Importer or authorized representative	Good distribution practice for medical devices (GDPMD).
3.	Distributor	Good distribution practice for medical devices (GDPMD).

(2) Upon completion of the conformity assessment procedure, an establishment may apply for—

(a) establishment licence to carry out its activity; and

(b) registration of its medical devices,

in accordance with the procedures and requirements as prescribed in these rules.

(3) The report and certificate of conformity assessment shall be submitted as one of the requirements for registration of medical device and licensing of establishment.

PART 1II
ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICES

11. Medical device shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons.—A medical device shall be designed and manufactured in such a way that when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, it shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risk which may be associated with its use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

12. Reduction of risk associated with a medical device.—(1) The solutions adopted by the manufacturer for the design and manufacture of the devices shall conform to the safety principles.

(2) When risk reduction is required the manufacturer shall control the risk so that the residual risk associated with each hazard is judged acceptable, according to the following principles, namely:—

(a) identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse;

(b) eliminate risks as far as reasonably practicable through inherently safe design and manufacture;

(c) reduce as far as is reasonably practicable the remaining risks by taking

adequate protection measures, including alarms; and

(d) inform users of any residual risk.

13. Medical device shall achieve the performance intended by the manufacturer.— A medical device shall achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions within the scope of the definition of a medical device.

14. Characteristics and performances of medical device shall not be adversely affected when it is subjected to normal stresses.— The characteristics and performances of a medical device referred to in rules 11, 12 and 13 shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the medical device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

15. Characteristics and performances of medical device shall not be adversely affected under transport and storage conditions.—A medical device shall be designed, manufactured and packed in such a way that its characteristics and performances during their intended use shall not be adversely affected under transport and storage conditions, for example, fluctuations of temperature and humidity, taking into account of the instructions and information provided by the manufacturer.

16. Benefits of a medical device shall outweigh its side effects.— The benefits of the use of a medical device shall be determined to outweigh any undesirable side effect for the performances intended.

17. Chemical, physical and biological properties.—(1) A medical device shall be designed and manufactured in such a way as to ensure the characteristics and performance referred to in rules 11 to 16, with particular attention to—

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

(b) the compatibility between the materials used and biological tissues;

(c) cells, body fluids and specimens, taking account of the intended purpose of the device; and

(d) the choice of materials used should reflect, where appropriate, matters such as hardness, wear and strength.

(2) Medical devices shall be designed, manufactured and packed in such a way.—

(a) as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the product in which particular attention should be paid to tissues exposed and to the duration and frequency of exposure;

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

accordance with the intended use;

(c) as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the devices; and

(d) as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the devices taking into account the devices and the nature of the environment in which these are intended to be used.

(3) Where a medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product or drug as defined in the relevant legislation that applies and which is liable to act upon the body with action ancillary to that of the medical device, the safety, quality and usefulness of the substance shall be verified, taking into account the intended purpose of the device.

18. Infection and microbial contamination.—(1) A medical device and its manufacturing processes shall be designed—

(a) in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons; and

(b) to allow easy handling and, where necessary.—

(i) reduce as far as reasonably practicable and appropriate any microbial leakage from the device or microbial exposure during use; and

(ii) prevent microbial contamination of the device or specimen where applicable, by the patient, user or other person.

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

(3) Where a medical device incorporates tissues, cells or substances of non-human origin, such tissues, cells and substances shall originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues, cells or substances and the following requirements shall be adhered to—

(a) retention of information on the geographical origin of the animals; and

(b) performance of appropriate processing, preservation, testing and handling of tissues, cells or substances of animal origin so as to ensure optimal safety, particularly, safety with regard to viruses and other transmissible agents shall be addressed by implementing validated methods of elimination or inactivation in the course of the manufacturing process.

(4) Where a medical device incorporates human tissues, cells or substances, the following requirements shall be adhered to, namely:—

(a) proper selection of sources, donors and tissues, cells or substances of human origin; and

(b) performance of appropriate processing, preservation, testing and handling of tissues, cells or substances of such origin so as to ensure optimal safety,

particularly, safety with regard to viruses and other transmissible agents shall be addressed by implementing validated methods of elimination or inactivation in the course of the manufacturing process.

(5) A medical device that is labelled as having a special microbiological state shall be designed, manufactured and packed to ensure that it remains so when placed in the market and remains so under the transport and storage conditions specified by the manufacturer.

(6) A medical device that is delivered in a sterile state shall be designed, manufactured and packed in a non-reusable pack and according to appropriate procedures, to ensure that it remains sterile when placed in the market and remains sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.

(7) A medical device that is labelled either as sterile or as having a special microbiological state should have been processed manufactured and, if applicable, sterilized by appropriate, validated methods.

(8) A medical device that is intended to be sterilized should be manufactured in appropriately controlled conditions.

(9) Packaging systems for non-sterile medical device shall be capable of keeping the medical device without deterioration at the level of cleanliness stipulated and, if the medical device is to be sterilized prior to use, the risk of microbial contamination shall be minimized and the packaging system should be suitable for the method of sterilization indicated by the manufacturer.

(10) The packaging and labelling of a medical device shall distinguish between identical or similar products placed in the market in both sterile and non-sterile conditions.

19. Manufacturing and environmental properties.—(1) If the medical device is intended for use in combination with other devices or equipment, the whole combination, including the connection system shall be safe and shall not impair the specified performance of the medical device.

(2) Any restrictions on use applying to such combinations referred to in sub-rule (1) shall be indicated on the label and in the instructions for use.

(3) A medical device shall be designed and manufactured in such a way as to remove or reduce, as far as reasonably practicable and appropriate,—

(a) the risk of injury, in connection with their physical features, including the volume and pressure ratio, dimensional and where appropriate ergonomic features;

(b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure and acceleration;

(c) the risks connected to their use in conjunction with materials, substances and gases with which they may come into contact during normal conditions of use;

(d) the risks of accidental penetration of substances into the medical device;

(e) the risk of incorrect identification of specimens; and

(f) risks arising where maintenance or calibration are not possible as with implants, from ageing of materials used or loss of accuracy of a

measuring or control mechanism.

(4) A medical device shall be designed and manufactured in such a way as.—

(a) to minimize the risks of fire or explosion during normal use and in single fault condition, with particular attention to medical device of which intended use includes exposure to or use in association with flammable substances or substances which could cause combustion; and

(b) to facilitate the safe disposal of any waste substances.

20. Medical device with a diagnostic or measuring function.—(1) A medical device with a measuring function, where inaccuracy could have a significant adverse effect on the patient, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for the intended purpose of the device and the limits of accuracy should be indicated by the manufacturer.

(2) A diagnostic medical device shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for its intended use, based on appropriate scientific and technical methods, in particular the design shall address sensitivity, specificity, trueness, repeatability, reproducibility, control of known relevant interference and limits of detection, as appropriate.

(3) Where the performance of a medical device depends on the use of calibrators and control materials, the traceability of values assigned to such calibrators and control materials shall be assured through a quality management system.

(4) Any measurement, monitoring or display scale shall be designed in line with ergonomic principles, taking account of the intended purpose of a medical device.

(5) Wherever possible, values expressed numerically shall be in commonly accepted, standardized units and understood by the users of the medical device.

21. Protection against radiation.—(1) A medical device shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation shall be reduced as far as practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

(2) Where a medical device is designed to emit hazardous or potentially hazardous levels of visible or invisible radiation necessary for a specific medical purpose, the benefit of which is considered to outweigh the risks inherent in the emission, such medical device shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance and it shall be possible for the user to control the emissions.

(3) Where a medical device is intended to emit potentially hazardous, visible or invisible radiation, it should be fitted, where practicable, with visual displays or audible warnings of such emissions.

(4) A medical device shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as practicable and appropriate.

(5) The operating instructions for medical device emitting radiation shall provide detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and ways of avoiding misuse and of eliminating the risks inherent in installation.

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

(7) A medical device emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.

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

22. Requirements for medical device connected to or equipped with an energy source.—(1) A medical device incorporating electronic programmable system, including software, shall be designed to ensure the repeatability, reliability and performance of these systems according to the intended use.

(2) In the event of a single fault condition in the system referred to in sub-rule (1), appropriate means shall be adopted to eliminate or reduce, as far as practicable and appropriate, consequential risks.

(3) A medical device where the safety of the patients depends on an internal power supply shall be equipped with a means of determining the state of the power supply.

(4) A medical device where the safety of the patients depends on an external power supply shall include an alarm system to signal any power failure.

(5) A medical device intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm system to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

(6) A medical device shall be designed and manufactured in such a way as to reduce, as far as practicable and appropriate, the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the usual environment.

(7) A medical device shall be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.

23. Protection against electrical risks.—A medical device shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the medical devices are installed and maintained as indicated by the manufacturer.

24. Protection against mechanical risks.— (1) A medical device shall be designed and manufactured in such a way as—

(a) to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts;

(b) to reduce to the lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance; and

(c) to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

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

(3) Accessible parts of the medical devices, excluding the parts or areas intended to supply heat or reach given temperatures and their surroundings shall be designed not to attain potentially dangerous temperatures under normal use.

25. Protection against the risks posed to the patient by supplied energy or substances.—A medical device for supplying the patient with energy or substances shall—

(a) be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user;

(b) be fitted with the means of preventing or indicating any inadequacies in the delivered amount which could pose a danger;

(c) incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy or substance source;

(d) clearly specify the function of any controls and indicators on the medical device; and

(e) as appropriate, bear instructions required for its operation or indicate operating or adjustment parameters by means of a visual system, that shall be understandable to the user and, as appropriate, to the patient.

26. Protection against the risks posed to the patient for medical device for self-testing or self-administration.—(1) A medical device for self-testing or self-administration shall be designed and manufactured in such a way—

(a) that it performs appropriately for its intended purpose taking into account the skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in user's technique and environment;

(b) that the information and instructions provided by the manufacturer shall be easy for the user to understand and apply; and

(c) as to reduce as far as practicable the risk of use error in the handling of the device and, if applicable, the specimen and also in the interpretation of results.

(2) A medical device for self-testing or self-administration shall, where reasonably possible, include a procedure by which the user can verify that, at the time of use, the product will perform as intended by the manufacturer.

27. Information supplied by the manufacturer.—(1) User of a medical device shall be provided with the appropriate information needed to use the medical device safely and to ensure the intended performance, taking account of their training and knowledge.

(2) The information referred to in sub-rule (1) shall be in a manner to be easily understood by the user.

28. Performance evaluation including, where appropriate, clinical evaluation.—(1) All data generated in support of performance evaluation of a medical device shall be obtained.

(2) Clinical investigations of a medical device on human subjects shall be carried out in accordance with the spirit of the Helsinki Declaration, which shall include each step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.

PART IV
COMMON SUBMISSION DOSSIER TEMPLATE (CSDT)

29. Preparation of common submission dossier template (CSDT).—(1) For the purpose of submission for conformity assessment, a manufacturer of a medical device shall prepare a CSDT as a summary of the technical documentation of the medical device.

(2) The CSDT shall contain the elements as specified in these rules and be prepared in English language.

(3) Where elements are not applicable to a particular medical device, the manufacturer shall provide justification for the non-applicability.

(4) The depth and detail of the information contained in the CSDT shall depend on—

(a) the classification of the subject medical device;

(b) the complexity of the subject medical device;

(c) novel technology that is incorporated with the medical device;

(d) whether it is an already marketed medical device type that is now being offered for an intended use different from the original one;

(e) whether it is new to the manufacturer;

(f) whether the medical device type has been associated with a significant number of adverse events, including use errors;

(g) whether it incorporates novel or potentially hazardous materials; and

(h) whether the medical device type raises specific public health concerns.

(5) The information contained in the CSDT shall be supported by relevant supporting documents which shall be—

(a) legible, within its validity period and submitted in full;

(b) signed and dated by an authorized person issuing the supporting documents; and

(c) submitted as annexures to the CSDT.

PART V
ELEMENTS OF COMMON SUBMISSION DOSSIER TEMPLATE (CSDT)

30. Executive summary of CSDT.— The CSDT shall contain an executive summary, which shall include the following information, namely:—

(a) an overview which covers an introductory descriptive information on the medical device, the intended uses and indications for use of the medical

device, novel features and a synopsis of the contents of the CSDT;

(b) commercial marketing history which covers the list of countries where the medical device is marketed and the dates of introduction into those countries;

(c) intended uses and indications in its label;

(d) list of regulatory approval or marketing clearance obtained including the registration status, intended use and indications of the medical device in other countries and copies of certificates or approval letters from each country;

(e) status of any pending applications for regulatory approval or marketing clearance; and

(f) important safety and performance related information, which shall include—

(i) summary of reportable adverse events and field corrective actions; and

(ii) a description of the medical device if the medical device contains animal or human cells, tissues or derivatives thereof, rendered non-viable cells, tissues or derivatives of microbial or recombinant origin and irradiating components, ionizing or non-ionizing.

31. Relevant essential principles and rule used to demonstrate conformity.— (1) The manufacturer shall—

(a) determine all the relevant essential principles that are applicable to the medical device;

(b) take into account the intended purpose of the device when determining the essential principles;

(c) list all the relevant essential principles applicable to the medical device and rule used to demonstrate conformity to each applicable essential principle in the CSDT.

(2) The rules that may be used to demonstrate conformity to each applicable essential principle referred to in clause (c) of sub rule (1) include compliance with the standards, recognized rules or internal industry rules, comparison to other similar marketed medical devices, etc.

(3) The specific documents shall be referenced in this element of CSDT to support the rule used to demonstrate conformity to the essential principles.

(4) The evidence of conformity shall be provided in tabular form with supporting documentation available for review as required using the format as set out in TABLE 2 below.

TABLE 2
EXAMPLE OF AN ESSENTIAL PRINCIPLES CONFORMITY CHECKLIST

S.No.	Essential principle.	Applicable to the medical device.	Rule of conformity.	Identity of specific document.
(1)	(2)	(3)	(4)	(5)

1.	Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.			
2.	The solutions adopted by the manufacturer for the design and construction of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order: — (i) identify hazards and the associated risks arising from the intended use and foreseeable misuse; (ii) eliminate or reduce risks as far as possible (inherently safe design and construction); (iii) where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated; and (iv) inform users of the residual risks due to any shortcomings of the protection measures adopted.			

NOTE. —The essential principles conformity checklist is to be prepared based on the list of essential principles of safety and performance of medical devices in these rules. The medical device to which the essential principles conformity checklist is applicable should be identified on the checklist itself. Where applicable, the various configurations or variants of the medical device covered by the checklist are to be identified in the checklist. The columns in the recommended format for the checklist should be completed as follow: —

(a) Applicable to the medical device.— Either a 'Yes' or 'No' answer is required. If the answer is 'No' this should be briefly explained. For example, for a medical device that does not incorporate biological substances, the answer to it would be 'No' – the medical device does not incorporate biological substances;

(b) Rule of conformity.— State the title and reference of the standard, industry or

in-house test rule, comparison study or other rule used to demonstrate compliance. For standards, this should include the date of the standard and where appropriate, the clause that demonstrates conformity with the relevant essential principle. Where a standard is referred to more than once in the checklist, the reference number and date can be repeated. Conformity with the essential principles can be demonstrated by other means if the recognized standards are not available.

(c) Identity of specific documents.— This column should contain the reference to the actual technical documentation that demonstrates compliance to the essential principle, i.e. the certificates, test reports, study reports or other documents that resulted from the rule used to demonstrate compliance, and its location within the technical documentation.

32. Description of medical device.—(1) The CSDT shall contain a detailed description of the medical device attributes.

(2) The detailed description shall include the following information, namely: —

(a) a complete description of the medical device;

(b) principles of operation or mode of action;

(c) risk class and applicable classification method for the medical device according to the rules of risk-based classification as specified in these rules;

(d) a description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the medical device;

(e) a description or complete list of the various configurations of the medical device to be registered using the format as set out in TABLE 3 below;

(f) a complete description of the key functional elements, its formulation, its composition and its functionality;

(g) an explanation of any novel features;

(h) where appropriate, the information shall be supported by labelled pictorial representation of the medical device in the form of diagrams, photographs or drawings with sufficient explanation to understand the drawings and diagrams;

(i) intended use of the medical device which it is suited according to the data supplied by the manufacturer in the instructions as well as the functional capability of the medical device;

(j) indications that the device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the medical device is intended;

(k) instruction for use;

(l) contraindications which the medical device should not be used because the risk of use clearly outweighs any possible benefit;

(m) warnings to inform on specific risk or hazard that a user needs to know before using the medical device;

(n) precautions to exercise special care necessary for the safe and effective use of the medical device;

(o) potential adverse effects or side effects from the use of the medical device, under normal conditions to the patient or user;

(p) alternative therapy for diagnosing, treating, curing or mitigating the disease or condition for which the medical device is intended;

(q) materials to describe their physical properties to the extent necessary to demonstrate conformity with the relevant essential principles; and

(r) other relevant specifications and descriptive information.

TABLE 3
LIST OF CONFIGURATIONS OF MEDICAL DEVICE TO BE REGISTERED

Name of medical device: *family/group/system:*		
Proposed grouping for medical device: *(family/group/system):*		
Name as per medical device label	*Identifier*	*Brief description of item*

Guides for completing list of configurations of medical device to be registered: —

(1) For the "*Name as per medical device label*" column—

(a) for a medical device family, list the names of the constituent members in this column. Enter the identifier associated with each constituent member in the "Identifier" column;

(b) for a medical device group, list the names of the constituent medical devices in this column. Enter the identifier associated with each constituent medical device in the "Identifier" column; and

(c) for a medical device system, list the names of each constituent component in this column. Enter the identifier associated with each constituent component in the "Identifier" column.

(2) For the "Identifier" column, identifier refers to a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the product owner and that identifies it and distinguishes it from similar devices. Examples of an identifier for a device are a barcode, catalogue, model or part number.

(3) For the "Brief description of item" column, give a brief description of the key distinguishing attributes or specifications of each item. Examples of a brief description of a constituent member of a family include the following: —

For percutaneous transluminal coronary angioplasty (PTCA) catheters:

10 mm balloon length and 2 mm balloon diameter.

(4) A list of configurations is to be provided with each family/group/system medical device application.

33. Summary of design verification and validation documents.—(1) The CSDT shall contain summary of design verification and design validation documents to the extent appropriate to the complexity and risk class of the medical device.

(2) The summary of design verification and design validation documents shall include—

(a) declarations or certificates of conformity to the standards recognized by the MDB as applied by the manufacturer; and

(b) summaries or reports of tests and evaluations based on other standards, manufacturer's rules and tests, or alternative ways of demonstrating compliance.

(3) The data summaries or tests reports and evaluations may cover, as appropriate to the complexity and risk class of the medical device,—

(a) a listing of and conclusions drawn from published reports that concern the safety and performance of aspects of the medical device with reference to the essential principles;

(b) engineering tests;

(c) laboratory tests;

(d) biocompatibility tests;

(e) animal tests;

(f) simulated use; and

(g) software validation.

34. Pre-clinical studies.—(1) The CSDT shall contain documentation on pre-clinical studies conducted for the medical device.

(2) The documentation under sub-rule (1) shall include the report, certification or declaration of—

(a) biocompatibility tests conducted on materials used in a medical device;

(b) pre-clinical physical tests conducted on the medical device; and

(c) pre-clinical animal studies to support the probability of effectiveness in humans.

(3) The report under sub-rule (2) shall contain information on the objectives, methodology, results, discussion and conclusions of the testing.

35. Software validation studies.— (1) The CSDT shall contain documentation on software validation studies to verify the correctness of software in medical device.

(2) The manufacturer shall compile objective evidence that validates the software design

and development process.

(3) The document shall include the results of all verification, validation and testing performed in-house and in a user's environment prior to final release, for all of the different hardware configurations identified in the labelling, and representative data generated from both testing environments.

36. Medical devices containing biological material.—(1) If the medical device contains biological material, the documentation on the studies substantiating the adequacy of the measures taken with regard to the risks associated with transmissible agents shall be provided in the CSDT.

(2) The documentation shall contain the following information, namely: —

(a) a list of all materials of animal, human, microbial or recombinant origin used in the medical device and in the manufacturing process of the medical device, which includes animal or human cells, tissues or derivatives, rendered non-viable cells, tissues or derivatives of microbial or recombinant origin;

(b) detailed information concerning the selection of sources or donors;

(c) detailed information on the harvesting, processing, preservation, testing and handling of tissues, cells and substances;

(d) process validation results to substantiate that manufacturing procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents; and

(e) full description of the system for record keeping allowing traceability from sources to the finished medical device.

37. Clinical evidence.— (1) The CSDT shall contain documentation on clinical evaluation to verify the clinical safety and performance of the medical device when used as intended by the manufacturer.

(2) The clinical evaluation may take the form of—

(a) a systematic review of existing bibliography;

(b) clinical experience with the same or similar medical devices; or

(c) clinical investigation.

38. Use of existing bibliography.— (1) The CSDT shall contain copies of all literature studies or existing bibliography, that the manufacturer is using to support safety and effectiveness.

(2) Bibliography shall be derived from relevant publications in a peer-reviewed scientific literature and shall include the objectives, methodology and results presented in context, clearly and meaningfully.

(3) The conclusions on the outcome of the clinical studies should be preceded by a discussion in context with the published literature.

39. Medical device labelling.— (1) The CSDT shall contain documentation on medical device labelling that accompanies the device any time while it is held for sale or shipped.

(2) The documentation under sub-rule (1) shall contain the following information, namely:—

(a) sample of labels on the device and its packaging;

(b) instructions for use;

(c) other literature or training material;

(d) instructions for installation and maintenance, if applicable; and

(e) any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform, if applicable.

(3) The promotional material and product brochures shall be provided as part of CSDT to aid in the evaluation of the medical device.

(4) Samples of labels on the device and its packaging shall be in compliance with labelling requirements as specified in these rules.

40. Risk analysis.—(1) The CSDT shall contain documentation on risk analysis conducted for the medical device.

(2) The documentation shall be provided in the form of a risk management report (RMR).

(3) The risk analysis shall be based upon standards adopted by the MDB and shall be appropriate to the complexity and risk class of the medical device.

41. Manufacturing information.—(1) The CSDT shall summarize or reference or contain documentation related to the manufacturing processes, including quality assurance measures, which is appropriate to the complexity and risk class of the medical device.

(2) The information of manufacturing process for the medical device shall be provided in the form of a list of resources and activities that transform inputs into the desired output.

42. Special requirement for medical device used in clinical investigation.—(1) For medical device used in clinical investigation, the following elements are not applicable, namely: —

(a) clinical evidence; and

(b) use of existing bibliography.

(2) The medical device shall be labelled to indicate that it is used in clinical investigation.

PART VI
DECLARATION OF CONFORMITY AND ITS FORMAT

43. General principles of declaration of conformity.—(1) For the purpose of registration of a medical device, a medical device manufacturer shall—

(a) certify that its medical device conforms to all applicable essential principles for safety and performance of medical device;

(b) certify that its medical device complies fully with the requirements of the DRAP Act and these rules; and

(c) draw up a written declaration of conformity.

(2) Notwithstanding sub-rule (1), the manufacturer shall provide documents sufficient

to support its declaration of conformity.

44. Contents of declaration of conformity.— The declaration of conformity shall at least contain the following information, namely:—

(a) a certification that each device that is subject to the declaration: —

(i) complies with all the applicable essential principles for safety and performance as prescribed in these rules;

(ii) has been classified according to the methods of classification under these rules ; and

(iii) has met all the applicable conformity assessment elements.

(b) sufficient information to identify the device to which the declaration of conformity applies;

(c) nomenclature of the medical device, preferably using the Global Medical Device Nomenclature (GMDN) code and term;

(d) the risk class allocated to the medical device according to methods of classification in these rules;

(e) the conformity assessment elements as specified in these rules have been applied;

(f) date from which the declaration of conformity is valid;

(g) name and address of the device manufacturer; and

(h) name, position and signature of the responsible person who has been authorized to complete the declaration of conformity on behalf of the manufacturer.

45. Template for declaration of conformity.— The manufacturer may use Template-1 for declaration of conformity as given below.

TEMPLATE-1

TEMPLATE FOR DECLARATION OF CONFORMITY

Name and address of manufacturer

[to be printed on company letterhead of manufacturer]

DECLARATION OF CONFORMITY

I, *(name of person responsible for manufacturing the medical device)*, hereby declare that the below mentioned medical device—

(i) complies with all the requirements under the Drug Regulatory Authority of Pakistan Act, 2012(XXI of 2012) and the Medical Devices Rules, 2015;

(ii) has been classified according to the methods of classification as specified in these rules; and

(iii) conforms to requirements on essential principles for safety and performance of medical devices under these rules.

(1) Particulars of medical device include: —

(a) Generic name:

(b) Specified name:
(c) Brand:
(d) Model:
(e) Manufacturer:
(f) Country of origin:
(g) Manufacturing site:
(h) Risk-based classification:
(i) Classification rule:
(j) GMDN code:
(k) Medical device registration number or any approval code:

(2) Quality management system (QMS) certificate:

(a) Conformity assessment body issuing the certificate:
(b) Certificate number:
(c) Issuance date:
(d) Expiry date:

Note. —

(i) For Class B, Class C and Class D medical devices, declaration of conformity to either of the following QMS standards is mandatory:

(a) ISO 13485; or
(b) Other quality management system standard recognized by the MDB;

(ii) For Class A medical devices that are not manufactured under either of the above mentioned quality management system standards, certification obtained for alternative quality management system standards shall be listed in this section, if applicable;

(iii) For Class A medical devices with measuring function, conformity assessment certificate and calibration and metrology report, issue date, expiry date, calibration should be provided; and

(iv) For Class A medical devices with sterilization, validation report and conformity assessment certificate number, issue date, expiry date should be provided.

(3) Standards applied:

(State and list all standards applicable for the above-mentioned medical device)

I am fully responsible with all the information provided in this declaration. This Declaration of Conformity is valid from …… (Day) …….. (Month) …….. (Year)

I fully understand and acknowledge that it is an offence under the Drug Regulatory Authority of Pakistan Act, 2012(XXI of 2012) and rules made there under to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading consequently to violate the said DRAP Act or the rules made thereunder.

Signature:

Name:

Designation:

Address:

Stamp:

Date:

Note. —The declaration of conformity, all documents and certificates and attestations provided by the applicant shall be duly certified to be true copy.

CHAPTER III
REGISTRATION OF CONFORMITY ASSESSMENT BODY

46. Requirements for registration of conformity assessment body (CAB).— For the purpose of registration of a conformity assessment body, it shall comply with requirements as specified in Chapter IV and shall apply for registration to the MDB ,however, foreign conformity assessment body of whom certified medical device has been approved by any of the regulatory authorities mentioned in rule 142 shall be exempted from registration by the MDB.

47. Application procedure for registration of conformity assessment body.— (1) For the purpose of registration of a conformity assessment body, an application shall be made to the MDB on the format as set out in Form-1.

(2) An application for registration of a conformity assessment body shall be accompanied with the following, namely:-

(a) application fee specified in rule 138; and

(b) documents or information specified in Form-1;

(3) The MDB may reject an application, if the applicant fails to deposit the specified fee or provide information, particulars or documents required under sub-rule (2) and shall inform the applicant of its decision in writing with reasons of such decision.

48. Procedure for grant of registration of conformity assessment body.—(1) Upon receipt of the application under rule 47 for registration of conformity assessment body, the MDB shall consider the application to register a conformity assessment body and may inspect the premises of the applicant as it considers necessary to verify any information, particulars or documents as provided by the applicant and may for this purpose constitute a panel of experts for the inspection.

(2) If the MDB is satisfied with all requirements pertaining to the application for registration of conformity assessment body including inspection of the premises, it shall register the conformity assessment body and keep it in the medical device register (MDR). The validity of registration shall be for a period of five years from the date of registration unless it is cancelled or suspended by the MDB before its expiry.

(3) The MDB shall assign a registration number and issue to the conformity assessment body a certificate of registration, as set out in Form-2.

49. Renewal of registration of conformity assessment body.—(1) An application for renewal of registration of conformity assessment body shall be made, on the format as set out in Form-1, sixty days before its expiry and shall be accompanied by the following, namely:—

(a) application fee as specified in RULE 138; and
(b) such document or information as specified in Form-1.

(2) The MDB may reject an application if the conformity assessment body fails to deposit specified fee or provide information, particulars, or documents as required under sub-rule(1).

(3) Upon receipt of the application to renew the registration under sub-rule (1), the MDB shall consider the application and may inspect the premises of the conformity assessment body as it considers necessary to verify any information as provided by the applicant under sub-rule (1).For this purpose, the MDB may constitute a panel of experts.

(4) If the MDB is satisfied with all the requirements pertaining to the application for renewal of registration including inspection of the premises, it shall renew the registration of conformity assessment body and keep the conformity assessment body in the medical device register for a period of five years from the date of expiry of previous registration certificate unless it is cancelled or suspended by the MDB before its expiry.

(5) If an application for renewal is made after expiry of the period of validity of certificate of registration but within sixty days after expiry of the period of validity, the applicant shall deposit an additional surcharge of rupees five thousand for each day the application is delayed.

(6) If an application for renewal is made after sixty days of expiry of the period of validity, the registration shall cease to exist and the conformity assessment body shall be responsible for all the illegal operations carried out during that period and the application shall be treated as a fresh application for grant of registration.

(7) If an application for renewal is made before the expiry of the period of validity of registration or within sixty days after expiry of the period of validity with deposition of additional surcharge, the registration shall continue to be in force until orders are passed on such application.

(8) In case the application for renewal of registration is rejected by the MDB, it shall inform the applicant of its decision in writing with reasons of such decision.

50. Changes concerning registered conformity assessment body.—(1) A registered conformity assessment body shall apply to the MDB for prior approval, if any change is proposed regarding any particular provided in relation to the registration of a conformity assessment body.

(2) An application under sub-rule (1) shall be—

(a) made on the format as set out in Form-1; and
(b) accompanied by the fee specified in rule 138.

(3) Upon receipt of the application under sub-rule (1), the MDB shall consider the proposed change and may inspect the conformity assessment body to verify any particulars, information or documents as provided by the conformity assessment body under sub-rule (2) and the proposed change shall not take effect until the MDB has granted its approval for the change.

(4) If the MDB, on the basis of information received or an inquiry conducted by it, is of opinion that—

(a) the approval of change in any particular of registration of the conformity assessment body was obtained by fraud or misrepresentation; or

(b) the circumstances in which the change in any particular of registration of the conformity assessment was approved no longer exist; or

(c) it is necessary in the public interest so to do,

the MDB may, after affording to the person, on whose application the change was approved, an opportunity of showing cause against the action proposed to be taken, cancel or suspend the registration or specify any further conditions to which the registration shall be subject and inform accordingly.

51. Conditions of certificate of registration of conformity assessment body.— (1) A certificate of registration of a conformity assessment body shall not be assigned or transferred to any other person or classes of persons except with prior written approval of the MDB.

(2) A registered conformity assessment body contravenes these rules, if it assigns or transfers its registration to any other person or classes of persons without the prior written approval of the MDB and registration may be cancelled or suspended as the MDB may deem fit under these rules.

(3) A certificate of registration issued to a registered conformity assessment body shall remain property of the MDB and shall be surrendered to the MDB without demand within fourteen days after either it willfully stops its operations or the registration is cancelled.

52. Conditions of registration of conformity assessment body.— (1) A conformity assessment body shall comply with all the conditions of the registration specified in these rules.

(2) If the MDB, on the basis of information received or an inquiry conducted by it, is of opinion that—

(a) the registration or renewal of registration of a conformity assessment body was procured by fraud or misrepresentation; or

(b) the circumstances in which a conformity assessment body was registered, no longer exist; or

(c) it is necessary in the public interest so to do,

the MDB may, after affording to the person, on whose application the conformity assessment body was registered, an opportunity of showing cause against the action proposed to be taken, cancel or suspend the registration or specify any further conditions to which the registration shall be subject and inform such person accordingly.

53. Cancellation or suspension of registration of conformity assessment body .—(1) Before cancellation or suspension of registration of a conformity assessment body, the MDB shall issue a show cause notice to the conformity assessment body for cancellation or suspension of registration due to non-compliance of any of the conditions of registration or contravention of any provisions of these rules.

(2) The conformity assessment body shall submit, in writing, reply of a show cause notice within fifteen days from issuance of the notice under sub-rule (1).

(3) The MDB, after giving a reasonable opportunity of being heard and being satisfied that the conformity assessment body has not complied with the conditions of registration or contravened the provisions of these rules, may cancel or suspend the registration of the conformity assessment body for a specified period:

Provided that the MDB shall inform the conformity assessment body, in writing, on the cancellation or suspension of the registration of a conformity assessment body.

(4) Where a registration is cancelled by the MDB pursuant to sub-rule (3), the conformity assessment body shall within fourteen days after being informed in writing of the cancellation return the certificate of registration to the MDB without demand.

54. Responsibility of the MDB with regard to certificates issued by the conformity assessment body.— The MDB shall not be responsible for and not bound by any certificate issued by a conformity assessment body with regard to a medical device or its establishment, when the MDB considers application for registration of a medical device or licensing of its establishment.

CHAPTER-IV
REQUIREMENTS FOR THE REGISTRATION OF CONFORMITY ASSESSMENT BODY

55. Requirements for registration of conformity assessment body.— (1) For the purpose of registration of conformity assessment body, each entity which intends to be a conformity assessment body shall apply for registration to the MDB.

(2) The conformity assessment body applying for registration shall be a sound organization to enable it to carry out conformity assessment under these rules and shall comply with, where applicable, requirements on —

(a) organization;
(b) resources and technical competency;
(c) independence and impartiality; and
(d) quality management system.

PART I
REQUIREMENTS ON ORGANISATION

56. Organization structure of conformity assessment body.— (1) A conformity assessment body shall be a legally defined entity that is registered in Pakistan and shall be registered by the MDB to operate as a conformity assessment body in Pakistan.

(2) The person responsible for the management and operations of the conformity assessment body in Pakistan shall be a Pakistani citizen.

(3) The conformity assessment body shall identify and document its organization structure showing duties, responsibilities, guidelines of the competent authority, relationship and the reporting structure within its organization, including committees established by the organization.

(4) If a conformity assessment body is part of a larger organization, the links and relationship between the conformity assessment body and such larger organization shall be clearly defined and documented.

57. Responsibilities of conformity assessment body.— (1) A conformity assessment body shall take full responsibility and shall comply with all the requirements for the tasks required in relation to the scope of the tasks for which it is being registered.

(2) The conformity assessment body shall conduct conformity assessment of its clients against the declared procedures and those required by these rules.

(3) The conformity assessment body shall—

(a) make adequate arrangements to ensure confidentiality of the information obtained in the course of carrying out its tasks; and

(b) ensure that no details, records, results or information of any kind are disclosed to any other party, except the MDB.

(4) The conformity assessment body shall, without delay, inform the MDB of any change regarding availability of resources, including sub-contractors and compliance with the designated conditions in accordance with these rules.

PART II
REQUIREMENTS ON RESOURCES AND TECHNICAL COMPETENCY

58. Resources of conformity assessment body.— A conformity assessment body shall be a sound organization with adequate competent staff and appropriate facilities, including test equipment, if applicable, to enable it to carry out the conformity assessment according to the scope for which it is being registered.

59. Technical competency of conformity assessment body.— (1) A conformity assessment body shall determine the competence required for any personnel to undertake any assignment under its scope of registration and shall establish and implement procedures to ensure the competence level of its personnel.

(2) The conformity assessment body shall possess sufficient scientific and technical personnel within the organization according to the technical areas as specified in Table 4 below or are supported by its associates with adequate experience and knowledge in order to be able to handle the technical and administrative tasks such as allocation of appropriate assessment personnel, review of assessment output and to advise on certification for the specific tasks and products it has been designated to cover.

TABLE 4
MEDICAL DEVICE TECHNICAL AREAS

S.No	Name	Code	Scope expression
(1)	(2)	(3)	(4)
1.	NON-ACTIVE MEDICAL DEVICES	**MD 0100:**	**GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES**
		MD 0101	Non-active devices for anaesthesia, emergency and intensive care
		MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
		MD 0103	Non-active orthopaedic and rehabilitation devices
		MD 0104	Non-active medical devices with measuring function
		MD 0105	Non-active ophthalmologic devices
		MD 0106	Non-active instruments

		MD 0107	Contraceptive medical devices
		MD 0108	Non-active medical devices for disinfecting, cleaning, rinsing
		MD 0109	Non-active devices for *in vitro* fertilization (IVF) and assisted reproductive technologies (ART)
		MD 0200:	**NON-ACTIVE IMPLANTS**
		MD 0201	Non-active cardiovascular implants
		MD 0202	Non-active orthopaedic implants
		MD 0203	Non-active functional implants
		MD 0204	Non-active soft tissue implants
		MD 0300:	**DEVICES FOR WOUND CARE**
		MD 0301	Bandages and wound dressings
		MD 0302	Suture material and clamps
		MD 0303	Other medical devices for wound care
		MD 0400:	**NON-ACTIVE DENTAL DEVICES & ACCESSORIES**
		MD 0401	Non-active dental equipment and instruments
		MD 0402	Dental materials
		MD 0403	Dental implants
2.	ACTIVE MEDICAL DEVICES	**MD 1100:**	**GENERAL ACTIVE MEDICAL DEVICES**
		MD 1101	Devices for extra-corporal circulation, infusion and haemopheresis
		MD 1102	Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anesthesia
		MD 1103	Devices for stimulation or inhibition
		MD 1104	Active surgical devices
		MD 1105	Active ophthalmologic devices
		MD 1106	Active dental devices
		MD 1107	Active devices for disinfection and sterilization
		MD 1108	Active rehabilitation devices and active prostheses
		MD 1109	Active devices for patient positioning and transport
		MD 1110	Active devices for *in vitro* fertilization (IVF) and assisted reproductive technologies (ART)
		MD 1111	Software

		MD 1200:	**DEVICES FOR IMAGING**
		MD 1201	Imaging devices utilizing ionizing radiation
		MD 1202	Imaging devices utilizing non-ionizing radiation
		MD 1300:	**MONITORING DEVICES**
		MD 1301	Monitoring devices of non-vital physiological parameters
		MD 1302	Monitoring devices of vital physiological parameters
		MD 1400:	**DEVICES FOR RADIATION THERAPY AND THERMO THERAPY**
		MD 1401	Devices utilizing ionizing radiation
		MD 1402	Devices utilizing non-ionizing radiation
		MD 1403	Devices for hyperthermia / hypothermia
		MD 1404	Devices for (extracorporal) shock-wave therapy (lithotripsy)
3.	ACTIVE IMPLANTABLE MEDICAL DEVICES	**AIMD 0100:**	**GENERAL ACTIVE IMPLANTABLE MEDICAL DEVICES**
		AIMD 0101	Active implantable medical devices for stimulation / inhibition
		AIMD 0102	Active implantable medical devices delivering drugs or other substance
		AIMD 0103	Active implantable medical devices substituting or replacing organ functions
4.	*IN-VITRO* DIAGNOSTIC (IVD) MEDICAL DEVICES	**IVD 0100:**	**LIST-A REAGENTS AND REAGENT PRODUCTS, INCLUDING RELATED CALIBRATORS AND CONTROL MATERIALS, FOR DETERMINING THE FOLLOWING BLOOD GROUPS:**
		IVD 0101	AB0 system
		IVD 0102	Rhesus (C, c, D, E, e)
		IVD 0103	Anti-Kell
		IVD 0200:	**LIST-A REAGENTS AND REAGENT PRODUCTS, INCLUDING RELATED CALIBRATORS AND CONTROL MATERIALS, FOR THE DETECTION, CONFIRMATION AND QUANTIFICATION IN HUMAN SPECIMENS OF MARKERS OF—**
		IVD 0201	HIV infection (HIV 1 and 2)
		IVD 0202	HTLV I and II
		IVD 0203	Hepatitis B, C and D

		IVD 0300:	**LIST-B REAGENTS, REAGENT PRODUCTS AND DEVICES FOR SELF - DIAGNOSIS, INCLUDING RELATED CALIBRATORS AND CONTROL MATERIALS, FOR DETERMINING, DETECTING, QUANTIFICATION, DIAGNOSING, EVALUATING—**
		IVD 0301	Anti-Duffy and anti-Kidd
		IVD 0302	Irregular anti-erythrocytic antibodies
		IVD 0303	Congenital infections: rubella, toxoplasmosis
		IVD 0304	Hereditary disease: phenylketonuria
		IVD 0305	Human infections: cytomegalovirus, chlamydia
		IVD 0306	HLA tissue groups: DR, A, B
		IVD 0307	Tumoral marker: PSA
		IVD 0308	Risk of trisomy 21 (incl. software)
		IVD 0309	Device for self-diagnosis: device for the measurement of blood sugar
		IVD 0400:	**DEVICES FOR SELF-TESTING**
		IVD 0401	Clinical chemistry
		IVD 0402	Haematology
		IVD 0403	Immunology
		IVD 0404	Molecular biology
		IVD 0405	Pregnancy and ovulation
		IVD 0406	Specimen receptacles
5.	SPECIFICS OF MEDICAL DEVICES AND ACTIVE MEDICAL DEVICES	**MDS 7000:**	**MD / AIMD SPECIFICS**
		MDS 7001	Medical devices incorporating medicinal substances, according to Directive 2001/83/EC
		MDS 7002	Medical devices utilizing tissues of animal origin, including Directive 2003/32/EC
		MDS 7003	Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC
		MDS 7004	Medical devices referencing the Directive 2006/42/EC on machinery

		MDS 7005	Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)
6.	SPECIFICS OF *IN-VITRO* DIAGNOSTIC (IVD) MEDICAL DEVICES	**MDS 7200:**	**IVD SPECIFICS**
		MDS 7206	IVDs in sterile condition
		MDS 7207	IVDs utilizing micromechanics
		MDS 7208	IVDs utilizing nano materials
		MDS 7209	IVDs utilizing biological active coating and/or material
		MDS 7210	IVDs utilizing material of human origin

(3) Depending on the scope of its registration, the qualification and experience of the technical personnel of the conformity assessment body as required in sub-rule (2) shall be in accordance with the requirements as specified in these rules.

(4) The conformity assessment body shall maintain records of qualification and experience of its personnel as prescribed in sub-rule (3).

(5) The conformity assessment body shall ensure that when carrying out quality management system audits, the team of auditors shall comprise of at least one member who is experienced in the evaluation of the technologies used by the manufacturer.

(6) When conducting an audit of quality management system of an establishment, the conformity assessment body shall ensure that it is conducted by a team that includes at least a member who is competent in the review of specific technical areas or technologies pertaining to the medical device that the establishment is dealing with or specific processes involved in the production or handling of the medical devices.

60. Sub-contracting by conformity assessment body.— If a conformity assessment body uses the services of a sub-contractor, the conformity assessment body shall—

(a) be responsible for all contracted tasks;

(b) be liable for the sub-contractor as if the conformity assessment body itself performs the tasks;

(c) ensure that its sub-contractors and their personnel conform to all the requirements of these rules;

(d) establish and implement procedure and maintain records on the assessment of the sub-contractor's qualifications and the tasks carried out by the sub-contractor on behalf of the conformity assessment body;

(e) not sub-contract the overall responsibility for reviewing the outcome of assessment and verification activities, which are the essential tasks for which it was registered;

(f) restrict the sub-contractor to perform only the sub-contracted tasks;

(g) prohibit the sub-contractor from further sub-contracting its duties;

(h) draw up a documented agreement between the conformity assessment body and the sub-contractor reflecting the requirements on the sub-contracted tasks,

including the requirements on confidentiality, impartiality, provision of access by the MDB and prohibition of the sub-contractors from further sub-contracting their duties;

(i) ensure that the sub-contracted tasks carried out by the sub-contractor is carried out according to detailed documented procedures which are the same as, or judged by the conformity assessment body to be equivalent to, those followed by the conformity assessment body itself;

(j) ensure that the sub-contractor fulfils only an objective role i.e the one which is restricted to factual reporting and supported recommendations, on the basis of which the conformity assessment body shall make assessments and judgments in relation to the requirements of the rules;

(k) inform the MDB of its intention to sub-contract duties in relation to the task for which it was registered;

(l) maintain an up-to-date register of all its sub-contractors, which shall be provided to the MDB without delay upon advice;

(m) maintain documented evidence that the sub-contractor has the necessary technical competence and facilities to carry out the sub-contracted activities;

(n) maintain the relevant documents and records of assessment of the qualifications of the sub-contractor in relation to the work contracted to the sub-contractor; and

(o) maintain sub-contractor register which shall include the following information: —

(i) the name of the sub-contractor organization;

(ii) its legal status and details of any relationship with a parent company, group of companies, or any other organization of which the sub-contractor is a part;

(iii) names of staff carrying out the sub-contracted tasks and evidence that they are competent to do so; and

(iv) the task performed by the sub-contractor and details of the procedures used in carrying out the sub-contracted task.

PART III
REQUIREMENTS ON INDEPENDENCE AND IMPARTIALITY

61. Independence and impartiality.—(1) A conformity assessment body shall be independent and not related to its clients and shall not be involved in activities relating to designing, manufacturing, importing or distributing the product category for which the conformity assessment body has been registered.

(2) The conformity assessment body shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the result of the inspections, especially from persons or groups of persons with an interest in the results of the assessments.

(3) The conformity assessment body or its subsidiaries shall not—

(a) involve in consultancy activities relating to the scope of activities for which it is registered; and

(b) provide consultancy services to establishment and seeking certification under

its own jurisdiction.

(4) The conformity assessment body shall establish and implement documented procedures and maintain records of the identification, review and resolution of all cases where conflict of interest is suspected or proven.

(5) The conformity assessment body shall require all staff acting on its behalf to declare any potential conflict of interest.

(6) The conformity assessment body shall maintain records of such declarations required under sub-rule (5).

(7) The conformity assessment body shall guarantee the impartiality of all inspection and evaluation personnel and ensure that the remuneration of personnel shall not depend on the number of controls and verifications that they carry out, or on the results of their activities.

62. Confidentiality and liability.—(1) The conformity assessment body shall observe strict professional confidentiality with regard to all information obtained in carrying out their tasks.

(2) The professional confidentiality to be observed by the conformity assessment body shall not affect obligation of the conformity assessment body with regard to legally required reporting and dissemination of warnings, nor its obligation to provide information under criminal and civil law.

(3) The conformity assessment body shall make appropriate arrangements to ensure that no details, records, results or information of any kind are disclosed to any other party except to the MDB.

(4) The conformity assessment body shall have public liability insurance commensurate with the scope of its services.

PART IV
QUALITY MANAGEMENT SYSTEM

63. Documentation.—(1) A conformity assessment body shall establish, maintain and implement within its organization an appropriate quality management system pertaining to its management and operations.

(2) The quality management system as required in sub-rule (1) shall include the following elements, namely: —

(a) description of the legal status of the conformity assessment body including the links and relationship with parent organizations, if relevant;

(b) responsible person;

(c) authorities, responsibilities and reporting structure within the conformity assessment body;

(d) scope of the services provided and the fees for the conduct of conformity assessment;

(e) particulars of assessment personnel, both internal and sub-contracted, including the following, namely:—

(i) assessment responsibilities;
(ii) records of relevant training and experience; and

(iii) justification or rationale for the defined scope of assessment responsibilities;

(f) procedures to carry out assessment and verification during conformity assessment on the clients, including the following, namely:—

(i) review on the completeness of application against the details provided under which conformity assessment has been sought;
(ii) review and verification on the compliance of the clients with the regulatory requirements;
(iii) conclusion of the assessment of the compliance of the clients with the scope being assessed;
(iv) issuance, refusal, suspension and withdrawal of or restrictions placed on the certificate;
(v) communications with other organizations, including the MDB relating to issuance, refusal, suspension and withdrawal of, or restrictions placed on a certificate, including records of all communications and actions taken as a result of such communications;
(vi) assessment and monitoring of sub-contractors, if used;
(vii) maintenance of record, including means to ensure security and confidentiality;
(viii) consideration of appeals against decisions made, including referral to the MDB, where necessary; and
(ix) means by which assessment and consultancy services are separated, whether these services are carried out by the conformity assessment body or any part of a larger organization to which it is linked, or its sub-contractors;

(g) records on the conclusions of assessment including a reasoned evaluation of the manufacturer's compliance with the standards specified; and

(h) the conformity assessment body shall—

(i) establish and maintain a system to control all quality management system documentation and to ensure that current issues of procedures are available at all relevant locations; and
(ii) ensure that the defined quality management system is effectively implemented.

64. Product testing by conformity assessment body.—(1) If the scope of the conformity assessment body covers product testing, it shall have relevant test equipment, testing protocols, standards and relevant accreditation.

(2) If the testing is sub-contracted, the conformity assessment body shall ensure that the requirements on sub-contractors are adhered to as specified in rule 61.

65. Conformity assessment process.— (1) A conformity assessment body shall establish the following, namely:—

(a) documentation including general terms and conditions, marketing materials, application forms and contracts, that an applicant would propose sending to potential new clients if registered;

(b) procedures to assess clients' conformity with the appropriate conformity assessment requirements and essential principles of safety and performance, including as applicable, those procedures specific to—

(i) design dossier reviews;
(ii) assessment of clinical and bio-compatibility data;
(iii) medical device containing animal tissues;
(iv) sterile medical device;
(v) other specialized technologies; and
(vi) clinical pathology aspects of *in-vitro* diagnostics, etc.;

(c) procedures how to take account of existing certifications and registrations received by the applicant from other conformity assessment bodies or other regulatory authorities;

(d) procedures to ensure conformity assessment certificates are only issued after a full assessment of all relevant information and that this assessment is subject to an independent check; and

(e) procedures aimed at ensuring the independence and impartiality of assessments and certification decisions.

PART V
REQUIREMENTS ON QUALIFICATION AND EXPERIENCE OF THE TECHNICAL PERSONNEL OF THE CONFORMITY ASSESSMENT BODY

66. Qualification of the technical personnel of the conformity assessment body.—(1) The conformity assessment body shall employ technical personnel having the following relevant qualification to conduct conformity assessment in medical device technical areas as specified in these rules: —

(a) have successfully completed a recognized university or a professional degree or equivalent qualification in one or more of the following fields:—

(i) Pharmacy;
(ii) biomedical engineering;
(iii) biology or microbiology or biotechnology;
(iv) chemistry or biochemistry;
(v) computer or software technology;
(vi) electrical, mechanical or bioengineering;
(vii) human physiology;
(viii) medicine or dentistry;
(ix) veterinary sciences;
(x) medical physics;
(xi) biophysics; or
(xii) other relevant fields.

(b) have preferably attended training on statutory requirements, including subsequent updates in the event of significant changes in medical device regulation;

(c) a quality management system auditor shall have passed appropriate training on auditing of relevant quality management system for medical device;

(d) a lead auditor shall be competent to plan and direct the team members so that in carrying out their separate tasks, the appropriate competence is applied effectively and fairly;

(e) record of all technical personnel of the conformity assessment body shall be provided to the MDB.

(2) The conformity assessment body shall maintain the following records of its technical

personnel, namely:—

(a) name of technical personnel;

(b) areas of competence and responsibility within the scope of activities for which the conformity assessment body has been registered;

(c) educational and professional qualifications;

(d) work experience relevant to the activities being performed; and

(e) details of training received relating to assessment activities.

67. Experience and knowledge of the technical personnel of the conformity assessment body.—(1) Technical personnel of a conformity assessment body preferably shall have relevant experience including the following, namely: —

(a) experience in closely-related industries and the workplace such as research, development and manufacturing;
(b) experience in the application of medical device technology and its use in health care services;
(c) experience of testing of medical device concerned for compliance with the relevant national or international standards;
(d) experience of conducting performance testing, evaluation studies or clinical investigation of medical device; or
(e) substantial relevant `experience in the diagnostic, medical devices or pharmaceutical industries, the health care professions, medical laboratories or testing institutes.

(2) If the technical personnel have completed postgraduate degree, the number of years for total experience may be reduced two years for M.Phil and four years for Ph.D.

(3) The technical expert shall have a minimum of three years work experience in medical devices-related industry.

(4) The knowledge of technical personnel may preferably be in the following areas:—

(a) proven knowledge of medical devices' law, relevant rules and relevant guidance documents;
(b) proven knowledge of quality management procedures, especially of relevant standards acquired through successful participation in relevant training courses or practical experience;
(c) knowledge of the current status of applicable and relevant product-related standards;
(d) technical knowledge and experience of the design, manufacture and quality control of medical devices;
(e) risk assessment and management as applied to medical devices, including relevant standards as well as the use of risk management tools encompassing the entire medical device lifecycle.

68. Qualification and experience of the technical personnel for special technology areas.—(1) A conformity assessment body whose scope of registration includes special technology areas relating certain types of medical device shall employ additional technical personnel possessing specific expertise in those special technology areas which, depending on the scope, may include—

(a) evaluation of biological and medical functionality and performance of

medical devices;

(b) evaluation of medical devices containing animal tissues;

(c) evaluation of medical devices containing human blood derivatives, including blood borne infectious agents and their epidemiology;

(d) evaluation of bio-compatibility and clinical data used by manufacturers to demonstrate compliance with the essential principles of safety and performance;

(e) evaluation of electrical safety of medical devices;

(f) evaluation of software used in medical devices;

(g) evaluation of performance characteristics of *in-vitro* diagnostic medical devices;

(h) assessment of the complexity and variability of biological test systems;

(i) development and use of standard methods for the evaluation and assessment of *in-vitro* diagnostics and medical devices for self-diagnosis;

(j) experience in the development and use of reference methods, reference materials and standards used in batch testing;

(k) experience and training in the batch testing of *in-vitro* diagnostic medical devices;

(l) knowledge of the complexity and variability of pathogens in so far as they affect the performance of those *in-vitro* diagnostic medical devices (HIV 1 and 2, HTLV-I and II, Hepatitis B, C and D);

(m) knowledge of the fundamental principles behind the sourcing controls and validation of inactivation methods for medical devices containing tissues from animal origin; or

(n) experience in medical device technology using tissues or derivatives and assessment of medical devices containing tissues from animal origin.

CHAPTER V

ESTABLISHMENT LICENCE

69. Types of establishment licences.— (1) The MDB shall issue following types of establishment licences, namely: **—-**

(a) licence to manufacture medical devices; and
(b) licence to import medical devices.

(2) If medical devices are manufactured, imported or sold on more than one premises, a separate licence shall be issued in respect of each such premises.

(3) The Provincial Governments shall in accordance with section 6 of the Act regulate the sale of medical devices in the prescribed manner and may for that purpose make such orders, and issue such directions to the importers, manufacturers, stockists, retailers or other dealers of medical devices, as they may deem fit.

70. Application procedure for establishment licence.— (1) An application for an establishment licence shall comply with the requirements as specified in these rules.

(2) The application for an establishment licence under sub-rule (1) for manufacturing or import shall on the format as set out in Form-3 or Form-3A, as the case may be, be made to the MDB

addressed to its Secretary.

(3) An application for an establishment licence under sub-rule (2) shall be accompanied with the following, namely:—

(a) application fee as specified in rule 138;
(b) such documents or information as specified in Form-3 or Form-3A, as the case may be; and
(c) certificate and report of conformity assessment where applicable.

(4) The MDB may reject an application if the applicant fails to deposit specified fee and provide information, particulars or documents as required under sub-rule (3) and shall inform the applicant of its decision in writing with reason of such decision.

71. Procedure for grant of establishment licence.— (1) Upon receipt of the application for establishment licence, the MDB shall consider the application and may inspect the premises of the establishment as it considers proper and necessary to verify any information, particulars, documents and other requirements under these rules. For this purpose, the MDB may constitute a panel of experts which may include inspectors or auditors of the registered conformity assessment body.

(2) If satisfied with all requirements pertaining to the application under sub-rules (2) and (3) of rule 70 including satisfactory inspection report of the establishment, the MDB upon approval shall issue a licence to the establishment for manufacturing or import on the format as set out in Form-4 or Form-4A, as the case may be.

(3) A licence issued under these rules shall, unless earlier suspended or cancelled, be valid for a period of five years from the date of its issuance and shall be entered in the medical device register (MDR).

(4) The licensee shall comply with all the prescribed conditions of licence for an establishment.

72. Conditions of establishment licence.— (1) The following shall be conditions for grant of establishment licence to manufacture medical devices: —

(a) The applicant shall provide premises which shall be suitable for intended use, in size and construction and shall be located in an appropriate area;

(b) the applicant shall provide adequate space, plant and equipment for the manufacturing operations;

(c) the manufacturing shall be conducted under the active directions and personal supervision of competent technical staff consisting of at least one person being the production incharge who shall be a whole-time employee and who has —

(i) a degree in pharmacy from a recognized university or any other recognized institution and has at least two years experience for the manufacture of the medical devices; or

(ii) a degree in bio medical engineering from a recognized university or any other recognized institution and has at least two years experience for the manufacture of the medical devices;

(d) the applicant shall establish an independent quality control department and maintain separate staff, premises and adequate laboratory equipment for

carrying out tests of the safety, quality and performance of the medical device being, or to be, used in the manufacture;

(e) the incharge of quality control department shall be a whole-time employee of the manufacturer and shall possess a degree in pharmacy from a recognized university or any other recognized institution and shall possess two years experience in testing of the medical devices. The licensee shall have a system of quality assurance appropriate to the medical devices;

(f) the applicant shall comply with the provisions of these rules;

(g) the applicant shall provide.—

(i) adequate facilities for first aid and fire fighting;

(ii) medical inspection of workers at the time of employment and periodical check up thereafter at least once a year;

(iii) facilities for vaccination and inoculation against the enteric or any other epidemic group of diseases; and

(iv) adequate precautions for safe-guarding the health of workers, including measures to avoid industrial accidents or diseases;

(2) Where a licence is granted to an establishment to manufacture medical devices, it shall be subject to the following conditions, namely:—

(a) The licence shall be kept in the licenced premises and shall be produced on the request of any member of the MDB or the concerned Inspector;

(b) the licensee shall maintain the inspection book provided by the MDB at the time of the issuance of the licence on which a member of the MDB or an Inspector shall record proceedings of each of his visit, his comments and the defect or irregularities noticed, if any, by him and such inspection book shall be signed by him as well as the licensee or his authorized agent;

(c) if any defect or irregularity is recorded in the inspection book, the licensee shall take steps to remove such defect or irregularity;

(d) a licensee who for any purpose is engaged in the culture or manipulation of pathogenic spore bearing micro-organisms shall provide separate laboratories, utensils and apparatus required for the culture or manipulation of such micro-organisms and they shall not be used for the manufacture of any other product;

(e) any change in the expert staff or significant alteration in the licensed premises or equipments or instruments shall take place in accordance with these rules;

(f) the licensee shall allow any member of the MDB or an Inspector to enter any premises and to inspect the plant and the process of manufacture and the means employed in production and testing of the medical devices and to take samples, where applicable, for test and analysis;

(g) the Licensee shall, on demand, furnish to the MDB or to such authority as the MDB may direct, from every batch or lot of a medical device, or from such batch or batches of medical devices as it may from time to time specify, a sample, where applicable, for examination and, if required, furnish full protocols of the tests which have been applied;

(h) the licensee shall on being informed by the MDB that any part of any batch or lot of a medical device has been found not to conform with the requirements of these rules and on being directed so to do, withdraw the remainder of the batch or lot of such device from sale and, so far as may in the particular circumstances as the case be practicable, recall all issues

already made from that batch or lot and dispose it of in such manner as may be directed by the MDB;

(i) the licensee or his authorized agent shall issue a warranty on the format as set out in Form-5 for any medical device sold by him;

(j) the licensee shall comply with the requirements and the conditions in respect of good manufacturing practices in the manufacture and quality control of medical devices;

(k) the licensee shall record the particulars of manufacture of each batch or lot of the medical devices manufactured by him and shall retain such records;

(l) the licensee shall ensure that.—

(i) any unhygienic practices such as eating and smoking shall not take place in any production or quality control area;

(ii) sufficiently clean, appropriately ventilated toilet facilities, including facilities for washing and room for changing clothes, shall be available for the use of manufacturing personnel where required;

(iii) high standard of personnel hygiene shall be observed by all persons concerned with production processes; and

(iv) no person known to be suffering from communicable disease or to be a carrier of such a disease and no person with open lesions or skin infection shall be engaged in production areas;

(m) if the MDB, on the basis of information received or an inquiry conducted by it, is of opinion that—

(i) the licence of establishment was procured by fraud or misrepresentation; or

(ii) the circumstances in which a licence was issued no longer exist; or

(iii) it is necessary in the public interest so to do,

the MDB may, after affording to the licensee an opportunity of showing cause against the action proposed to be taken, cancel or suspend the licence or specify any further conditions to which the licence shall be subjected to and inform such licensee accordingly.

(3) The following shall be conditions for grant of establishment licence to import and sell thereof medical devices, namely: —

(a) The applicant shall provide premises which shall be suitable for intended use, in size and construction and shall be located in an appropriate area;

(b) the applicant shall provide adequate space for proper storage and handling of medical devices;

(c) the applicant shall comply with the provisions of these rules.

(4) Where a licence is granted to an establishment to import and sell thereof medical devices, it shall be subject to the following conditions, namely:—

(a) The licensee shall comply with good distribution practices;

(b) the licensee or his authorized agent shall issue a warranty on the format as set out in Form-5 for the medical device sold by him;

(c) the licensee shall be responsible for the quality, safety and performance of the medical device imported by him;

(d) the licensee shall maintain complete batch-record of import and sale of medical device imported by him;

(e) the licensee shall keep sufficient quantity of samples, where practicable, of the medical device imported by him;

(f) if the MDB, on the basis of information received or an inquiry conducted by it, is of opinion that.—

(i) the licence of establishment was procured by fraud or misrepresentation; or

(ii) the circumstances in which a licence was issued no longer exist; or

(iii) it is necessary in the public interest so to do,

the MDB may, after affording to the licensee an opportunity of showing cause against the action proposed to be taken, cancel or suspend the licence or specify any further conditions to which the licence shall be subjected to and inform such licensee accordingly.

73. Renewal of establishment licence.— (1) An application for renewal of establishment licence for manufacturing or import shall, sixty days before its expiry, be made to the MDB on the format as set out in Form-3 or Form-3A, as the case may be, and shall be accompanied by the following, namely:—

(a) application fee as specified in rule 138;

(b) documents or information specified in Form-3 or Form-3A, as the case may be; and

(c) certificate and report of conformity assessment where applicable.

(2) The MDB may reject an application if the establishment fails to deposit specified fee and provide information, particulars, or documents as required under sub-rule (1).

(3) Upon receipt of the application for renewal of establishment licence, the MDB shall consider the application and may inspect the premises of the establishment as it considers proper and necessary to verify any information, particulars, documents and other requirements under these rules. For this purpose, the MDB may constitute a panel of experts which may include inspectors or auditors of registered conformity assessment body.

(4) If satisfied with all the requirements pertaining to the application including satisfactory inspection report of an establishment, the MDB may approve renewal of establishment licence for a period of five years from the date of expiry of previous licence unless it is cancelled or suspended by the MDB before its expiry.

(5) If an application for renewal is made after expiry of the period of validity of licence but within sixty days after expiry of the period of validity, the applicant shall deposit an additional surcharge of ten percent of the renewal fee for establishment licence for each day the application is delayed.

(6) If an application for renewal is made after sixty days of expiry of the period of validity, the establishment licence shall cease to exist and the application shall be treated as a fresh application for grant of establishment licence.

(7) If an application for renewal is made before the expiry of the period of validity of licence or within sixty days after expiry of the period of validity along-with deposition of additional surcharge, the licence shall continue to be valid until orders are passed on such application.

(8) If an application for renewal is made after sixty days of expiry of the period of validity, the establishment shall be responsible for all the illegal operations carried out during that period.

(9) In case the application for renewal of establishment licence is rejected by the MDB, it shall inform the applicant of its decision in writing with reasons of such decision.

74. Changes concerning establishment licence.— (1) A licensed establishment shall apply to the MDB for prior approval, if any change is proposed regarding the particulars provided in relation to the licensing of establishment.

(2) For the purposes of sub-rule (1), a change that affects the activities of licensed establishment, includes but is not limited to a change of one or more of the following, namely:—

(a) the premises of the establishment;

(b) the quality system certification issued to the establishment by the conformity assessment body;

(c) the conformity assessment body, responsible for conformity assessment of the establishment; or

(d) class or type of medical device that he manufactures, imports, distributes, installs, tests, commissions, maintains or places in the market;

(3) An application under sub-rule (1) for change in particulars in manufacturing or import shall be—

(a) made on the format as setout in Form-3 or Form-3A, as the case may be; and

(b) accompanied by the relevant application fee specified in rule 138;

(4) Upon receipt of the application under sub-rule (3), the MDB shall consider the proposed change and may inspect the establishment along with the auditor or inspector of conformity assessment body to verify the particulars, information or documents as provided by the establishment and the proposed change shall not take effect until the MDB has given its approval for the change.

(5) If any establishment contravenes these rules, its licence may be cancelled or suspended as the MDB may deem fit, after affording him the opportunity of being heard.

(6) If the MDB, on the basis of information received or an inquiry conducted by it, is of opinion that—

(a) the approval of change in any particulars of establishment licence was obtained by fraud or misrepresentation; or

(b) the circumstances in which the change in any particulars of establishment licence was approved no longer exist; or

(c) it is necessary in the public interest so to do,

the MDB may, after affording to the licensee an opportunity of showing cause against the action proposed to be taken, cancel or suspend the licence or specify any further conditions to which the licence shall be subject and inform such licensee accordingly.

75. General conditions for establishment licence.— (1) A licensee shall comply with all the conditions of the establishment licence under these rules including applicable good manufacturing practices (GMP) or good distribution practices (GDP) or good storage practices (GSP).

(2) A licence for an establishment issued by the MDB shall not be assigned or transferred to any other person or classes of persons except with prior written approval of the MDB.

(3) If an establishment does not comply sub-rule (1) or contravenes sub-rule (2), its licence may be cancelled or suspended as the MDB may deem fit after providing the licensee an opportunity of being heard.

(4) An establishment licence issued to an establishment shall remain the property of the MDB, and shall within fourteen days after its cancellation be surrendered to it without demand.

76. Cancellation or suspension of establishment licence.— (1) Before cancellation or suspension of licence of an establishment, the MDB shall issue a show cause notice to the establishment for cancellation or suspension of licence due to non compliance of any of the conditions of licence or contravention of any provision of these rules.

(2) The establishment shall submit, in writing, reply to the show cause notice within fifteen days from the date of issuance of the notice.

(3) The MDB, being satisfied that the establishment has not complied with the conditions of licence or contravened the provisions of the DRAP Act or these rules, may cancel or for a specified period suspend the licence of the establishment.

(4) The MDB shall inform the establishment, in writing, on the cancellation or suspension of the licence of the establishment.

(5) Where a licence is cancelled by the MDB pursuant to sub-rule (4), the establishment shall within fourteen days after being informed in writing of the cancellation return the establishment licence to the MDB without demand.

(6) Where an establishment licence is cancelled or suspended by the MDB, the registrations granted to the establishment shall automatically cease to exist or remain suspended, as the case may be.

CHAPTER VI
CLASSIFICATION OF MEDICAL DEVICES

77. Classification of medical devices.- (1) For the purpose of registration, the medical devices shall be classified in accordance with these rules.

(2) In case of any dispute between conformity assessment body and the establishment over classification of a medical device, the establishment or, as the case may be, the conformity assessment body may request in writing to the MDB to decide on the dispute and the MDB shall inform both the parties in writing of its decision.

78. Methods of classification of medical devices. — (1) A manufacturer, prior to making of application for registration under these rules, shall be responsible to classify his medical device, in accordance with these rules.

(2) All medical devices shall be classified into four classes, namely, Class A, Class B, Class C and Class D depending on the level of risk it poses to patients, users and other persons.

(3) The manufacturer may use—

(a) the classification methods in PART I of this Chapter to classify medical devices other than *in-vitro* diagnostic medical devices; and

(b) the classification methods in PART II of this Chapter to classify *in-vitro* diagnostic medical devices.

(4) The manufacturer shall take the following considerations when classifying his medical device, namely: —

(a) the intended purpose and mechanism of action of the medical device;

(b) if more than one method is applicable, the higher classification shall apply;

(c) the classification shall be consistent with the information accompanying the medical device, including its label, instruction for use, brochures and operating manuals;

(d) if a medical device is to be used in combination with other medical device, the classification shall be applied separately for each medical device;

(e) the duration of use shall be specified for all invasive medical devices;

(f) accessories shall be classified separately from the medical devices they are used with;

(g) if a medical device is not used in a specific part of the body, it shall be classified based on the most critical specified use;

(h) software intended to drive or influence the use of a medical device shall be classified in the same classification as the medical device; and

(i) based on its intended purpose, a software may be a medical device in its own and classified accordingly.

PART I
CLASSIFICATION METHODS FOR MEDICAL DEVICES, OTHER THAN *IN-VITRO* DIAGNOSTIC MEDICAL DEVICES

79. Classification of non-invasive medical devices. — (1) All non-invasive medical devices which come into contact with injured skin become extremely sensitive and as such for this sub-rule shall be classified as—

(a) Class A, if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates only, i.e. they heal by primary intent, e.g., simple wound dressings, cotton wool, etc;

(b) Class B, if they are intended to be used principally with wounds which have breached the dermis, including medical devices principally intended to manage the micro-environment of a wound, e.g., non-medicated impregnated gauze dressings, etc; or

(c) Class C, if they are intended to be used principally with wounds which have

breached the dermis and can only heal by secondary intent. Medical devices used to treat wounds where the subcutaneous tissue is partially exposed and the edges of the wound are not sufficiently close to be pulled together.

Explanation.—To close the wound, new tissue must be formed within the wound prior to external closure and the device manufacturer claims that they promote healing through physical methods other than primary intent, e.g., dressings for chronic ulcerated wounds, dressings for severe burns, etc.

(2) All non-invasive medical devices shall, for the purpose of this sub-rule, be in—

(a) Class A, if intended for channeling or storing body liquids, body tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body, e.g., administration sets for gravity infusion, syringes without needles, etc;

(b) Class B—

(i) if intended for channeling or storing body liquids, body tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body and connected to an active medical device in Class B or a higher class. Connection to an active medical device covers those circumstances where the safety and performance of the active medical device is influenced by the non- active medical device and *vice versa*, e.g., syringes and administration sets for infusion pumps, anesthesia breathing circuits, etc; or

(ii) if they are intended for use of channelling blood, storing or channelling other body liquids or for storing organs, parts of organs or body tissues, e.g., tubes used for blood transfusion, organ storage containers, blood bags that do not incorporate an anti-coagulant, etc; or

(c) Class C, if they are blood bags.

Explanation.— Such medical devices are indirectly invasive as they channel or store liquids that will eventually be delivered into the body.

(3) All non-invasive medical devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids, intended for infusion into the body shall be in —

(a) Class C, if the modification does not include simple mechanical filtration or centrifugation, e.g., haemodialisers, devices to remove white blood cells from whole blood, etc; or

(b) Class B, if the procedure consists of filtration, centrifugation or exchange of gas or of heat, where modification includes simple mechanical filtration or centrifugation, e.g., devices to remove carbon dioxide, particulate filters in an extracorporial circulation system, etc.

Explanation.— Such medical devices are indirectly invasive in the sense that they treat or modify substances that will eventually be delivered into the body. They are normally used in conjunction with an active medical device within the scope of either sub-rule (1) or clause (i) and (ii) of sub-rule (2) or sub-rule (4) of rule 81.

(4) All other non-invasive medical devices which either do not touch the patient or contact only intact skin, shall be in Class A, e.g., urine collection bottles, compression hosiery, non-

invasive electrodes, hospital beds, etc.

80. Classification of invasive medical devices. — (1) All invasive medical devices with respect to body orifices, other than those which are surgically invasive and which are not intended for connection to an active medical device or are intended for connection to a Class A medical device only, shall be in —

(a) Class A—

(i) if they are intended for transient use, e.g., examination gloves, enema devices, etc; or

(ii) if they are intended for short-term use in the oral cavity as far as the pharynx, in an ear canal upto the ear drum or in a nasal cavity, e.g., dentures intended to be removed by the patient, dressings for nasal bleedings, etc; or

(b) Class B—

(i) if they are intended for short-term use, e.g., urinary catheters, tracheal tubes etc; or

(ii) if they are intended for long-term use in the oral cavity as far as the pharynx, in an ear canal upto the ear-drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, e.g., orthodontic wire, fixed dental prosthesis, etc; or

(c) Class C, if they are intended for long- term use, e.g., urethral stents, contact lenses. Removal of the lens for cleaning or maintenance shall be considered as part of the continuous use.

Explanation.— Medical devices related to this sub-rule tend to be diagnostic and therapeutic instruments used in ENT, ophthalmology, dentistry, proctology, urology and gynaecology. Classification depends on the duration of use and the sensitivity or vulnerability of the orifice to such invasion.

(2) All invasive medical devices with respect to body orifices, other than those which are surgically invasive which are intended to be connected to an active medical device classified as Class B or a higher class, shall be classified as Class B. They are independent of the time for which they are invasive, e.g., tracheal tubes connected to a ventilator, suction catheters for stomach drainage, dental aspirator tips, etc.

(3) All surgically invasive medical devices intended for transient use shall be in —

(a) Class A, if they are reusable surgical instruments, e.g., manually operated surgical drill bits and saws etc:

Provided that surgical instruments connected to an active device shall be in a higher class than Class A; or

(b) Class B—

(i) including those that create a conduit through the skin e.g., syringe needles or lancets, surgical instruments e.g., single-use scalpels or surgical staplers or single-use aortic punch, surgical gloves and various types of catheter or sucker, etc; or

(ii) surgical instruments, other than those in Class D, if supplied sterile and intended for single use: or

(c) Class C, if intended to —

(i) supply energy in the form of ionizing radiation, e.g., catheter incorporating or containing sealed radioisotopes, etc; or

(ii) have a biological effect or be wholly or mainly absorbed.

Explanation.—The biological effect shall be an intended one rather than unintended. The term absorption shall be the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body. This rule does not apply to those substances that are excreted without modification from the body, e.g., insufflation gases for the abdominal cavity; or

(iii) administer medicinal products by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, e.g., insulin pen for self-administration etc.

Explanation.—Administration of medicines implies storage or influencing the rate or volume of medicine delivered and not just channeling. Potentially hazardous manner refers to the characteristics of the medical device and not the competence of the user; or

(d) Class D, if they are intended specifically —

(i) for use in direct contact with the central nervous system; or

(ii) to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, e.g., angioplasty balloon catheters and related guide wires, dedicated disposable cardiovascular surgical instruments, etc.

(4) All surgically invasive medical devices intended for short-term use shall be in—

(a) Class B.

Explanation.— Medical devices of this class are mostly used in the context of surgery or post-operative care or are infusion devices or are catheters of various types, e.g., infusion canola, temporary filling materials, non-absorbable skin closure devices, tissue stabilizers used in cardiac surgery etc. These include medical devices that are used during cardiac surgery but do not monitor or correct a defect;

(b) Class C, if they are intended to—

(i) administer medicinal products.

Explanation.— Administration of medicines implies storage or influencing the rate or volume of medicine delivered and not just channeling;

(ii) undergo chemical change in the body except if the devices are placed in the teeth, e.g., surgical adhesive, etc;

(iii) supply energy in the form of ionizing radiation, e.g., brachytherapy device, etc;

(c) Class D, if they are intended—

(i) to have a biological effect or to be wholly or mainly absorbed, e.g., absorbable suture, biological adhesive, etc.

Explanation.— The biological effect is an intended one rather than unintentional. Absorption refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body; or

(ii) specifically for use in direct contact with the central nervous system, e.g., neurological catheter, etc; or

(iii) specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, e.g., cardiovascular catheters, temporary pacemaker leads, carotid artery shunts, etc.

(5) All implantable medical devices and long- term surgically invasive medical devices shall be in—

(a) Class B, if they are intended to be placed into the teeth, e.g., bridges, crowns, dental filling materials, etc otherwise in Class C.

Explanation.— Most of the medical devices in Class C are implants used in the orthopaedic, dental, ophthalmic and cardiovascular fields, e.g., maxilla-facial implants, prosthetic joint replacements, bone cement, non-absorbable internal sutures, posts to secure teeth to the mandibula bone without a bioactive coating; or

(b) Class D, if they are—

(i) intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, e.g., prosthetic heart valves, spinal and vascular stents, etc; or

(ii) intended to be life supporting or life sustaining; or

(iii) intended to be active implantable medical devices, e.g., pacemakers, their electrodes and their leads, implantable defibrillators, etc; or

(iv) intended to have a biological effect or to be wholly or mainly absorbed, e.g., implants claimed to be bioactive, etc.

Explanation.— Hydroxy-apatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer; or

(v) intended to administer medicinal products, e.g., rechargeable non-active drug delivery system, etc; or

(vi) intended to undergo chemical change in the body except if the devices are placed in the teeth.

Explanation.— Bone cement is not within the scope of the term chemical change in the body since any change takes place in the short rather than long term; or

(vii) breast implants.

81. Classification of active medical devices. — (1) All active therapeutic medical devices shall be in —

(a) Class B, if they are intended to administer or exchange energy.

Explanation.— Such medical devices are mostly electrically powered equipment used in surgery, medical devices for specialized treatment and some stimulators, e.g., muscle stimulators, powered dental hand pieces, hearing aids, neonatal phototherapy equipment, ultrasound equipment for physiotherapy, etc; or

(b) Class C, if their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionizing radiation, taking account of the nature, the density and site of application of the energy, e.g., lung ventilators, baby incubators, electrosurgical generators, external pacemakers and defibrillators, surgical lasers, lithotripters, therapeutic X-ray and other sources of ionizing radiation etc.

Explanation.— The term 'potentially hazardous' refers to the type of technology involved and the intended application.

(2) All active medical devices shall be in Class C—

(i) if they are intended to control or monitor the performance of active therapeutic medical devices in Class C; or

(ii) if they are intended directly to influence the performance of such medical devices.

Examples are external feedback systems for active therapeutic medical devices, etc; or

(iii) if they are intended to emit ionizing radiation and intended for diagnostic or interventional radiology, including devices which control or monitor such devices, or those which directly influence their performance.

Explanation.— These include medical devices for the control, monitoring or influencing of the emission of ionizing radiation.

(3) Active medical devices intended for diagnosis shall be in—

(a) Class B, which include equipment for ultrasonic diagnosis or imaging, capture of physiological signals, interventional radiology and diagnostic radiology, if they are intended to—

(i) image *in-vivo* distribution of radiopharmaceuticals, e.g., gamma or nuclear cameras; or

(ii) allow direct diagnosis or monitoring of vital physiological processes, e.g., electronic thermometers, stethoscopes and blood pressure monitors, electrocardiographs, etc; or

(b) Class A, if they are intended to supply energy which will be absorbed by the

human body except for devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, e.g., magnetic resonance equipment, diagnostic ultrasound in non-critical applications, evoked response stimulators, etc; or

(c) Class C, if they are specifically intended for—

(i) monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance, variations in cardiac performance, respiration, activity of central nervous system, e.g., monitors or alarms for intensive care, biological sensors, oxygen saturation monitors, apnoea monitors; or

(ii) diagnosing in clinical situations where the patient is in immediate danger, e.g., ultrasound equipment for use in interventional cardiac procedures.

(4) All active medical devices intended to administer or remove medicinal products, body liquids or other substances to or from the body shall be in —

(a) Class B.

Explanation.— Such medical devices are mostly drug delivery systems or anaesthesia equipment, e.g., suction equipment, feeding pumps, jet injectors for vaccination, nebuliser to be used on conscious and spontaneously breathing patients where failure to deliver the appropriate dosage characteristics is not potentially hazardous; or

(b) Class C, if the administration or removal of medicinal products, body liquids or other substances to or from the body is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode and route of administration, e.g., infusion pumps, anaesthesia equipment, dialysis equipment, hyperbaric chambers, nebuliser where the failure to deliver the appropriate dosage characteristics could be hazardous etc.

(5) All active medical devices other than those specified in sub-rule (1) to (4) shall be in Class A, e.g., examination lamps, surgical microscopes, powered hospital beds and wheelchairs, powered equipment for the recording, processing, viewing of diagnostic images, dental curing lights etc.

82. Additional methods for classification of medical devices. — All medical devices shall be in —

(a) Class D—

(i) if they are incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product and which is liable to act on the human body with action ancillary to that of the devices, e.g., antibiotic bone cements, heparin-coated catheters, wound dressings incorporating antimicrobial agents to provide ancillary action on the wound, blood bags incorporating an anti- coagulant; or

(ii) if they are manufactured from or incorporating animal or human cells, tissues or derivatives thereof, whether viable or non-viable, e.g., porcine heart valves, catgut sutures, etc; or

(iii) if they are implantable or long-term invasive medical devices, e.g., intrauterine contraceptive medical device, etc; or

(b) Class A, if manufactured from or incorporate non- viable animal tissues or their derivatives that come in contact with intact skin only, e.g., leather components of orthopaedic appliances, etc; or

(c) Class C—

(i) if they are intended specifically to be used for sterilizing medical devices, or disinfecting as the end point of processing, e.g., medical devices for disinfecting or sterilizing endoscopes, disinfectants intended to be used with medical devices etc.

Explanation.— This clause (i) does not apply to products that are intended to clean medical devices by means of physical action e.g., washing machines, etc; or

(ii) if they are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses; or

(iii) if they are used for contraception or the prevention of the transmission of sexually transmitted diseases, e.g., condoms, contraceptive diaphragms, etc; or

(d) Class B, if they are intended for disinfecting medical devices prior to end point sterilization or higher level disinfection, e.g., washer disinfectors, etc.

PART II

CLASSIFICATION METHODS TO CLASSIFY *IN-VITRO* DIAGNOSTIC MEDICAL DEVICES (IVD)

83. Classification of *in-vitro* diagnostic medical devices. — (1) IVD medical devices intended for the following purposes shall be in Class D:-

(a) detection of the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, cells, tissues or organs in order to assess their suitability for transfusion or transplantation; or

(b) detection of the presence of, or exposure to, a transmissible agent that causes a life-threatening often incurable disease with a high risk of propagation.

Examples. — Tests to detect infection by HIV, HCV, HBV, HTLV, pyrogenicity tests (endotoxin activity assay) for detection of bacterial contamination of blood components and all types of assays, such as first-line assays, confirmatory assays and supplemental assays.

(2) IVD medical devices shall be in.—

(a) Class C, if intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissues or organs that are intended for transfusion or transplantation.

Examples.— HLA, anti-Duffy, anti-Kidd other Duffy systems except those classified as Class D in this sub-rule; or

(b) Class D, if intended to be used for ABO, rhesus (C, c, D, E, e) and anti-Kell

determination.

(3) IVD medical devices shall be in Class C, if intended to be used for the following purposes, namely:—

(a) detection of the presence of, or exposure to, a sexually transmitted agent, e.g., sexually transmitted diseases, such as chlamydia trachomatis, neisseria gonorrhoeae;

(b) detection of the presence of, in cerebrospinal fluid or blood, an infectious agent with a risk of limited propagation, e.g., neisseria meningitidis or cryptococcus neoformans;

(c) detection of the presence of an infectious agent where there is a significant risk that an erroneous result would cause death or severe disability to the individual or fetus being tested, e.g., diagnostic assay for CMV, chlamydia pneumoniae, methycillin resistant staphylococcus aureus;

(d) pre-natal screening of women in order to determine their immune status towards transmissible agents, e.g., immune status tests for rubella or toxoplasmosis;

(e) determination of infective disease status or immune status, and where there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient, e.g., enteroviruses, CMV and HSV in transplant patients;

(f) screening for selection of patients for selective therapy and management, or for disease staging, or in the diagnosis of cancer, e.g., personalized medicine;

(g) human genetic testing, e.g., huntington's disease, cystic fibrosis, etc;

(h) monitoring levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient, e.g., cardiac markers, cyclosporin, prothrombin time testing;

(i) management of patients suffering from a life-threatening infectious disease, e.g., HCV viral load, HIV viral load and HIV and HCV geno- and subtyping; or

(j) screening for congenital disorders in the fetus, e.g., spina bifida or down syndrome.

(4) IVD medical devices shall be classified as—

(a) Class C,—

(i) if they are intended for self-testing, e.g., blood glucose monitoring;
(ii) if they are intended for blood gases and blood glucose determinations for near- patient testing.

Explaination.— Other IVD medical devices that are intended for near-patient should be classified in their own right using the classification rules.

(b) Class B, which are self-testing devices from which the result is not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test, e.g., pregnancy self-test, fertility testing, urine test-strips, etc; or

(c) Class A, including—

(i) reagents or other articles which possess specific characteristics, intended by the manufacturer to make them suitable for *in-vitro* diagnostic procedures related to a specific examination;

(ii) instruments intended by the manufacturer specifically to be used for *in-vitro* diagnostic procedures; or

(iii) specimen receptacles.

Examples are selective or differential microbiological media excluding the dehydrated powders which are considered not to be a finished IVD medical device, identification kits for cultured microorganisms, wash solutions, instruments and plain urine cup, etc.

(5) IVD medical devices not covered in sub-rules (1) to (4) shall be in Class B, e.g., blood gases, H. pylori and physiological markers such as hormones, vitamins, enzymes, metabolic markers, specific IgE assays and celiac disease markers, etc.

(6) IVD medical devices that are controlled without a quantitative or qualitative assigned value shall be in Class B.

CHAPTER VII
GROUPING OF MEDICAL DEVICES

84. General principles of grouping. — (1) For the purpose of registration, the medical devices shall be grouped in accordance with these methods of grouping.

(2) Medical devices may be grouped into one of the following categories, namely:

(a) single;
(b) family;
(c) system;
(d) set;
(e) in-vitro test kit; or
(f) in-vitro cluster.

(3) The basic methods of grouping consist of the following, namely:—

(a) one generic proprietary name;
(b) one manufacturer; and
(c) one common intended purpose.

(4) All procedures shall be complied with when applying the grouping methods to medical devices.

(5) For the purpose of grouping, the corporate headquarters may be regarded as a manufacturer for its subsidiaries and regional manufacturing sites.

85. Methods of grouping.— (1) A medical device shall be grouped as a single medical device if its proprietary name is identified by the manufacturer with a specific intended use and it is sold as a distinct packaged entity and may be offered in a range of package sizes.

(2) A group of medical devices shall be grouped as a family if it consists of a collection of medical devices and each medical device in that collection.—

(a) is from the same manufacturer;
(b) is of the same risk classification;

(c) has the same medical device proprietary name;
(d) has a common intended purpose;
(e) has the same design and manufacturing process; and
(f) has variations that are within the scope of the permissible variants;

(3) A permissible variant under clause (f) of sub-rule (2) shall be a characteristic of a medical device if—

(a) the manufacturing processes for the medical devices are the same, or very similar;

(b) the intended purpose of the medical devices is the same; and

(c) the risk profile of the medical devices, taking into account the factors specified in clauses (a) and (b), is the same.

(4) If a group of medical devices satisfies the conditions to be grouped as a family, but the proprietary names of the individual medical devices are different, the medical devices shall be listed separately on the medical device register based on their proprietary names.

(5) The proprietary name of each individual medical device that is grouped as a family shall be put on the label of each of the member of medical device family and individual medical device names may contain additional descriptive phrase.

(6) A group of medical devices shall be grouped as a system if it consists of a number of constituent-components of medical devices which are—

(a) from the same manufacturer;

(b) intended to be used in combination to complete a common intended purpose;

(c) compatible when used as a system; and

(d) sold under a system name or the labelling, instructions-for-use, brochures or catalogues for each constituent-component state that the constituent-component is intended for use with the system.

(7) A group of medical devices shall be grouped as a set if it consists of a collection of two or more medical devices, assembled together as one package by a manufacturer and have.—

(a) a single proprietary set name;

(b) a common intended use; and

(c) a classification which is allocated based on the highest class of the device within the set.

(8) Information on all medical devices within a set shall be submitted as part of one medical device registration application.

(9) Medical devices shall be supplied in the market as a set that is listed on the medical device register.

(10) Medical devices that are registered as part of a set shall have a single medical device registration before they are sold separately as an individual medical device.

(11) If a medical device in a set is supplied for use in another set, such a medical device

shall be included in the registration application of that other set.

(12) The set name indicated for the group of medical devices shall appear in the product label affixed on the external package of the set. Individual medical devices in the set shall not be labelled with that set name. Individual medical devices in the set may contain additional descriptive phrases.

(13) An *in-vitro* medical device shall be grouped as *in-vitro* diagnostic test kit if it consists of reagents or articles that are.—

(a) from the same manufacturer;

(b) intended to be used in combination to complete a specific intended purpose;

(c) sold under a single test kit name or the labelling, instructions-for-use, brochures or catalogues for each reagents or article states that the component is intended for use with the in-vitro diagnostic test kit; and

(d) compatible when used as a test kit;

(14) Information on all reagents or articles within an *in-vitro* diagnostic test kit shall be submitted as part of one medical device registration application.

(15) Reagents or articles within an *in-vitro* diagnostic test kit that are listed on the medical device register shall be supplied in the market.

(16) If the reagents or articles in an *in-vitro* diagnostic test kit are intended to be used in more than one *in-vitro* diagnostic test, such reagents or articles shall be included in the medical device registration application of each of the other *in-vitro* diagnostic test. Reagents or articles from another manufacturer may be registered with the *in-vitro* diagnostic test group.

(17) An *in-vitro* medical device shall be grouped as in-vitro diagnostic cluster if it comprises of a number of *in-vitro* diagnostic reagents or articles that are.—

(a) from the same manufacturer;

(b) within risk classification A or B;

(c) of a common test methodology as listed in the Table 5 under this rule; and

(d) of the same in vitro diagnostic cluster category as listed in Table 5 under this rule**.**

(18) The in-vitro diagnostic cluster may include analyzers that are designed for use with the reagents in the *in-vitro* diagnostic cluster.

(19) Information on all reagents or articles within an in-vitro diagnostic cluster shall be submitted as part of one medical device registration application.

(20) Reagents or articles within an in-vitro diagnostic cluster that are listed on the medical device register shall be supplied in the market.

(21) Individual reagents or articles that are listed as part of a cluster can be supplied separately.

(22) If a reagent or article is intended for multiple usage categories and can be grouped in

more than one *in-vitro* diagnostic cluster, the applicant can choose to group the reagent or article as part of any one of the *in-vitro* diagnostic clusters it qualifies and information to support all the intended uses of the reagent or article must be submitted as part of the medical device registration application.

TABLE 5
LIST OF METHODOLOGY AND CLUSTER CATEGORY FOR *IN-VITRO* DIAGNOSTIC CLUSTER

S.No	**METHODOLOGY**	**CLUSTER CATEGORY (CLOSED LIST)**	**EXAMPLE OF ANALYTES (NON-EXHAUSTIVE LIST)**
(1)	(2)	(3)	(4)
1.	Clinical chemistry	Enzymes	Acid phosphatase; alpha-amylase; creatinekinase; gamma-glutamyltransferase; lactate dehydrogenase; lipase
		Substrates	Albumin; bilirubin; urea or blood urea nitrogen; cholesterol; creatinine; glucose
		Electrolytes reagents	Ammonia; bicarbonate; calcium; chloride; magnesium; phosphate inorganic/phosphorus
		Electrolyte electrodes	Ammonia electrodes; carbon dioxide (bicarbonate) electrodes; calcium electrodes; chloride electrodes; magnesium electrodes;potassium electrodes
		Substrate electrodes/ biosensors	Creatinine electrodes; glucose electrodes; glycated hemoglobin; electrodes; lactate electrodes; urea electrodes; bilirubin electrodes
2.	Immuno-chemistry	Immunoglobulins (without IgE).	Immunoglobulin A; immunoglobulin D; immunoglobulin G; immunoglobulin M; kappa and lambda chain; immunofixation kits
		Complement components	Complement component C1q; complement component C1 inactivator; complement component C3/C3c; complement component for Bb; complement component C4; complement component C5a
		Transport proteins	Albumin; ceruloplasmin; haptoglobin; hemopixin; lactoferrin; pre-albumin/transthyretin
		Lipoproteins	Apolipoprotein AI; apolipoprotein AII; apolipoprotein B; apolipoprotein E sub-typing; lipoprotein (a)
		Other specific proteins	a1-acid glycoprotein; a1-antitrypsin; a2- macroglobulin; a1-microglobulin; fibronectin; immunoreactive trypsin
		Allergy	Immunoglobulin E–total;

			immunoglobulin E– screen; immunoglobulin E–specific, monotest/monoresult; allergene specific IgA; allergene specific IgG
		Cancer markers	BR-marker CA15-3; GI-marker CA19-9, CA242; carcinoembryonicantigen; total prostatic specific antigen; alphafetoprotein (AFP); p53
		Thyroid function markers	Free triiodothyronine; free thyroxine; thyroid stimulating hormone; T–uptake; thyroglobulin; neonatal thyroxine
		Fertility/pregnancy hormones/ proteins	Androstenedione; estradiol; prolactin; human chorionic; gonadotropin total; human placental lactogen; estriol
		Diabetes assays (hormones)	C-peptide; glucagon; insulin; glycosylated/glycated haemoglobin; islet cell Ab; proinsulin
		Renal metabolism assays	Aldosterone; angiotensin I/II; angiotensin converting enzyme; cortisol; renine
		Bone and mineral metabolism assays	Bone alkaline phosphatase; calcitonin; cross-linked C-telopeptides; cross-linked N-telopeptides; cyclic adenosine; monophosphate; hydroxyproline
		Endocrine hormones and peptides	Adrenocorticotropic hormone; human growth hormone; insulin-like growth factor I; insulin-like growth factor binding protein 1; vasointestinal peptide; vasopressin
		Neuroendocrine function assays	Bombesin; 17-hydroxy-ketosterone; β-endorphin; neurotensin; somatostatin; substance P
		Other individual and specified hormones	Gastrin; gonadotropin-releasing hormone; melatonine; pepsinogen; adrenalin; dopamine
		Anaemia	Erythropoietin; ferritin; folate; iron; iron binding capacity; soluble transferrin receptor
		Vitamins	Vitamin B1; vitamin B2; vitamin B6; vitamin B12; vitamin D (cholecalciferol); intrinsic factor (blocking antibody)
		Non-immunosuppressive therapeutic drug monitoring	Phenobarbitol; digitoxin; gentamicin; valproic acid; caffeine; theophylline; methotrexate
		Immunosuppressive therapeutic drug monitoring	Cyclosporine; tacrolimus; rapamycin (sirolimus); mycophenolate
		Toxicology	Amphetamines; cocaine; barbiturates; morphines; phencyclidine; acetaminophen; catecholamines; ethanol; salicylate

		Auto-immune diseases	Anti-nuclear antibodies (ANAs); anti-topoisomerase; organ-specific auto antibodies; circulating immuno-complex; TSH receptor antibodies; anti-cardiolipin antibodies
		Rheumatoid-inflammatory diseases markers	Anti-streptococcal hyaluronidase; anti-streptokinase; anti-streptolysin O; C-reactive protein; anti-staphylolysin; anti-streptococcal screening
		Liver function	MEGX; carbohydrate deficient transferring
		Cardiac markers	BNP/proBNP; creatine kinase-MB; myoglobin; troponin I/T; homocysteine; high-sensitivity C-reactive protein
		Bacterial infection - immunology	*Bacillus subtilis; escherichia coli*
		Viral infection – immunology	Influenza virus
		Parasitic infection - immunology	*Entamoebahistolytica; leishmania*
		Fungal infection - immunology	*Candida albicans; aspergillus*
3.	Haematology/ histology/cytology (Blood tests for transfusions excluded)	Hemoglobin testing	Hemoglobin determinations (totalHb); fractional oxyhemoglobin (FO2Hb); fractional carboxyhemoglobin(FCOHb); fractional methemoglobin(FMetHb); fractional deoxyhemoglobin(FHHb)
		General coagulation tests	Prothrombin time; thrombin time; activated clotting time; activated partial thromboplastin time
		Haemostasis (coagulation)	Prothrombin; thrombin; fibrinogen; protein C and protein S reagents; C1-inhibitors; heparin; alpha- antiplasmin; fibrin; factor XIII; platelet factor 4; plasminogen
		Other hematology tests	Complete blood count; hematocrit; erythrocyte; sedimentation rate
		Cytokines (lymphokines)/ immunomodulators	Interferons; soluble antigens/receptors; tumor necrosis factors; interleukins; colony stimulating factors; tumor necrosis factors receptors; interleukins receptors
		Histology/cytology reagents	Cytochemical staining; embedding, fixing, mounting media; stain solutions; immuno histology kits
4.	Microbiology - culture	Culture media	Dehydrated culture media (DCM); additives for DCM; prepared media (tubes, bottles,

	(i) cytochemical staining (ii) embedding, fixing, mounting media (iii) stain solutions (iv) immunohistology kits		plates); cells, media, serum for viral culture
		Susceptibility testing Identification of bacteria by testing for the susceptibility of the bacteria to the certain antibiotics	Erythromycin susceptibility test for *staphylococcus aureus;* tobramycin susceptibility test for *pseudomonas aeruginosa;* Fungal susceptibility testing
		Biochemical culture identification (ID)	Gram negative manual ID; Gram positive manual ID; Other ID kits manual - anaerobes, fastidious; mycoplasma
		Immunological culture identification (ID)	Streptococci grouping slide tests; serotyping (E.coli, salmonella, shigella etc.)
		Nucleic acid (NA) based culture identification (ID)	NA identification – MRSA; NA identification – other resistance markers
		Serological identification (ID)	For parasitology and mycology (fungi and yeast)
5.	Molecular biology	Oncogenes Genes, whose mutation or enhanced expression, turns a normal cell into a cancer cell.	p53; MYC (8q24) TERC (3q26)
		Bacterial infections (detection by NA reagents)	Staphylococcal detection; E.coli detection
		Viral infections (detection by NA reagents)	Influenza and para-influenza NA reagents
		Fungal infections	Fungi NA reagents

CHAPTER VIII
REGISTRATION OF MEDICAL DEVICES

86. M**edical devices registration. —** (1) The MDB shall register medical devices which include any instrument, apparatus, implement, machine, appliance, implant, reagent for *in-vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings or animals for one or more of the specific medical purposes of.—

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(c) investigation, replacement, modification or support of the anatomy or of a physiological process;

(d) supporting or sustaining life;

(e) control of conception;

(f) disinfection of medical devices;

(g) providing information by means of *in-vitro* examination of specimens derived from the human body,

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means.

(2) All Class A medical devices and establishments manufacturing, importing, exporting or selling Class A devices, other than those having measuring function, active or sterile, shall be regulated according to the enlistment rules to be notified by the Authority.

87. Application procedure for medical devices registration.— (1) An application to register a medical device shall be made by—

(a) an establishment having valid licence to manufacture medical devices; or

(b) an importer in his capacity as sole authorized representative in Pakistan having valid establishment licence.

(2) An application for registration of medical device for local manufacture or import shall be made to the MDB on the format as set out in Form-6 or Form-6A, as the case may be.

(3) An application to register medical devices shall be accompanied by the following, namely:—

(a) application fee as specified in rule 138 ; and

(b) information or documents or samples, where practicable, specified in Form-6 or Form-6A, as the case may be.

(4) The MDB may reject an application, if the applicant fails to deposit specified fee or provide information, particulars, documents or samples of the medical device as required under sub-rule (3).

(5) The manufacturing methods and testing procedures shall conform to the principles of validation.

(6) Complete labelling and prescribing information shall be same as approved in the country of origin or as approved in European Union, USA, Japan, Canada or Australia.

88. Procedure for grant of registration of medical device.— (1) Upon receipt of the application form, prescribed application fee and information, particulars, documents or samples, where practicable, of the medical device under rule 87, the MDB shall consider the application to register the medical device and may inspect the premises in which the medical device is being or to be manufactured as it considers necessary to verify any information, particulars, documents or samples of the medical device as provided by the applicant.

(2) If the MDB is satisfied with all requirements pertaining to the application for medical device registration, it shall register the medical device and enter it in the medical device register.

(3) The registration of the medical device shall be for a period of five years from the date of registration unless it is cancelled or suspended by the MDB before its expiry.

(4) The MDB shall assign a registration number and issue a certificate of registration on the format as set out in Form-7 or Form-7A for the medical device for local manufacture or import, as the case may be.

(5) In case the application for registration is rejected by the MDB, it shall inform the applicant of its decision in writing with reasons of such decision.

89. Renewal of registration of medical device.— (1) An application for the renewal of a medical device registration for local manufacture or import shall be made, on the format as set out in Form-6 or Form-6A, as the case may be, sixty days before its expiry and shall be accompanied by the following, namely: —

(a) application fee as specified in rule 138;

(b) information or documents or samples, where practicable, specified in Form-6 or Form-6A, as the case may be.

(2) The MDB may reject an application if the registration holder fails to deposit specified fee or provide information, particulars, documents or samples of the medical device as required under sub-rule (1).

(3) Upon receipt of the application form, application fee, information, particulars, documents or samples, where practicable, of the medical device under sub-rule (1), the MDB shall consider the application to renew the registration of a medical device and may inspect the premises in which the medical device is being manufactured as it considers proper and necessary to verify any information, particulars, documents or samples, where practicable, of the medical device as provided by the applicant under sub-rule (1).

(4) If the MDB is satisfied that all the requirements pertaining to the application for renewal of medical device registration have been fulfilled, it shall renew the registration of the medical device and enter the medical device in the medical device register for a period of five years from the date of expiry of previous registration certificate unless it is cancelled or suspended by the MDB before its expiry.

(5) If an application for renewal is made after expiry of the period of validity of certificate of registration but within sixty days after expiry of the period of validity, the applicant shall pay an additional surcharge of ten percent of the renewal fee for registration for each day the application is delayed.

(6) If an application for renewal is made after sixty days of expiry of the period of validity, the registration shall cease to exist and the application shall be treated as a fresh application for grant of registration.

(7) If an application for renewal is made before the expiry of the period of validity of registration or within sixty days after expiry of the period of validity along with deposition of additional surcharge, the registration shall continue to be valid until orders are passed on such application.

(8) If an application for renewal is made after sixty days of expiry of the period of validity, the establishment shall be responsible for all the illegal operations carried out during that period related to the medical device.

(9) In case the application for renewal of registration of a medical device is rejected by the MDB, it shall inform the applicant of its decision in writing with reasons of such decision.

90. Changes concerning registered medical device.— (1) The registration holder shall apply to the MDB for prior approval, if any change is proposed regarding the particulars provided in

relation to the registration of a medical device or any proposed change that may affect safety or performance of the medical device.

(2) An application under sub-rule (1) for change in the registration particulars of medical device for local manufacture or import shall be.—

(a) made on the format as set out in Form-6 or Form-6A, as the case may be; and

(b) accompanied by the relevant application fee specified in rule 138;

(3) Upon receipt of the application for change relating to a registered medical device, the MDB shall consider the proposed change and if required, may inspect the establishment to verify any particulars, information or documents as provided by the registration holder under sub rule (2) and the registration holder shall not manufacture the medical device with proposed change and shall not place it into the market until the MDB has given its approval for the change.

(4) If any registration holder contravenes sub-rule (1) or sub-rule (3), its registration may be cancelled or suspended as the MDB may deem fit after giving to the registration holder the opportunity of being heard.

(5) If the MDB, on the basis of information received or an inquiry conducted by it, is of opinion that—

(a) the approval of change in any particular of registration of the medical device was obtained by fraud or misrepresentation; or

(b) the circumstances in which the change in any particular of registration of the medical device was approved no longer exist; or

(c) it is necessary in the public interest so to do,

the MDB may, after affording to the registration holder an opportunity of showing cause against the action proposed to be taken, cancel or suspend the registration or specify any further conditions to which the registration shall be subject and inform accordingly.

91. Certificate of registration of medical device.— (1) A certificate of registration of a medical device shall not be assigned or transferred to any other person or classes of persons except with prior written approval of the MDB.

(2) If a registration holder assigns or transfers his registration of the medical device to any other person or classes of persons without the prior written approval, the MDB may cancel or suspend the registration of medical device as it may deem fit, after giving to the registration holder the opportunity of being heard.

(3) A certificate of registration issued for a medical device shall be surrendered to the MDB without demand within fourteen days after the registration of the medical device is cancelled by the MDB under sub-rule (2).

92. C*onditions of registration of medical device.—* (1) A registration holder shall comply with all the conditions for the grant of medical device registration provided for in these rules.

(2) The import, manufacture and sale thereof of medical devices shall be in accordance with the provisions of these rules.

(3) The indications, contra-indications, side effects, precautions, warnings, directions for use etc, if any, as have been approved for the purpose of registration of a medical device shall be clearly specified in the labelling and promotion.

(4) Each medical device shall be produced in sufficient quantity so as to ensure its regular and adequate supply in the market.

(5) The manufacture or import of any medical device shall not, without the prior approval of the MDB, be discontinued for such period which may result in its shortage:

Provided that in the circumstances beyond the control of a manufacturer or importer of a medical device which may lead to reduction in the production or import of that medical device, the circumstances may be intimated to the MDB. In case of failure to comply, the registration holder shall be held responsible for creating willful shortage leading to its black marketing and the registration may be cancelled or suspended as the MDB may deem fit, after giving to the registration holder the opportunity of being heard.

(6) In case of an imported medical device, the importer shall ensure regular and adequate supply of the medical device in Pakistan.

(7) The registration holder or his authorized agent shall for any medical device sold by him issue a warranty thereof on the format as set out in Form-5.

(8) In respect of new medical device, records, including adequately organized and indexed files, shall be maintained containing full information regarding.—

(a) clinical investigations and tests conducted by the manufacturer or reported to him by any person concerning that medical device;

(b) reports from the scientific literature or the bibliography therefrom that are available to him concerning that medical device;

(c) experiences, investigations, studies and tests involving the physical or chemical properties or any other properties of that medical device;

(d) any error in the labelling of that medical device;

(e) any bacteriological or any significant chemical or physical or other change or deterioration in any batch or lot of that medical device;

(f) any failure of one or more distributed batches of that medical device to meet the required specifications;

(g) any unexpected side effects, injury, toxicity or sensitivity reaction associated with the clinical uses, studies, investigations and tests respecting that medical device; and

(h) any unusual failure of that medical device to demonstrate its expected performance activity.

(9) The following information shall be supplied to the MDB, namely:—

(a) report in duplicate of all records respecting the information contemplated by clauses (d) and (e) of sub-rule (8); and

(b) as soon as possible and in any event within fourteen days, reports in duplicate of all records respecting the information contemplated by clauses (f), (g) and (h) of sub-rule (8).

(10) If a medical device or any of its component, which is imported or manufactured by a company in Pakistan, is also approved for registration and free sale by its subsidiary, sister concern,

associate or parent company in the country where it was originally developed or in any of the countries, namely, USA, European Union countries, Canada, Japan or Australia, and if that medical device, at any time, for safety reasons is withdrawn or banned or certain restrictions are imposed in any of the said countries, then it shall be the responsibility of the manufacturer in Pakistan or, as the case may be, the importer, to immediately withdraw the medical device from the market in Pakistan or, as the case may be, to impose similar restriction and to inform the MDB within fourteen days of such an information having come to its knowledge and having taken the necessary action. The MDB, after getting the said intimation, shall take similar action for the same medical device available from other sources within the shortest possible time.

(11) If a clinical information for a medical device is approved by a regulatory authority in any of the said countries, the same clinical information shall be considered as approved for medical device registration in Pakistan unless modified by the MDB on the basis of scientific data available to it, and such clinical information may include indication, contra-indications, adverse effects, precautions, warnings, directions for use etc.

(12) If any adverse reaction of medical device, not otherwise included in the application for registration, is reported in any of the said countries, it shall be the responsibility of the concerned manufacturer or, in case of imported medical device, the importer to report it to the MDB within thirty days.

(13) The manufacturer or, as the case may be, the importer shall supply the information in relation to safety, performance, production, quality or availability of the medical device as and when required by the MDB with a view to ensure safety, performance and quality of the medical device under these rules.

(14) If a person contravenes these rules, he shall after being heard be liable for suspension or cancellation of his registration of medical device by the MDB, without prejudice to any other punishment under the DRAP Act and these rules.

(15) If the MDB, on the basis of information received or an inquiry conducted by it, is of opinion that—

(a) the registration of a medical device was procured by fraud or misrepresentation; or

(b) the circumstances in which a medical device was registered no longer exist; or

(c) it is necessary in the public interest so to do,

the MDB may, after affording to the registration holder an opportunity of showing cause against the action proposed to be taken, cancel or suspend the registration or specify any further conditions to which the registration shall be subject and inform accordingly.

93. Cancellation or suspension of registration of medical device.— (1) Before cancellation or suspension of registration of a medical device, the MDB shall issue a show cause notice to the establishment for cancellation or suspension of registration due to non-compliance of any of the conditions of registration or contravention of any provisions of these rules.

(2) The establishment shall submit, in writing, reply to the show cause notice within fifteen days from the date of issuance of the notice.

(3) The MDB, after being satisfied that the establishment has not complied with the conditions of registration or contravened the provision of the DRAP Act or these rules, may cancel or for a specified period suspend the registration of the medical device.

(4) The MDB shall inform the establishment, in writing, on the cancellation or suspension of the registration of a medical device.

(5) Where a registration is cancelled by the MDB pursuant to sub-rule (4), the establishment shall within fourteen days after being informed in writing of the cancellation return the certificate of registration to the MDB without demand.

CHAPTER IX
IMPORT AND EXPORT

94. Import of medical devices.— A medical device may be imported subject to the following conditions, namely :-

(a) the importer shall possess valid medical device establishment licence and medical device registration and have facilities for proper storage to preserve its properties; and

(b) the importer shall, within fifteen days of establishing the letter of credit or remittance, intimate, to the MDB or an officer authorized by it, such action on the format as set out in Form-8.

95. Permit to import medical device's components or raw materials.— (1) No person shall import medical device's components or raw materials for manufacturing medical device unless he possess—

(a) valid establishment licence to manufacture medical devices; and

(b) valid medical device registration;

(2) A single application shall be made, and a single permit shall be required, in respect of the import of more than one medical device's components or raw materials manufactured by the same manufacturer:

96. Application for import permit.— (1) An application for import permit of medical device's components or raw materials shall, on the format as set out in Form-9, be made to the MDB and shall be accompanied by a fee as specified in rule 138 and an undertaking in Form-10, signed by or on behalf of the manufacturer.

(2) An application on the format as set out in Form-11 for import permit for small quantity of medical devices, components or raw materials for the purpose of clinical investigation, examination, test or analysis shall be made to the MDB alongwith a fee as specified in rule 138.

(3) Permit for import of medical device's components or raw materials for commercial purposes shall be issued on the format as set out in Form-12 and for the import of small quantity of medical devices, components or raw materials for clinical investigation, examination, test or analysis shall be issued on the format as set out in Form-13.

(4) Import permit, unless earlier suspended or cancelled, shall be valid for three years and shall be subject to valid establishment licence and medical device's registration, and may be renewed by the MDB if an application for its renewal is made three months prior to expiry of existing permit:

Provided that if application for renewal of an import permit is made, the existing import permit shall continue to be valid until orders are passed on such application.

97. Import of medical devices, components or raw materials.— No person shall import any medical device or any component thereof or any raw material thereof for manufacturing medical device unless authorized by the Authority or an officer or body authorized in this behalf by it with approval of the Board.

98. Conditions of permit for import of medical device's components or raw materials.— The permit for import of medical device's components or raw materials shall be subject to the following conditions, namely: —

(a) the manufacturer shall give an undertaking on the format as set out in Form-10 and shall observe the under-taking all the times ;

(b) the permit holder shall allow the MDB or any officer authorized by it in this behalf to enter, with or without prior notice, any premises where the medical device's components or raw materials are stocked to inspect the means, if any, employed for testing and to take samples, where practicable;

(c) the permit holder shall ensure proper storage facilities for preserving the properties of the medical device's components or raw materials; and

(d) the permit holder shall maintain a complete record of utilization of the medical device's components or raw materials.

99. Conditions of a permit to import small quantities of medical devices, components or raw materials for clinical investigation, etc. — A permit to import small quantities of medical devices, components or raw materials thereof including those, the import of which is otherwise prohibited under the DRAP Act and the rules made thereunder for the purposes of clinical investigation, examination, test or analysis shall be subject to the following conditions, namely: —

(a) permit holder shall exclusively use the medical devices, components or raw materials for the purpose for which these have been imported;

(b) permit holder shall allow the MDB or an officer authorized by it in this behalf to enter, with or without prior notice, the premises where the medical devices, components or raw materials are kept and to inspect the premises and investigate the manner in which the medical devices, components or raw materials are being used and to take samples thereof, where practicable; and

(c) permit holder shall submit complete record of import, manufacturing and utilization.

100. Import of medical devices for personal use. — Small quantities of medical devices including those the import of which is otherwise prohibited under the DRAP Act and the rules made thereunder may be imported for personal use subject to the following conditions, namely: —

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

(b) the quantity of any medical device so imported shall be restricted to meet personal requirement only;

(c) any medical device imported for personal use but not forming part of bonafide personal baggage may be allowed to be imported subject to the following conditions, namely: —

(i) The MDB or any officer authorized by it in this behalf, on an application being made to it prior to the import, and being satisfied that the medical device is for bonafide personal use, has granted permission for the import of the said medical device; and

(ii) the quantity to be imported is, in the opinion of the MDB, reasonable and restricted to meet personal requirement only.

101. General conditions of import. — (1) An importer of medical devices or components or raw materials, except where such import is for personal use, shall comply with the following general conditions, namely: —

(a) the importer shall, on being informed by the MDB that any part of any batch or lot of a medical device or component or raw material has been found to be in contravention of the provisions of the DRAP Act or the rules made thereunder and on being directed so to do, withdraw the remainder of that batch or lot from sale and so far as practicable, recall the issues already made from that batch or lot and dispose of in such manner as the MDB may direct;

(b) the importer shall ensure that the import of each batch of a medical device or component or raw material is accompanied by.—

(i) a copy of the test report of the medical device or component or raw material from the competent authority or any other such agency of the country of export or from the manufacturer;

(ii) intimation on Form-14 of arrival of the consignment of imported medical devices or components or raw materials other than those imported for personal use alongwith three copies of the invoices to the officer authorized to grant clearance on receipt of information at the port of importation;

(iii) an undertaking by the applicant on a stamp paper that the quality and safety of the medical devices, components or raw materials and their genuineness is in accordance with these rules and that responsibility lies on the importer with regard to the documents or information or particulars provided and if found incorrect or misrepresenting at any stage, shall be held responsible and action shall be taken against the defaulters under the DRAP Act and the rules made thereunder.

(2) If the MDB, on the basis of information received or an inquiry conducted by it, is of opinion that—

(a) the import permit was procured by fraud or misrepresentation; or

(b) the circumstances in which an import permit was issued no longer exist; or

(c) it is necessary in the public interest so to do,

the MDB may, after affording to the import permit holder an opportunity of showing cause against the action proposed to be taken, cancel or suspend the import permit or specify any further conditions to which the permission shall be subject and inform accordingly.

102. Procedure at customs port.— (1) No medical device or component or raw material for manufacturing medical devices shall be released from the customs unless a clearance certificate has been obtained by the importer from an officer authorized in this behalf.

(2) If the Collector of Customs or an officer authorized by him has reason to suspect that any medical device or component or raw material does not comply with the provisions of the DRAP Act or the rules made thereunder, he may, or if requested by an officer authorized in this behalf, take samples, where practicable, from the consignment and forward these to the notified laboratory and may detain these from the consignment of which samples have been taken until a standard report of a notified laboratory on such samples is received:

Provided that if the importer gives an undertaking in writing not to dispose of the medical device or the component or the raw material without the consent of the Collector of Customs and to

return the consignment or such portion thereof, as may be required, the Collector of Customs may make over the consignment to the importer.

(3) If an importer who has given an undertaking under the proviso to sub-rule (2) is required by the Collector of Customs to return the consignment or any portion thereof, he shall return the consignment or portion thereof within ten days of receipt of the notice.

(4) If the laboratory reports to the Collector of Customs that the samples of the medical device or the component or the raw material in a consignment do not conform to the specification or that the medical device or the component or the raw material contravenes in any other respect, the provisions of the DRAP Act or the rules made thereunder and that the contravention is such that it cannot be remedied by the importer, the Collector of Customs shall communicate the report forthwith to the importer who shall within two months of his receiving the communication, either export all the medical devices or components or raw materials of that description in the consignment to the country from which these were imported or surrender these to the MDB for disposal in such manner as it may deem fit:

Provided that the importer may, within fifteen days of the receipt of the report, make a representation against the report to the Collector of Customs who shall forward the representation with a further sample to the MDB which after obtaining, if necessary, the report of the laboratory shall pass orders thereon which shall be final.

(5) If the laboratory reports to the Collector of Customs that the samples of any medical device or component or raw material contravene in any respect the provisions of the DRAP Act or these rules and that the contravention is such that it can be remedied by the importer, the Collector of Customs shall communicate the report forthwith to the importer and permit him to import the consignment, on his giving an undertaking in writing not to dispose of that medical device or component or raw material without remedying the said contravention.

(6) An officer authorized by the MDB may, for the purpose of this rule, physically inspect the consignment and draw samples, where practicable, from each batch or lot for test and analysis as may be necessary and, if the consignment has been released by the Customs, may order the importer not to sell or offer for sale or dispose of the medical device or component or raw material for a period not exceeding one month with a view to obtain a test report:

Provided that the authorized officer may prohibit its disposal with the approval of the MDB for a further period not exceeding three months at a time if he has sufficient reason to believe that the import, in any way, is in contravention of any of the provisions of the DRAP Act or these rules in which case the importer shall not dispose of medical device or component or raw material until a certificate authorizing the sale of the batch or lot has been issued to him.

103. Suspension or cancellation of a permit to import medical devices, components or raw materials .— If the permit holder fails to comply with any of the conditions of a permit to import medical devices, components or raw materials or violates any of the provisions of the DRAP Act or these rules, the MDB may, after giving the permit holder an opportunity of being heard, by an order in writing stating the reasons thereof, suspend or cancel the permit for such period as it thinks fit or cancel either wholly or in respect of some of the medical devices, components or raw materials to which it relates or, if the nature of offence is so serious that it is likely to endanger the public health, may prohibit the import of all other medical devices, components or raw materials of the said manufacturer.

104. Application for export permit.— (1) No establishment shall export any medical device without permission of the Authority or a body or an officer authorized by it with the approval of the Board.

(2) An establishment intending to apply for an export permit for medical device shall be—

(a) the establishment being licensed under these rules; and

(b) the one whose medical device to be exported is registered under these rules; and

(3) An application on the format as set out in Form-15 for an export permit shall be made to the MDB and accompanied with the application fee as specified in rule 138.

(4) The MDB may reject an application if the applicant fails to deposit the requisite fee or to submit the required information, particulars or documents.

105. Export ermit for medical device. — (1) Subject to sub-rule (3) of rule 104, an export permit for medical device shall be issued on the format as set out in Form-16.

(2) A single application shall be made and a single permit shall be issued in respect of the export of more than one medical devices manufactured by the same manufacturer.

106. Application for export permit for the purpose of clinical investigation, examination, test or analysis.—(1) An application for a permit to export small quantity of medical devices including those the export of which is otherwise prohibited under the DRAP Act and the rules made thereunder, for the purpose of clinical investigation, examination, test or analysis shall be made to the MDB on the format as set out in Form-17 alongwith fee as specified in rule 138.

(2) The application under sub-rule (1) shall also be accompanied by an undertaking on a stamp paper duly attested by an oath commissioner regarding the genuineness of the documents, information or particulars provided, that if found incorrect or misrepresenting at any stage, the applicant shall be held responsible and action shall be taken against him under the DRAP Act and these rules.

(3) An export permit for small quantity of medical devices for the purpose of clinical trial, examination, test or analysis shall be issued on the format as set out in Form-18.

107. Duration of permit to export medical devices.— A permit to export medical devices issued under rules 105 and 106, unless earlier suspended or cancelled, shall be valid for three years:

Provided that if application for renewal of permit is made three months before the expiry of the existing permit issued under rule 105, the current permit shall continue to be valid until orders are passed on such application.

108. Conditions of export permit.— (1) A permit for export of medical devices shall be subject to the following conditions, namely—

(a) the permit holder shall on demand, furnish to the permitting authority from every batch or lot as the permitting authority may from time to time specify, samples, where practicable, in such quantity as the permitting authority may consider adequate for any examination, test or analysis required to be made and the permit holder shall, if so required, furnish full protocols of the tests, if any, which have been applied;

(b) if the permitting authority so directs, the permit holder shall not export or offer for export any batch or lot in respect of which a sample is, or protocols are, furnished under clause (a) until a certificate authorizing the export of the batch or lot has been issued to him by the permitting authority;

(c) the permit holder shall, on being informed by the permitting authority that any part of any batch or lot of a medical device has been found by the

authority not to conform to the required specifications and on being directed so to do, withdraw the remainder of that batch or lot from export and, so far as may, in the particular circumstances of the case, be practicable, recall the issues already made from that batch or lot;

(d) the permit holder shall maintain a record of all exports made by him of each medical device;

(2) If the MDB, on the basis of information received or an inquiry conducted by it, is of opinion that—

(a) the export permit was procured by fraud or misrepresentation; or

(b) the circumstances in which an export permit was issued no longer exist; or

(c) it is necessary in the public interest so to do,

the MDB may, after affording to the export permit holder an opportunity of showing cause against the action proposed to be taken, cancel or suspend the permit or specify any further conditions to which the permission shall be subject and inform accordingly.

109. General conditions regarding export.—An exporter of medical devices, except where such export is for personal use, shall comply with the following general conditions, namely: —

(a) The exporter shall allow any person authorized in this behalf to enter, with or without prior notice, any premises where the medical devices to be exported are stocked, to inspect the storage facilities and take samples, where practicable, for testing;

(b) the exporter shall, on being informed by the MDB or an officer authorized by it in this behalf that any part of any batch or lot of medical device has been found in contravention of any of the provisions of the DRAP Act or these rules and on being directed so to do, withdraw the remainder of that batch from export and so far as practicable, recall the issues already made from that batch or lot and dispose of it in such manner as the MDB may direct; and

(c) the exporter shall maintain a record of all exports of medical devices, components or raw materials made by him and such record shall be open to inspection by any person authorized in this behalf.

110. Procedure at customs port.—(1) If the Collector of Customs or an officer authorized in this behalf has reason to suspect that any medical device does not comply with the provisions of the DRAP Act or these rules or if requested by an officer authorized for this purpose by the MDB, he may take samples, where practicable, of any medical device from the consignment and forward them to the notified laboratory and may detain the medical device from the consignment of which samples have been taken until a standard report of the notified laboratory on such samples is received:

Provided that if the exporter gives an undertaking in writing not to export or dispose of the medical devices without the consent of the Collector of Customs and to return the consignment or such portion thereof as may be required, the Collector of Customs may make over the consignment to the exporter.

(2) If an exporter who has given an undertaking under the proviso to sub-rule (1) is required by the Collector of Customs to return the consignment or any portion thereof, he shall return the consignment or portion thereof within ten days of receipt of the notice.

(3) If the laboratory reports to the Collector of Customs that the samples of any medical device in a consignment do not conform to the provisions of the DRAP Act or these rules and that the disconformity, if any, is such that it cannot be remedied by the exporter, the Collector of Customs

shall communicate the report forthwith to the exporter who shall cause the medical device to be destroyed or surrender them to the MDB for disposal in such manner as it may deem fit:

Provided that the exporter may, within fifteen days of receipt of the report, make a representation against the report to the Collector of Customs who shall forward the representation with a further sample to the MDB which after obtaining the report of the laboratory shall pass orders thereon which shall be final.

(4) If the laboratory reports to the Collector of Customs that the samples of any medical device is not in conformity with the provisions of the DRAP Act or these rules and that the disconformity is such that it cannot be remedied by the exporter, the Collector of Customs shall communicate the report forthwith to the exporter and permit him to withdraw the medical device on his giving an undertaking in writing not to export that medical device without remedying the said disconformity.

111. Export of medical devices for personal use.— Small quantities of medical devices including those the export of which is otherwise prohibited under the DRAP Act and these rules may be exported for personal use subject to the following conditions, namely:—

(a) the medical device shall form part of the passenger's bonafide baggage and shall be intended for his exclusive personal use;

(b) the quantity of any medical device so exported shall be restricted to meet personal requirement only:

Provided that any medical device exported for personal use but not forming part of bonafide personal baggage may be allowed to be exported subject to the following conditions, namely:—

(i) the MDB or any officer authorized by it in this behalf, on an application being made to it prior to the export, and being satisfied that the medical device is for bonafide personal use, has granted permission for the export of the said medical device; and

(ii) the quantity to be exported is, in the opinion of the MDB, reasonable and restricted to meet personal requirement only.

112. Documents to accompany the consignments of medical devices for export .—All consignments of medical devices sought to be exported shall be accompanied by an invoice or other statement showing the name and address of the manufacturer and the names and quantities of the medical devices, certificate of test or analysis for each batch or lot, undertaking, duly attested by an oath commissioner, on a stamp paper by the director or his authorized representative for the genuineness of the documents and quality , safety and performance of the medical devices.

113. Suspension or cancellation of export permit .—If the permit holder fails to comply with any of the conditions of export permit or violates any of the provisions of the DRAP Act or these rules, the MDB may, after giving the permit holder an opportunity of being heard, by an order in writing stating the reasons thereof, suspend or cancel the permit wholly or in respect of some of the medical devices for such period as it thinks fit or, if the nature of offence is so serious that it is likely to endanger the public health, may, without prejudice to take a penal action for appropriate punishment by the competent court, prohibit the export of all other medical devices of the said manufacturer.

CHAPTER X
LABELLING OF MEDICAL DEVICES

114. General provisions of labelling of medical devices.— (1) No person shall—

(a) place any medical device in the market unless it has been appropriately labelled; and

(b) use or operate any medical device on another person unless the appropriate label has been provided with the medical device when it is used on the other person for investigational purposes;

(2) A registered medical device shall be labelled to include a statement to the effect that the medical device has been registered under these rules.

(3) The label shall not contain any statement to the effect, whether directly or indirectly, that the placement in the market, or usage or operation of the medical device is being promoted or endorsed by the MDB or the Authority or Government or any of its organizational bodies.

(4) The label of a medical device shall be legible, permanent and prominent.

115. Location of labelling of medical devices.— The label shall be appropriately located depending on a particular medical device and its intended use, in accordance with the following manners, namely: —

(a) where it is practicable, the label shall be provided on or is attached to the medical device itself;

(b) if it is impracticable to provide the label on or to attach the label to the medical device itself, the label shall be provided on the packaging of the individual medical device;

(c) in the case of medical devices that are packaged together because individual packaging of the medical devices is not practical, the label shall be provided as leaflet, packaging insert, document or other media supplied with a single or multiple medical devices; and

(d) if multiple medical devices are supplied to a single user or location or packed together as one package, it may be appropriate to provide only a single copy of the label but more copies shall be supplied upon request.

116. Format of labelling of medical devices.— (1) The format of labelling shall be in accordance with the international standards for medical devices' labelling.

(2) If a symbol or code in whatever form is used in the label of a medical device, an explanation of the symbol or code shall be provided.

117. Language used for labelling of medical devices.— The language used for labelling of medical devices shall be English, however, the use of Urdu language shall be required for home-used medical devices.

118. General contents of labelling of medical devices.— The label of a medical device shall contain the following information, namely: —

(a) details of medical device to enable user to identify it, which include name, model if any, lot or batch or serial number, registration number, date of manufacturing, date of expiry and maximum retail price fixed by the manufacturer;

(b) name and complete address of the manufacturer of the medical device, his licence number and where the medical device is manufactured outside

Pakistan, also the name and complete address of the importer or authorized representative of manufacturer of the medical device;

(c) technical details concerning the medical device;

(d) description and intended use of the medical device;

(e) instructions for use of the medical device;

(f) any side-effects, limitations, warnings and precautions on the safe use of the medical device;

(g) any necessary post-market servicing needs for the medical device;

(h) any decommissioning or disposal information; and

(i) storage or handling.

119. Specific contents of labelling of medical devices.— Where a medical device requires specific contents of labeling, the following specific contents shall be required in the labeling in addition to general contents under rule 118, namely:—

(a) identification for a custom-made medical device or a special access medical device and a statement that it shall be only used by a qualified practitioner for patient under his care;

(b) special storage or handling;

(c) verification that a medical device has been properly installed and can operate correctly and safely, the nature and frequency of preventative and regular maintenance, replacement of consumable components and calibration needed to ensure optimal and safe operation of a medical device;

(d) further treatment or handling, such as sterilization, calibration, etc., that is needed before a medical device can be used;

(e) identification for a sterile medical device, its indication for sterility and precautions and instructions if the sterile packaging is damaged and where appropriate, description of re-sterilization methods;

(f) the requirement for sterilization of a medical device before it is used and instructions for cleaning and sterilizations processes;

(g) identification for a single-use medical devices;

(h) identification for a reusable medical device, information and instruction for cleaning, disinfecting, packaging and, where appropriate, the method of re-sterilization and any restriction on the number of reuse;

(i) identification for a medical device that is intended for clinical or performance investigations prior to placement in market and an indication that it shall be used by qualified investigator only and in the case of an in-vitro diagnostic medical device, a statement to indicate that the performance specifications of the device have not been established;

(j) identification for a medical device that is intended for presentation or demonstration purposes;

(k) sufficient details to obtain a safe combination for a medical device that is to be installed with or connected to other medical devices or equipment or with dedicated software, in order to operate as required for its intended purpose;

(l) particular risks in connection with implantation of an implantable medical device;

(m) the risks of reciprocal interference posed by a reasonably foreseeable presence of a medical device during specific investigation or treatment;

(n) the details of the nature, type, intensity and distribution of the radiation emitted by radiation emitting medical device; and

(o) indication for custom-made medical device that it is for use by a single individual and has been manufactured according to a written prescription or pattern.

120. Instructions for use on label of medical devices. — An instruction for use shall contain the following details on any contra-indications, warnings and precautions to be taken, namely: —

(a) precautions to be taken if there are changes in the performance or malfunction of the medical device;

(b) precautions with respect to exposure to environmental conditions like magnetic fields, external electrical influences, electrostatic discharge;

(c) pressure or variations in pressure, temperature, humidity, acceleration, thermal ignition sources, proximity to other devices, etc;

(d) where drugs or medicinal products are incorporated into the device as an integral part this should be indicated in the label;

(e) adequate information regarding the drug or medicinal products which a device is designed to administer, including any limitations in the choice of substances to be delivered;

(f) precautions to be taken against any special, unusual risks related to the disposal of the device;

(g) for medical device with measuring function, the degree of accuracy claimed by the manufacturer; and

(h) requirements for special facilities, special training or particular qualifications for the medical device user.

121. Additional information on the label of *in-vitro* diagnostic medical devices.— For an *in-vitro* diagnostic medical device, the following additional information shall be included in its label, namely: —

(a) indication of its intended use either for monitoring, screening or diagnostic purposes;

(b) indication that it is for *in-vitro* diagnostic use;

(c) test principle;

(d) specimen type, collection, handling and preparation;

(e) reagent description and any limitation e.g., use with a dedicated instrument only;

(f) assay procedure including calculations and interpretation of results;

(g) information on interfering substances that may affect the performance of the assay;

(h) analytical performance characteristics, such as sensitivity, specificity, accuracy, trueness and precision;

(i) reference intervals; and

(j) use of drawings and diagrams.

CHAPTER XI
RESPONSIBILITIES AND OBLIGATIONS

122. General responsibilities and obligations of licensees and registration holders.— (1) Licensees and registration holders shall conduct its operation in accordance with the provisions of these rules and shall comply with all the conditions of the licence and registration issued by the MDB and on being required by the MDB or its authorized officer, the licensee and registration holder shall—

(a) produce or furnish his licence, certificate of registration or permit, as the case may be, to the MDB or the authorized officer for inspection; and

(b) produce or furnish such information, documents or samples, where practicable, of the medical device, as the MDB or the authorized officer may specify or require in relation to the compliance by the establishment with the requirements of these rules.

(2) A licensee who contravenes sub-rule (1) shall, without prejudice to the power of the MDB to suspend or cancel his licence or registration, be guilty of an offence and shall on conviction be punishable as specified in the DRAP Act.

(3) Any letter written to the Authority or MDB by the licensee or registration holder shall be signed by the director of the establishment or firm or organization, giving the name, designation and complete address with stamp and in case of authorized officer in this behalf, shall also be accompanied by the authorization letter from the director.

123. R esponsibilities and obligations of manufacturer.— (1) A manufacturer shall—

(a) ensure that the medical device, he manufactures, complies with the essential principles of safety and performance of the medical device;

(b) ensure the compliance of the conditions of licence, registration, permit and all other rules;

(c) keep record of all the batches or lots of the medical devices, he manufactures;

(d) be responsible for any post-market issues relating to its medical device; and

(e) be responsible for any regulatory matters with the MDB relating to its medical device.

(2) A manufacturer who operates outside Pakistan shall authorize a sole representative in Pakistan on its behalf relating to any matter as specified in sub-rule (1).

(3) A manufacturer or a sole representative in Pakistan under sub-rule (2) who contravenes sub-rule (1) shall, without prejudice to the power of the MDB to suspend or cancel his licence or registration, be guilty of an offence and shall on conviction be punished as specified in the DRAP Act.

124. Responsibilities and obligations of importer or authorized representative.— (1) An importer being sole authorized representative shall—

(a) obtain an appropriate authorization from manufacturer or the sole authorized representative, as the case may be;

(b) import and distribute in the market only registered medical devices;

(c) conduct its operations in accordance with the requirements of the DRAP Act and these rules;

(d) ensure that the medical devices he imports and distributes comply with the essential principles of safety and performance of the medical device;

(e) ensure the compliance of the conditions of licence, registration and permit under these rules;

(f) keep record of all the batches or lots of the medical devices he imports and distributes;

(g) in case of the importer be responsible for any post-market issues related to safety and performance of its medical devices;

(h) be responsible for any regulatory matter with the MDB relating to its medical device; and

(i) distribute only to licensed retail sellers medical devices accompanied by a warranty on the format as set out in the Form-5.

(2) An importer who contravenes sub-rule (1) shall, without prejudice to the power of the MDB to suspend or cancel his licence or registration, as the case may be, be guilty of an offence and shall on conviction be punished as specified in the DRAP Act.

125. Post-marketing surveillance and vigilance system.— (1) For the purpose of post-marketing surveillance and vigilance of marketed medical devices, a licensee shall establish, maintain and implement an appropriate and effective post-marketing surveillance and vigilance system of medical devices he is dealing with which shall also include the following elements, namely: —

(a) distribution records;

(b) complaint handling system;

(c) mandatory problem reporting, including investigation of problem or incident;

(d) field corrective action; and

(e) recall procedure.

(2) Any person who, in compliance or purported compliance with sub-rule (1), furnishes the MDB or an authorized officer with any record which is false or misleading, his licence or registration, as the case may be, shall be cancelled or suspended as the MDB may think fit, after affording him the opportunity of being heard.

126. Inspector .— An Inspector appointed under the Act shall perform functions and exercise powers under Schedule V of the DRAP Act in relations to these rules.

127. Analysis by quality control laboratories.— An Inspector, may where he thinks so to do, send a sample of a medical device to a quality control laboratory established or set up or notified by the Authority for the purpose of analysis of the sample of a medical device.

CHAPTER XII
EXEMPTIONS, PROHIBITIONS AND SAMPLING

128. Exemption from operation of the rules.— The conformity assessment bodies, medical devices' establishments and medical devices specified in column (2) of the Table below shall, in terms of section 36 of the Act, be exempted from operation of these rules from its commencement for a period as specified in column (3) thereof, namely: —

TABLE

S.No	Class of medical device, establishment or conformity assessment body	Proposed exemption period
(1)	(2)	(3)
1.	Conformity assessment bodies (CABs).	Six months.
2.	Class D medical devices and establishments manufacturing or importing Class D medical devices.	One year.
3.	Class C medical devices and establishments manufacturing or importing Class C medical devices.	Eighteen months.
4.	Class A (active, sterile or having measuring function) or B medical devices and establishments manufacturing or importing Class A (active, sterile or having measuring function) or B medical devices.	Two years.

129. Fabrication of custom-made medical devices.— (1) No person shall fabricate a custom-made medical device, unless that person—

(a) is a qualified practitioner and who shall fabricate the custom-made medical device only for the use of patient under his care; and

(b) fabricates a custom-made medical device either in—

(i) a hospital, medical clinic, dental clinic or health clinic under the Federal or a Provincial Government; or

(ii) a private healthcare facility.

(2) The person referred to in sub-rule (1) shall also be subjected to the duties and conditions determined by the MDB.

(3) The prohibition on an unregistered medical device shall not apply in the case where the unregistered medical device is a custom-made medical device.

(4) Any person who contravenes sub-rule (1) or (2) shall be guilty of an offence punishable under the DRAP Act.

130. Sampling of medical device for testing.— (1) The MDB, may at any time in writing as it thinks fit, require from the establishment that samples, where practicable, of the registered medical devices be sent for appropriate conformity assessment, including but not limiting to analysis or testing.

(2) Any expense incurred for or arising out of the sampling, testing or analysis of the medical devices shall be borne by the establishment.

CHAPTER XIII
USAGE, OPERATION, MAINTENANCE, ETC.

131. Usage, operation, maintenance, etc of medical device. — (1) Any person using a medical device in a healthcare facility shall ensure that the medical device is used for its intended purpose and in accordance with manufacturer's instructions.

(2) A person using or operating a medical device in a healthcare facility shall put in place an appropriate maintenance management system within the healthcare facility which shall include the following requirements, namely:—

(a) relating to procurement of registered medical devices;

(b) relating to inspection and verification of the safety and performance of the medical device prior to acceptance for use;

(c) maintaining and keeping up to date an appropriate medical device inventory of all medical devices within the healthcare facility;

(d) a procedure to ensure that the medical device is properly maintained and calibrated so as to ensure its safety and performance requirements;

(e) a procedure for and destruction or disability of a disposable medical device, immediately after its use;

(f) a procedure that will enable the healthcare facility to response in a timely manner to any of the following incidents, namely:—

(i) medical device safety alerts, advisory notices, recalls;

(ii) adverse events due to the medical device;

(iii) defective medical device; or

(iv) that compromises the safety, quality and performance of the medical device; and

(g) relating to procedure enabling the healthcare facility to report to the relevant manufacturer and the MDB, an adverse event relating to the medical device.

(3) Where applicable, for the purposes of sub-rule (2), the requirements shall be in accordance with the manufacturer's requirements or recommendations or standards determined by the MDB.

(4) No person shall be a medical device's service provider, unless—

(a) the person possesses the authorization from the manufacturer or its authorized agent;

(b) the person is competent to address any regulatory matter and issue arising from the safety, quality and performance of the medical device as approved by the MDB;

(c) the person installs, tests, commissions, maintains and services a medical device in accordance with manufacturer's instructions or applicable or relevant qualitative and quantitative safety and performance parameters; and

(d) the person has put in place a system to.—

(i) maintain medical device inventory and maintenance records in respect of a medical device installed, tested, commissioned, maintained and serviced;

(ii) maintain record of reported problems or complaints relating to the safety and performance characteristics of a medical device installed, tested, commissioned, maintained and serviced;

(iii) report incident occurring in respect of a medical device installed, tested, commissioned, maintained and serviced; and

(iv) undertake corrective or preventive action in relation to a medical device installed, tested, commissioned, maintained and serviced.

132. Practitioner to keep record of implants.— (1) A qualified practitioner who has placed into the body of a person an implanted medical device shall maintain proper records of the following matters, namely:—

(a) the name, address, phone number and identity card number, if any, of that person;

(b) the date on which the implant was placed into the body of that person;

(c) the name and description of the implant; and

(d) the lot or batch number of the implant.

(2) Any person who contravenes sub-rule (1) shall be guilty of an offence, punishable under the DRAP Act and the Act and the rules made thereunder and without prejudice to any action that may be taken under any law for the time being in force.

133. Qualification and competency of a person using or operating a medical device.— (1) No person shall use or operate a medical device unless that person is trained on the proper and correct usage, operation and application thereof.

(2) For the purposes of proper usage of a medical device, a person shall be trained by the manufacturer or its authorized representative or a competent trainer, based on the appropriate conditions as required for such training on the following, namely:—

(a) safety precautions in operating the medical device;

(b) proper operating procedures, including but not limited to, features unique to the particular manufacturer or model of the medical device;

(c) recognition and correction of common operational problems;

(d) recognition of defective equipment and potential hazards;

(e) user-care and maintenance of the medical device;

(f) relevant regulatory knowledge in relation to safety and performance of a medical device; and

(g) proper procedures for conducting a basic safety and performance inspection, checking and test for the medical device, where applicable.

134. Qualification and competency of a person installing, testing or maintaining a medical device. — (1) No person shall install, test, commission, maintain or calibrate a medical device unless that person is trained to properly install, test, commission, maintain or calibrate the medical device, as the case may be.

(2) For the purpose of sub-rule (1) and, as the case may be, a person installing, testing, commissioning, maintaining or calibrating a medical device shall be trained by the manufacturer or authorized representative or a competent trainer on—

(a) safety precautions to properly install or test, as the case may be, the medical device;

(b) proper procedures in case of an active medical device, for conducting an electrical and other relevant safety test and qualitative and quantitative performance test for the medical device; and

(c) proper procedures for decontaminating the medical device.

CHAPTER XIV
MEDICAL DEVICE BOARD (MDB)

135. Medical Device Board.— (1) There shall be a Medical Device Board (MDB), responsible for registration of conformity assessment bodies and medical devices, licensing of establishments and issuance of permits for export and import of medical devices, their components and raw materials and for the matters ancillary thereto.

(2) The MDB shall consist of the following, namely: —

(a) Director, Medical Devices and Medicated Cosmetics, Drug Regulatory Authority of Pakistan who shall be its *ex-officio* Chairman;

(b) Additional Director, Medical Devices and Medicated Cosmetics, Drug Regulatory Authority of Pakistan who shall be its ex-officio member and Secretary;

(c) Director General Health, or his nominee not below BS-19, of each Province who shall be ex-officio member;

(d) one urologist or nephrologist having relevant experience of not less than five years, to be nominated by the Authority;

(e) two pharmacists having relevant experience of not less than five years in manufacturing or quality control of medical devices, to be nominated by the Authority;

(f) one biomedical engineer having relevant experience of not less than five years, to be nominated by the Authority;

(g) one radiologist having relevant experience of not less than five years, to be nominated by the Authority;

(h) one software or electromechanical engineer having relevant experience of not less than five years, to be nominated by the Authority;

(i) one general or orthopedic surgeon having relevant experience of not less than five years, to be nominated by the Authority;

(j) one cardiovascular surgeon or interventional cardiologist having relevant experience of not less than five years, to be nominated by the Authority;

(k) one hospital pharmacist having relevant experience of not less than five years, to be nominated by the Authority; and

(l) one pathologist or medical technologist having relevant experience of not less than five years, to be nominated by the Authority;

(3) The MDB may co-opt any other person who is expert of any specialty for the disposal of relevant cases.

(4) The members of the MDB, other than its *ex-officio* members, shall hold office for two years and shall be eligible for re-nomination.

(5) A member, other than its *ex-officio* member, may resign by writing under his hand addressed to the Authority.

(6) No person who is a member of the Appellate Board or the Policy Board shall be a member of the MDB.

(7) The Chairman himself or on the directions of the Authority may call meeting of the MDB.

(8) In the absence of Chairman from a meeting, the MDB members may elect one of the members to preside over at meeting.

(9) Where the MDB requires examination or evaluation of applications for the grant of licence, registration, remedial action in good manufacturing practices or other cases ancillary thereto, the following sub-committee shall examine the cases and report its examination to the MDB: —

(a) Secretary of the MDB;

(b) Deputy Director (Medical Devices and Medicated Cosmetics Division);

(c) expert member or members nominated by MDB.

(10) The quorum to conduct a meeting shall be one-half of the total members including the Chairman of the MDB.

(11) The MDB shall follow policy guidelines issued by the Policy Board of the Authority.

(12) The Secretary of the MDB or any officer of the Medical Devices and Medicated Cosmetics Division nominated by the MDB may perform any specific function of the MDB including the disposal of its day-to-day business.

(13) The MDB shall, for the purpose of these rules, fix responsibility of offences before referring a case to the Court.

(14) After approval of the MDB, the Secretary of MDB and in his absence due to any reason any officer of the Division authorized by the MDB shall sign the establishment licence and the registration certificate.

(15) The MDB may appoint a panel of experts or inspectors for inspection of any establishment to submit its report to the MDB.

(16) The MDB may extend the sealing period not exceeding three months of the licensed establishment on the request of the Inspector for the purpose of investigation.

Provided that the investigation shall be completed within three months by the Inspector and complete case shall be submitted for consideration of the MDB:

(17) No act or proceeding of the MDB shall be invalid merely on the ground of the existing of any vacancy in, or any defect in its constitution.

(18) The MDB may, in case of minor contravention, advise the establishment for improvement or if considered necessary, issue warning or take other action as it may deem fit for the purpose of improvement.

(19) The MDB shall issue recall notices for withdrawal of stock from the market, if any medical device is declared unsafe and sub-standard by the notified laboratory. Likewise, the marketing authorization holder shall inform the MDB for the recalls within fifteen days after the identification of problem.

(20) The MDB may direct the Inspector for investigation of cases and implementation of recall notices effectively.

(21) The MDB may in public interest, recommend to the appropriate authority to restrict or stop the import of any medical device or classes of medical devices, which are produced in sufficient quantity in Pakistan.

CHAPTER XV
APPEAL

136. Analysis by appellate laboratory.— Where an establishment is aggrieved by result of a test of quality control laboratory, the MDB shall send to the appellate laboratory, established or set up or notified for this purpose by the Authority, the portion of sample of the medical device lying with it and result and report of such appellate laboratory shall be conclusive evidence of the facts stated therein.

CHAPTER XVI
MEDICAL DEVICE REGISTER

137. Contents of the medical device register.— The MDB shall maintain a medical device register on the format as set out in Form-19 regarding registered conformity assessment bodies and medical devices, licensed establishments and decisions of the MDB for cancellation or suspension of registrations of conformity assessment bodies and medical devices and licences of establishments, as the case may be.

CHAPTER XVII
FEE

138. Fee for various activities.— The fee specified in column (4) of the Table below shall be payable in respect of an activity specified in column (3) thereof, namely: **—**

TABLE

S.No	Subject	Description	Fee payable (Rs)
(1)	(2)	(3)	(4)
1.	REGISTRATION OF MEDICAL DEVICES	Fee for registration of medical device for local manufacture.	20,000
		Fee for renewal of registration of medical device for local manufacture.	10,000
		Fee for registration of medical device for import.	100,000
		Fee for renewal of registration of medical device for import.	50,000

		Note: If any medical device to be imported is not manufactured locally then registration fee shall be Rs. 50,000 and its fee for renewal of registration shall be Rs. 25,000.00, whereas fee for change in particulars of registered medical device shall be fifty percent of the registration fee.	
2.	REGISTRATION OF CONFORMITY ASSESSMENT BODIES	Fee for registration of conformity assessment body.	100,000
		Fee for renewal of registration of conformity assessment body.	50,000
		Note: Fee for change in particulars of registered conformity assessment body shall be fifty percent of the registration fee.	
3.	ESTABLISHMENT LICENCES	Fee for licence to manufacture medical devices.	100,000
		Fee for licence to import medical devices.	20,000
		Fee for renewal of licence to manufacture medical devices.	50,000
		Fee for renewal of licence to import medical devices.	10,000
		Note: Fee for change in particulars of licensed establishment shall be fifty percent of the licensing fee.	
4.	IMPORT PERMITS	Fee for import permit or its renewal.	5,000
5.	EXPORT PERMITS	Fee for export permit or its renewal.	1,000
6.	APPEAL	Fee for appeal.	50,000
7.	ADVERTISEMENT	Fee for advertisement.	20,000
8.	MISCELLEANEOUS	Fee for any other activity having commercial significance.	5,000

CHAPTER XVIII
ADVERTISMENT OF MEDICAL DEVICES

139. Medical device advertising.— No person himself or on behalf of any other person shall advertise a medical device by any means except as provided under these rules..

140. Procedure for medical device advertising.— (1) For the purpose of advertising a medical device, an application shall be made to the MDB on the format as set out in Form-20.

(2) An application for advertisement shall be accompanied with the following, namely:—

(a) application fee as prescribed in rule 138; and

(b) documents or information as specified in Form-20.

(3) The permission for advertisement shall be issued on the format as set out in Form-21.

(4) The MDB may reject an application if the applicant fails to deposit specified fee or provide information, particulars or documents as required under sub-rule (2). In case the application for advertisement is rejected by the MDB, it shall inform the applicant of its decision in writing with reasons of such decision.

141. Conditions for advertising.— (1) The MDB may allow the advertisement of a medical device, approve the contents of such advertisement and specify conditions subject to which such advertisement shall be made:

Provided that the MDB may, if in its opinion the public interest so requires, withdraw the approval granted for any advertisement or modify or alter any condition thereof:

Provided further that before withdrawing its approval under the first proviso, the MDB shall provide the establishment the opportunity of being heard.

(2) The approval of the advertisement shall be valid for a period of two years.

(3) No person shall advertise a medical device for any purpose except for which it has been registered.

(4) Where the information on intended use is provided, the advertisement material shall contain instructions for use and other necessary precautions as may be applicable.

(5) No advertisement under these rules shall contain any direct or indirect comparison in any way with any other medical device for the purpose of attracting customers or with a view to discredit other such product.

(6) Advertisement material shall be presented with courtesy and good taste and words, whereas phrases implying urgency, uniqueness or such expressions which are absolute in character, such as "the most potent", "the most rapid", "the most efficacious", or which make exaggerated claims or to general claims, such as "effective in all cases" or "effective against all complaints" or superlatives shall be avoided.

(7) Advertisement of a medical device shall include such information or any risks and other precautions as may be necessary for the protection of public health and also its maximum retail price.

(8) A medical device may be advertised to the medical, pharmaceutical and allied professions, without referring to the MDB, through medical representatives or through professional journals and publications which are meant for circulation exclusively amongst the members of the said professions:

Provided that one copy of each issue of such journal or publication shall be sent to the Division of Medical Devices and Medicated Cosmetics of the Authority.

(9) A medical device, where necessary, may be advertised to the medical, pharmaceutical and allied professions through a documentary film.

(10) No person shall spend more than five per cent of his turnover on advertisement and other promotional activities in respect of medical devices.

(11) The MDB may, after giving an opportunity of being heard, prohibit any advertisement in any form as it is found to violate any provision of these rules.

CHAPTER XIX
MISCELLANEOUS

142. Outsourcing.— (1) Out sourcing of manufacturing of medical devices may be allowed subject to fulfillment of the following conditions, namely: —

(a) the establishment performing the outsourcing (contract acceptor) has been licensed and its medical device registered by the MDB and approved by any regulatory authority of USA, Japan, Australia, Canada, Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Netherlands, Norway, Spain, Sweden, Switzerland and United Kingdom or pre-qualified by World Health Organization;

(b) the contract giver shall possess establishment licence issued by the MDB; and

(c) if the contract giver is of foreign jurisdiction, the MDB shall determine the conditions of out sourcing.

(2) Outsourcing of manufacturing processes or analysis of medical devices may be allowed subject to the conditions as may be prescribed.

(3) Permission granted by the MDB may be revoked, if the MDB is of the opinion that the circumstances in which the permission for outsourcing was granted does not exist further or the permission is being misused or if the establishment is contravening any of the provisions of these rules or the DRAP Act:

Provided that before revoking the permission an opportunity of being heard shall be provided.

143. Standards of testing. — The standards for testing of medical devices shall be in accordance with the international standards.

144. Fee to be non-refundable. — Any fee specified under rule 138 and deposited in respect of any activity shall be non-refundable.

145. Contravention and punishments. — Whoever himself or by any other person on his behalf contravenes any of the provisions of the DRAP Act and the rules made thereunder shall be punished as provided for in the DRAP Act.

146. Repeal. — The provisions of rules made under the Drugs Act, 1976 (XXXI of 1976) so far as they regulate medical devices and their directive covered under these rules are hereby repealed from the dates and in respect of the medical devices and activities thereof specifies under rule 128.

FORM-1
[see rule 47(1), 49(1) and 50(2)]

APPLICATION FORM FOR REGISTRATION OR RENWWAL OF REGISTRATION OF CONFORMITY ASSESSMENT BODY (CAB)

Note:

(a) This form shall also be used for proposed changes in particulars of registered CAB. For this purpose, provision of relative information is mandatory. (In case of any proposed change, please mention details of change)
(b) Use separate sheet if necessary.
(c) Number all the attached documents submitted with this application form.

1. Organization Profile

S.No	Description	
(1)	(2)	
1.	Name of organization:	
2.	Address:	
3.	Address outside Pakistan , if any:	
4.	Telephone No., including cell No:	
5.	Fax number:	
6.	E-mail address:	
7.	Website:	
8.	Certification manager	Name
		Position
		Address
		Telephone No.
		Cell No.
		Fax No.
		E-mail address
9.	Local representative	Name
		Position
		Address
		Telephone No.
		Cell No.
		Fax No.
		E-mail address
10.	Organization chart:	Please attach
11.	Business of organization (Please tick)	Certification
		Product certification

		Testing
		Others (please specify)
12.	Legal status of organization. Please provide documentation, identifying its status.	
13.	No. of employees	
14.	Has the organization already registered or designated as a conformity assessment body in the field of medical devices or one or more related fields. If yes, please provide details, including the scope of designation and supporting documents.	
15.	If organization is part of larger organization, provide details about the larger organization and its structure, indicating in particular its relationship with the organization.	

2. **Applied scope of registration**

S. No	**Scope of registration**	**Please tick**
(1)	(2)	(3)
1.	Assessment on quality management system	
2.	Assessment on good distribution practices	
3.	Product approval reviews (technical reviewer)	

3. **What are the medical devices' technical areas which your organization seeks for registration? Please list it according to Table 4 of these rules.**

S.No	**CODE**	**MD scope expression**
(1)	(2)	(3)

4. **Resources of organization**

S.No	Resources
(1)	(2)
1.	Test facilities: (Please state their addresses and test capabilities and give details, including documentary proof of any accreditation)

2.	In-house expert, specialist or auditor: (Please list their names, areas of competence and provide CVs)
3.	Sub-contracts: (Please specify theirs names, addresses, contract details and areas of competence. For sub-contracted test laboratories, please state their testing capabilities along with other details, including documentary proof of any accreditation claimed by them)
4.	Public liability insurance taken out by organization, if any: (The insurance must cover its conformity assessment activities. Please provide a copy of the insurance certificate) Sum insured: Insurer's name and address: Renewal date:

5. **Assessment Information.**

S.No	Detail information	Remarks
(1)	(2)	(3)
1.	Please attach a copy of the system documentation of organization's quality management system (QMS).	
2.	Procedures by which cases of conflicts of interest or potential conflicts of interest are identified and resolved.	Indicate where in the QMS documentation these procedures can be located.
3.	Procedures by which the organization ensures impartiality of its employees and sub-contractors.	Indicate where in the QMS documentation these procedures can be located.
4.	Procedures for sub-contracting including documented procedures for monitoring sub-contractor's performance.	Indicate where in the QMS documentation these procedures can be located.
5.	Mechanisms that ensure confidentiality between the organization and its clients.	Indicate where in the QMS documentation these procedures can be located.
6.	Procedures according to which conformity assessment within the scope of recognition will be carried out by the organization and its sub-contractors, if any.	Indicate where in the QMS documentation these procedures can be located.
7.	Agreements between the organization and its sub-contractors, if any.	Please attach.

DECLARATION

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect, it shall lead to action to be taken by the MDB under the DRAP Act and the rules made there under.

Applicant's signature:

Name:

Designation and stamp:

Date:

Documents needed to be submitted with the application form including:

1. Copy of the organization chart.
2. Job descriptions of the key personnel.
3. List and job descriptions of qualified auditors.
4. Qualification and job descriptions of qualified auditors/personnel/assessors/testers.
5. Statements with respect to independence and impartiality (lf the organization provides consultancy services, please provide details as to how the consultancy is separated from the organization activity).
6. Details as to how the CAB activities being applied for, would fit into the current structure and be financed.
7. Internal quality management including—

   (a) internal quality manual;

   (b) details of document control procedures;

   (c) procedures for corrective and preventive actions including complaint handling; and

   (d) procedures regarding internal audits and management review.

8. Personnel: —

   (a) Technical qualification and experience of experts held within the applicant organization;

   (b) documented agreement with the appointed sub-contractors and copies of their auditors' qualifications and experiences;

   (c) procedures for authorization and monitoring of assessment and verification of staff;

   (d) overview of training programs related to medical devices regulation requirements, ISO-13485, etc;

   (e) procedures to ensure the avoidance of conflicts of interest and ensuring confidentiality and

   (f) copy of medical device authority (MDA) or division's certificate of attendance and competency certificate, if any.

9. Details of relevant in-house and sub-contractors facilities, relevant accreditations, if any, and terms of agreements of the sub-contractors.
10. Copies of the documents that would propose sending to potential new clients if registered, e.g., general terms and conditions, marketing materials, application form and contracts.

11. Procedures to assess client's conformity with the appropriate conformity assessment requirements and EPSP.

12. Procedures to take account of existing certifications and registrations.

13. Details of procedures to ensure conformity assessment.

14. Procedures aimed at ensuring the independence and impartiality of assessments and certification decisions.

FORM-2
[see rule 48(3)]

F.No……..

DRUG REGULATORY AUTHORITY OF PAKISTAN

Islamabad, the dated……..

CERTIFICATE OF REGISTRATION OF A CONFORMITY ASSESSMENT BODY (CAB)

Certified that M/s……..,being a conformity assessment body, is here by registered under the DRAP Act, 2012 and the Medical Devices Rules, 2015 subject to conditions appearing hereinafter: —

Name of CAB and complete address: ……..

Scope of registration: ……

Medical devices' technical areas:

S.No	CODE	MD scope expression
(1)	(2)	(3)

2. This registration shall be valid for a period of five years from the date mentioned above unless earlier suspended or cancelled.

3. This registration is subject to the provisions specified in the DRAP Act, 2012 and the rules made there under.

Secretary
Medical Device Board
Seal:

FORM-3

[see rule 70(2), 73(1) and 74(3)**]**

APPLICATION FORM FOR GRANT OR RENEWAL OF AN ESTABLISHMENT LICENCE TO MANUFACTURE MEDICAL DEVICES

Note: This form shall also be used if change is proposed regarding the particulars provided in relation to the licensed establishment to manufacture medical devices**.** For this purpose, provision of relative information is mandatory.

I/We ……..of M/s……..hereby apply for grant or renewal of establishment licence to manufacture medical devices or approval for proposed change regarding the particulars provided in relation to the licensed establishment to manufacture medical devices at the premises situated at …….

1. Purpose of application, whether for grant or renewal of establishment licence to manufacture medical devices or proposed change of any particular of a licensed establishment (In case of any proposed change, please mention details of change)

2. For renewal of licence, provide following information:
   (i) Licence number and date:
   (ii) Validity date:
   (iii) Last renewal date and its validity:
   (iv) Attach certificate of licence and last renewal:

3. Establishment details:

   (i) Establishment name and address:
   (ii) Type of ownership i.e partnership, proprietorship, public limited, private limited etc:
   (iii) Business registration as issued by the Registrar of Companies or any other authorized body:
   (iv) Names of partners/proprietors/directors:
   (v) addresses of partners/proprietors/directors:
   (vi) Date of establishment:
   (vii) Initial investment and details of equity shares:
   (viii) Present investment and details of equity shares:
   (ix) Attach profit and loss statement as per audited accounts for last 5 years, if applicable:
   (x) Details of premises:
   (xi) Details of section wise equipments and machinery for manufacturing and instruments for quality control :
   (xii) Names and qualifications of production incharge and quality control incharge for supervising manufacturing processes and quality control department respectively and other technical staff working in these departments:
   (xiii) Proof of fee deposited:

4. Quality management system (QMS):

   (i) Has the QMS been certified?
   (ii) Provide report and certificate issued by conformity assessment body (CAB):
   (iii) Name of CAB:
   (iv) CAB registration number:

5. Post-market surveillance system:

   (i) Maintenance of distribution records (summary of procedure) :
   (ii) Complaint handling (summary of procedure) :
   (iii) Mandatory problem reporting (summary of procedure) :
   (iv) Recall (summary of procedure) :
   (v) Field corrective action (summary of procedure) :

6. Details of medical devices intended to be manufactured:

   (i) Type of medical device whether it is a general medical device or *in-vitro* diagnostic medical device?
   (ii) Classes of medical devices whether Class A, Class B, Class C or Class D:

7. Any other relevant information that may be required by the MDB.

DECLARATION

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to action to be taken by the MDB under the DRAP Act, the Act and the rules made there under.

Name(s)……..

Designations……..

Signature(s)……..

Stamp……..

Date…….

FORM-3A
[see rule 70(2), 73(1) and 74(3)**]**

APPLICATION FORM FOR GRANT OR RENEWAL OF AN ESTABLISHMENT LICENCE TO IMPORT MEDICAL DEVICES

Note: This form shall also be used if change is proposed regarding the particulars provided in relation to the licensed establishment to import medical devices. For this purpose, provision of relative information is mandatory.

I/We ……..of M/s……..hereby apply for grant or renewal of establishment licence to import medical devices or approval of proposed change regarding the particulars provided in relation to of establishment licence to import medical devices at the premises situated at …….

1. Purpose of application, whether for grant or renewal of establishment licence to import medical devices or proposed change of any particular of a licensed establishment.(In case of any proposed change, please mention details of change):

2. For renewal of licence, provide following information:—
   (i) Licence number and date:
   (ii) Validity date:
   (iii) Last renewal date and validity:
   (iv) Attach certificate of licence and last renewal:

3. Establishment details: —
   (i) Establishment name and address including godown address, if any:
   (ii) Type of ownership i.e. partnership, proprietorship, public limited, private limited, etc:
   (iii) Business registration number as issued by the Registrar of Companies or any other authorized body:
   (iv) Names of partners/proprietors/directors:
   (v) Addresses of partners/proprietors/directors:
   (vi) Date of establishment:
   (vii) Initial investment and details of equity shares:
   (viii) Present investment and details of equity shares:
   (ix) Profit and loss statement as per audited accounts for last 5 years, if applicable:
   (x) Details of premises including covered area, dimensions, etc:
   (xi) Details of equipments and machinery for storage and distribution of medical devices:
   (xii) Proof of fee deposited:
   (xiii) Name, qualification, registration No, CNIC No. and address of qualified person(s) for supervising sale and distribution and other technical staff working including the following information:—

      (a) three attested copies of the registration certificates issued by the concerned council.
      (b) four attested copies of CNIC of each of partners/proprietors/directors and qualified persons.
      (c) four attested passport size photographs of each of the partners/proprietors/directors and qualified persons.
      (d) affidavit binding of the partners/proprietors/directors and qualified persons, duly verified to the effect that they:—
         (I) shall comply with the provisions of DRAP Act, 2012 and the rules made there under,
         (II) have not been convicted of any offence from any court of law.
         (III) shall inform MDB and the inspector as soon as possible when either of the party ceases to have interest in the licence issued under these rules
         (IV) shall not sell or stock any expired, spurious, substandard, unregistered, misbranded, counterfeit or any medical device in violation of the DRAP Act, 2012 and the rules made there under.

4. Quality management system (QMS):

   (i) Has the QMS been certified?
   (ii) Provide report and certificate issued by conformity assessment body (CAB):
   (iii) Name of CAB:
   (iv) CAB registration number:

5. Post-market surveillance system:

   (i) Maintenance of distribution records (summary of procedure):

(ii) Complaint handling (summary of procedure):
(iii) Mandatory problem reporting (summary of procedure):
(iv) Recall (Summary of procedure):
(v) Field corrective action (summary of procedure):

6. Details of medical devices intended to be imported:—

(i) Type of medical device whether it is a general medical device or *in-vitro* diagnostic medical device?
(ii) Classes of medical devices whether Class A, Class B, Class C or Class D:

7. Any other relevant information that may be required by the MDB:

DECLARATION

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to action to be taken by the MDB under the DRAP Act, the Act and the rules made there under.

Name(s)……..

Designations……..

Signature(s)……..

Stamp……..

Date…….

FORM-4
[see rule 71(2)**]**

DRUGS REGULATORY AUTHORITY OF PAKISTAN

LICENCE TO MANUFACTURE MEDICAL DEVICES

Licence No.

Date of issue:

M/s……..is hereby licensed to manufacture medical devices at the following premises:-
……
……

2. This licence permits the manufacture of…….

3. This licence shall, in addition to the conditions specified in the Medical Devices Rules, 2015 made under the DRAP Act, 2012, be subject to the following conditions namely:-

(a) The licence shall be in force for a period of five years from the date of issue unless earlier suspended or cancelled.

(b) The licence authorizes the sale by way of wholesale dealing and storage for sale by the licensee of the products manufactured under this licence, subject to the conditions applicable to licences for sale.

(c) Name of the approved expert staff.

....
....

Secretary
Medical Device Board
Seal:

FORM-4A
[see rule 71(2)**]**

DRUGS REGULATORY AUTHORITY OF PAKISTAN

LICENCE TO IMPORT MEDICAL DEVICES

Licence No.

Date of issue:

M/s……..is hereby licensed to import registered medical devices at the following premises:

……..

2. This licence permits the import and wholesale of …….

3. Name(s) of proprietor(s) along with the residential address and CNIC Number(s)

(i) ……..
(ii) …….

4. Name(s) of the person(s) incharge who will personally supervise the import and sale of medical devices by way of wholesale along with registration No, residential address and CNIC No.

(i) ……..
(ii) …….

5. Addresses of godowns , if any, where medical devices shall be stored……

6. The licence will be in force for a period of five years from the date of issue unless earlier suspended or cancelled.

7. This licence shall, in addition to the conditions specified in the Medical Devices Rules, 2015 made under the DRAP Act, 2012, be subject to the following conditions namely:-

(i) The persons mentioned above shall personally supervise the sale of medical devices.
(ii) The licence and registration certificate from the Pharmacy council of the person(s) incharge, personally supervising the sale of medical devices shall be displayed in a prominent place in the premises open to public.
(iii) No medical device requiring special storage conditions of temperature and humidity shall be stored or sold unless the precaution necessary for preventing the properties of

the components have been observed throughout the period during which it remained in possession of the licensee.

Secretary
Medical Device Board
Seal:

FORM-5
[see rule 72(2)(i), 72(4)(b), 92(7) and 124(1)(i)**]**

Warranty under Medical Devices Rules, 2015

Title of firm:

Invoice No. and date:

Name and address of purchaser:

Licence No:

Valid upto:

Issued by:

I…….being a person, resident in Pakistan, carrying on business at (full address)……under the name of…….holding valid licence No……issued by…….and having authority or being authorized by M/s (full address)……., authorized vide letter No…….dated……., do hereby give this warranty that the medical devices here-under described as sold by me and contained in the bill of sale, invoice, bill of lading or other document describing the medical devices referred to herein do not contravene in any way the provisions of the DRAP Act, 2012 and the rules framed there-under.

S.No	Name of medical devices	Batch or lot No	Expiry date
(1)	(2)	(3)	(4)

Total items:

Descriptions of bill of sale, invoice, bill of lading or other document (if any).

Name of warrantor:
Designation:
Stamp:
Signature:
Date:

FORM-6
[see rule 87(2), 89(1) and 90(2)**]**

APPLICATION FORM FOR REGISTRATION OR RENEWAL OF REGISTRATION OF A MEDICAL DEVICE FOR LOCAL MANUFACTURE.

Note: This form shall also be used if change is proposed regarding any particulars provided in relation to the registration of a registered medical device. For this purpose, provision of relative information is mandatory.

I (name and designation)……..of M/s……..hereby apply for registration or renewal of registration or proposed change of any particular of registered medical device for local manufacture, namely ……,details of which are mentioned below along with enclosures.

1. Purpose of application, whether registration or renewal of registration or proposed change of any particular of registered medical device for local manufacture? (In case of proposed change, please mention all the details of change).

2. In case of renewal of registration, provide following information:
   (i) Registration number and date:
   (ii) Validity date:
   (iii) Last renewal date and validity:
   (iv) Provide certificate of registration and last renewal:

3. General information :

   (i) Medical device brand name:
   (ii) Does the medical device contain any active ingredient, poison or drug?
   (iii) Type of medical device whether it is a general medical device or *in-vitro* diagnostic medical device?
   (iv) Class of medical device whether Class A, Class B, Class C or Class D:
   (v) Classification rule, sub-rule and clause that applies to the medical device based on the classification methods of medical devices under Medical Devices Rules, 2015 to justify the class chosen above:
   (vi) Medical device category applicable to the device from the medical device technical areas listed in these rules:
   (vii) HS code for the medical device, if applicable:
   (viii) GMDN code for the medical device, if applicable:
   (ix) Pre-market clearance or approval received from US FDA, TGA Australia, Health Canada, regulatory authorities of EU countries and Japan, if any. Provide copy of certificate of pre- market clearance or approval to show evidence:
   (x) Name and registration number of conformity assessment body (CAB) by whom conformity assessment of the medical device has been done:
   (xi) Conformity assessment report and certificate for the medical device, as applicable:
   (xii) Quality management system certificate of manufacturer. If the manufacturing process consists of a number of sub-assembly processes, quality management system certificate of manufacturing sites where each of these sub-assembly processes are carried out must be provided:
   (xiii) GMP certificate, if any:
   (xiv) Shelf life:
   (xv) Unit price of medical device:
   (xvi) Storage condition:
   (xvii) Last inspection report:
   (xviii) Is the medical device for export only?
   (xix) Proof of fee deposited:

4. Information of manufacturer :

   (i) Details of the manufacturer. The details shall also include complete address, telephone number, fax number ,name of responsible persons and its official website) :

(ii) Establishment licence No, date of issuance and renewal. (Also attach copy of valid establishment licence :

(iii) If the manufacturing process of a product consists of a number of sub-assembly processes, the details of manufacturing sites where each of these sub-assembly processes are carried out must be identified and provided along with name of process:

5. Grouping of medical device :

(i) Specify medical device grouping applicable to the medical device :
(ii) Specify whether constituent-components or medical devices grouped together are manufactured by the same manufacturer. In case of different manufacturers, specify names and complete addresses of manufacturers along with constituent-components or medical devices:
(iii) List the constituent-components or medical devices that are grouped together:

6. Information on validation for medical devices with sterile or with measuring function, where applicable:

7. Common submission dossier template "CSDT" (Mandatory for Class C and Class D medical devices) :

(i) The template for CSDT shall be in accordance with these rules:
(ii) Documents to support the information written in the CSDT :

8. Post-market vigilance history:

(i) Please indicate whether the device has any history of previous recalls, reportable adverse incidents, banning in other countries or post market surveillance studies:
(ii) Please indicate if the application of registration or the registration of the medical device has been rejected, suspended or cancelled in other countries. Also provide reasons for the rejection or suspension or cancellation of the device application or registration:

9. Declaration of conformity:— Please attach the complete, signed and attested declaration of conformity (DoC). The DoC need to be printed on the establishment's letterhead, filled and signed by responsible person on the template as specified in these rules.

10. This section is applicable only to Class A and Class B medical devices where CSDT is not provided with application.

(i) Please list all the relevant essential principles applicable to the medical device and rule used to demonstrate conformity to each applicable essential principle. The evidence of conformity shall be provided in tabular form with supporting documentation available for review as required using the format under these rules.
(ii) Attach a detailed description of following medical device attributes, as applicable.

(a) complete description of the medical device;
(b) principles of operation or mode of action;

(c) description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the medical device;
(d) description or complete list of the various configurations of the medical device to be registered using the format under these rules
(e) complete description of the key functional elements, its formulation, its composition and its functionality;
(f) explanation of novel features, if any;
(g) as appropriate, labelled pictorial representation of the medical device in the form of diagrams, photographs or drawings with sufficient explanation to understand the drawings and diagrams;
(h) intended uses of the medical device;
(i) indications that the device will diagnose, treat, prevent, cure or mitigate;
(j) instructions for use;
(k) contraindications;
(l) warnings to inform on specific risk or hazard that a user needs to know before using the medical device;
(m) precautions to exercise special care necessary for the safe and effective use of the medical device;
(n) potential adverse effects or side effects;
(o) commercial marketing history which covers the list of countries where the medical device is marketed and the dates of introduction into those countries;
(p) list of regulatory approval or marketing clearance obtained including the registration status, intended use and indications of the medical device in other countries and copies of certificates or approval letters from each country;
(q) status of any pending applications for regulatory approval or marketing clearance;
(r) any other relevant specifications and descriptive information.

(iii) As applicable, attach documentation on software validation studies to verify the correctness of software in medical device. The document shall include the results of all verification, validation and testing performed prior to final release.

(iv) As applicable, following information to be provided on medical devices containing biological material:

(a) list of all materials of animal, human, microbial or recombinant origin used in the medical device and in the manufacturing process of the medical device, which includes animal or human cells, tissues or derivatives, rendered non-viable cells, tissues or derivatives of microbial or recombinant origin;
(b) detailed information concerning the selection of sources or donors;
(c) detailed information on the harvesting, processing, preservation, testing and handling of tissues, cells and substances;
(d) process validation results to substantiate that manufacturing procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents; and
(e) full description of the system for record keeping allowing traceability from sources to the finished medical device.

(v) Provide documentation on medical device labelling containing the following information—

(a) sample of labels on the medical device and its packaging;
(b) instructions for installation and maintenance, if applicable;
(c) any information and instructions given to the patient, including

instructions for any procedure the patient is expected to perform, if applicable. And

(d) promotional material and product brochures.

(vi) Provide complete documentation related to the manufacturing and quality control processes.

11. Any other relevant information that may be required by the MDB.

DECLARATION

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to action to be taken by the MDB under the DRAP Act, the Act and the rules made there under.

Name of applicant……..

Designation…….

Signature……..

Stamp…….

Date…….

FORM-6A

[see rule 87(2), 89(1) and 90(2)**]**

APPLICATION FORM FOR REGISTRATION OR RENEWAL OF REGISTRATION OF A MEDICAL DEVICE FOR IMPORT

Note: This form shall also be used if change is proposed regarding the particular provided in relation to the registration of a registered medical device for import. For this purpose, provision of relative information is mandatory.

I (name and designation)……..of M/s……..hereby apply for registration or renewal of registration or proposed change of any particular of registered medical device for import, namely ……,details of which are mentioned below along with enclosures.

1. Details of importer:

(i) Name of establishment:
(ii) Complete addresses:
(iii) Name of responsible persons:
(iv) Establishment licence No, date of issuance and renewal. Also attach copy of valid establishment licence:
(v) Telephone numbers, fax numbers, email addresses, official websites, etc:

2. Purpose of application whether registration or renewal of registration or proposed change of any particular of a registered medical device for import :(In case of proposed change, please mention all the details of change)

3. For renewal of registration, provide following information:

(i) Registration number and date:
(ii) Validity date:
(iii) Last renewal date and validity:
(iv) Provide certificate of registration and last renewal.

4. General Information :

(i) Medical device brand name:
(ii) Does the medical device contain any active ingredient, poison or drug?
(iii) Type of medical device whether it is a general medical device or *in-vitro* diagnostic medical device?
(iv) Class of medical device whether Class A, Class B, Class C or Class D:
(v) Classification rule, sub-rule and clause that applies to the medical device based on the classification methods of medical device under Medical Devices Rules 2015 to justify the class chosen above:
(vi) Medical device category applicable to the device from the medical device technical areas listed in these rules :
(vii) HS code for the medical device, if applicable :
(viii) GMDN code for the medical device, if applicable :
(ix) Pre-market clearance or approval received from US FDA, TGA Australia, Health Canada, regulatory authorities of EU countries and Japan, if any. Provide copy of certificate of pre-market clearance or approval to show evidence:
(x) Name and registration number of conformity assessment body (CAB) by whom conformity assessment of the medical device has been done:
(xi) Conformity assessment report and certificate for medical device, as applicable :
(xii) Quality management system certificate of manufacturer. If the manufacturing process consists of a number of sub-assembly processes, quality management system certificate of manufacturing sites where each of these sub-assembly processes are carried out must be provided:
(xiii) GMP certificate, if any?
(xiv) Free sale certificate attested by embassy of Pakistan in the country of origin:
(xv) Sole agent certificate or agreement with manufacturer abroad with scope of products and validity date, attested by embassy of Pakistan in the country of origin:
(xvi) Shelf life as approved in the country of origin. Provide certificate or any document showing regulatory approval of the shelf life in the country of origin:
(xvii) Complete stability profile to support shelf life:
(xviii) Unit price of medical device:
(xix) Storage condition:
(xx) Attach last inspection report conducted by the concerned regulatory authority or notified body :
(xxi) Is the medical device for export only?
(xxii) Proof of fee deposited:

5. Information of manufacturer:

(i) Provide the details of the manufacturer. The details also include complete address, telephone number, fax number and its official website:
(ii) If the manufacturing process of a medical device consists of a number of sub-assembly processes, the details of all manufacturing sites where each of these sub-assembly processes are carried out must be provided along with processes:
(iii) If multiple sites manufacture the same product, details of each of these sites must be provided including design and manufacturing activities:
(iv) Credentials of the manufacturer abroad attested by embassy of Pakistan in the country of origin:

6. Grouping of medical device :

   (i) Specify medical device grouping that is applicable to the medical device under these rules :
   (ii) Specify whether constituent-components or medical devices that are grouped together are manufactured by the same manufacturer. In case of different manufacturers, specify names and complete addresses of manufacturers along with constituent-components or medical devices:
   (iii) List the constituent-components or medical devices that are grouped together :

7. Information on validation for medical devices with sterile or with measuring function, where applicable:
8. Common submission dossier template "CSDT" (Mandatory for Class C and Class D medical devices):

   (i) The template for CSDT should be in accordance with these rules :
   (ii) Documents to support the information written in the CSDT :

9. Post-market vigilance history :

   (i) Please indicate whether the medical device has any history of previous recalls, reportable adverse incidents, banning in other countries or post market surveillance studies.
   (ii) Please indicate if the application for registration or the registration of the medical device has been rejected or suspended or cancelled in other countries. Also provide reasons for the rejection, suspension or cancellation of the medical device application or registration.

10. Declaration of conformity (DoC):—Please attach the complete, signed and attested DoC. The DoC need to be printed on the manufacturer's letterhead, filled and signed by the responsible person on the template as specified in these rules.

11. This section is applicable only to Class A and Class B medical devices where CSDT is not provided with application.

    (i) List all the relevant essential principles applicable to the medical device and rules used to demonstrate conformity to each applicable essential principle. The evidence of conformity shall be provided in tabular form with supporting documentation as required using the format under these rules.

    (ii) Attach a detailed description of following medical device attributes, as applicable.
       (a) complete description of the medical device;
       (b) principles of operation or mode of action;
       (c) description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the medical device;
       (d) description or complete list of various configurations of the medical device to be registered using the format under these rules
       (e) complete description of the key functional elements, its formulation, its composition and its functionality;
       (f) explanation of novel features, if any;

(g) as appropriate, labelled pictorial representation of the medical device in the form of diagrams, photographs or drawings with sufficient explanation to understand the drawings and diagrams;
(h) intended uses of the medical device;
(i) indications that the medical device will diagnose, treat, prevent, cure or mitigate and includes a description of the target patient population for which the medical device is intended;
(j) instructions for use;
(k) contraindications;
(l) warnings to inform on specific risk or hazard that a user needs to know before using the medical device;
(m) precautions to exercise special care necessary for the safe and effective use of the medical device;
(n) potential adverse effects or side effects;
(o) commercial marketing history which covers the list of countries where the medical device is marketed and the dates of introduction into those countries;
(p) list of regulatory approval or marketing clearance obtained including the registration status, intended use and indications of the medical device in other countries and copies of certificates or approval letters from each country;
(q) specify status of any pending applications in other countries for regulatory approval or marketing clearance;
(r) any other relevant specifications and descriptive information.

(iii) Report or certificate containing information on the objectives, methodology, results, discussion and conclusions of the biocompatibility tests conducted on materials used in the medical device

(iv) Attach the report or certification containing information on the objectives, methodology, results, discussion and conclusions of the pre-clinical physical tests conducted on the medical device,

(v) As applicable, attach documentation on software validation studies to verify the correctness of software in medical device. The document shall include the results of all verification, validation and testing performed prior to final release.

(vi) As applicable, following information to be provided on medical devices containing biological material:

(a) list of all materials of animal, human, microbial or recombinant origin used in the medical device and in the manufacturing process of the medical device, which includes animal or human cells, tissues or derivatives, rendered non-viable cells, tissues or derivatives of microbial or recombinant origin;
(b) detailed information concerning the selection of sources or donors;
(c) detailed information on the harvesting, processing, preservation, testing and handling of tissues, cells and substances;
(d) process validation results to substantiate that manufacturing procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents;
(e) full description of the system for record keeping allowing traceability from sources to the finished medical device.

(vii) As applicable, documentation on clinical evaluation to verify the clinical safety and performance of the medical device.

(viii) Attach documentation on medical device labelling containing the following information:—

(a) sample of labels on the medical device and its packaging;

(d) instructions for installation and maintenance, if applicable;

(e) any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform, if applicable. and

(f) The promotional material and product brochures.

(ix) Provide documentation on risk analysis in the form of a risk management report (RMR).

(x) Provide complete documentation related to the manufacturing and quality control processes.

12. Any other relevant information that may be required by the MDB.

DECLARATION

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to action to be taken by the MDB under the DRAP Act, the Act and the rules made there under.

Name of applicant……..

Designation…….

Signature……..

Stamp…….

Date…….

FORM-7

[see rule 88(4)**]**

F.No……..

DRUGS REGULATORY AUTHORITY OF PAKISTAN

Islamabad, the dated……..

M/s……..

CERTIFICATE OF REGISTRATION OF A MEDICAL DEVICE FOR LOCAL MANUFACTURE

The medical device as per details given below has been registered under the DRAP Act, 2012 and the rules made there-under subject to the conditions appearing hereinafter:

Registration No.	Name of medical device	Brief description	Class	Shelf life
(1)	(2)	(3)	(4)	(5)

Name and complete address of manufacturer:

Names and complete addresses of manufacturing sites:

2. This registration shall be valid for a period of five years from the date mentioned above unless earlier suspended or cancelled.

3. The name shall be changed in case it has resemblance with already registered medical device.

4. This registration is subject to the conditions specified in the DRAP Act, 2012 and the rules made there-under.

Secretary
Medical Device Board
Seal:

FORM-7A
[see rule 88(4)**]**

F.No……..
DRUGS REGULATORY AUTHORITY OF PAKISTAN

Islamabad, the dated……..

M/s……..

CERTIFICATE OF REGISTRATION OF A MEDICAL DEVICE FOR IMPORT

The medical device as per details given below has been registered under the DRAP Act and the rules made there-under subject to the conditions appearing hereinafter:

Registration No.	Name of medical device	Brief description	Class	Shelf life
(1)	(2)	(3)	(4)	(5)

Name and complete address of manufacturer:

Names and complete addresses of manufacturing sites:

2. This registration shall be valid for a period of five years from the date mentioned above unless earlier suspended or cancelled.

3. The name shall be changed in case it has resemblance with already registered medical device.

4. This registration is subject to the conditions specified in the DRAP Act, 2012 and the rules made there-under.

Secretary
Medical Device Board
Seal:

FORM-8
[see rule 94(b)]
INTIMATION REGARDING IMPORT

To
The Medical Device Board,
Drug Regulatory Authority of Pakistan,
Islamabad.

I/We.....of.....have established the letter of credit (LC) or remittance to conduct import of medical device, details of which are as follows:--

(i) Name of the medical device: ----------

(ii) Registration No: ----------

(iii) Name and address of manufacturer: ----------

(iv) Name and address of exporter: ----------

(v) Date of establishing LC or Remittance: ----------

(vi) Quantity to be imported: ----------

(vii) Rate per unit: ----------

(viii) Total C and F value: ----------

(xi) Mode of shipment: ----------

(x) Expected date of arrival: ----------

(xi) Scope of establishment licence: ----------

DECLARATION

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to action to be taken by the MDB under the DRAP Act, the Act and the rules made there under.

Date---------- Signature----------

Name and address of establishment with stamp:

FORM 9
[See rule 96 (1)]
APPLICATION FOR PERMIT TO IMPORT MEDICAL DEVICES' COMPONENT OR RAW MATERIAL

I/We ----------hereby apply for import of medical devices' component or raw material, specified below, manufactured by---------- of----------.

NAMES OF MEDICAL DEVICES' COMPONENTS OR RAW MATERIAL

(i) **……**
(ii) **……**
(iii) **……**

2. I/We----------enclose herewith an undertaking in Form-10 signed by or on behalf of the manufacturer as required under the rules.

3. In view of above, necessary permit to the said medical device's component or raw material may be granted.

DECLARATION

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to action to be taken by the MDB under the DRAP Act, the Act and the rules made there under.

Date ……..

Signature …….

Name and address of establishment with stamp:

FORM 10
[See rule 96 (1)]
FORM OF UNDERTAKING TO ACCOMPANY AN APPLICATION FOR PERMIT TO IMPORT MEDICAL DEVICE'S COMPONENT OR RAW MATERIAL

Whereas M/s----------of----------intends to apply for a permit under the rules, for the import into Pakistan of the medical device's component or raw material specified below manufactured by us.

(i) ……..
(ii) …….
(iii) …….

We----------of----------hereby give this undertaking that—

(1) the said applicant has made a contract with us for import of medical device's component or raw material mentioned in the undertaking;

(2) we declare that we are bonafide licenced manufacturer of the medical device's component or raw material covered under this undertaking at the premises specified below and we shall report change, if any, in the said premises;

(3) we shall comply with the conditions imposed on a permit under the rules;

(4) the medical device's component or raw material mentioned below conform to the provisions of the Drug Regulatory Authority of Pakistan Act, 2012 and rules made there under.

Name of the medical device's component or raw material:
……..

Particulars of the premises where manufacture is carried on:……..

Date---------- Signature ----------

Name and address of establishment with stamp:

FORM 11
[See rule 96 (2)]
APPLICATION FOR PERMIT TO IMPORT MEDICAL DEVICES OR COMPONENTS OR RAW MATERIAL FOR THE PURPOSE OF CLINICAL INVESTIGATION, EXAMINATION, TEST OR ANALYSIS

I/We----------of----------by occupation----------hereby apply for a permit to import the medical devices, components or raw material specified below for the purpose of clinical investigation, examination, test or analysis at----------and I/We undertake to comply with the conditions applicable under the rules.

Name of medical devices or components or raw material:	Quantities:
(i) …….	……..
(ii) …….	
(iii) …….	……..

Manufactured by----------

2. In view of above, necessary permit to the said medical devices or components or raw material may be granted.

DECLARATION

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to action to be taken by the MDB under the DRAP Act, the Act and the rules made there under.

Date---------- Signature----------

Name and address of applicant with stamp:

FORM 12
[see rule 96(3)]
PERMIT TO IMPORT MEDICAL DEVICE'S COMPONENTS OR RAW MATERIAL FOR COMMERCIAL PURPOSE

Permit No: ----------

M/s---------- of----------is/are hereby permitted to import into Pakistan during the period for which this permit is in force the medical device's components or raw material specified below, manufactured by----------of----------.

(i) ……
(ii) ……
(iii) …….

2. This permit is subject to the conditions prescribed in the rules and shall be in force for a period of three years from the date stated below unless it is sooner suspended or cancelled under the rules:

Date---------- Name, signature and stamp of Import Permitting Authority----------

FORM 13
[see rule 96(3)]
PERMIT TO IMPORT MEDICAL DEVICES OR COMPONENTS OR RAW MATERIAL FOR CLINICAL INVESTIGATION, EXAMINATION, TEST OR ANALYSIS

Permit No: ----------

M/s----------of---------- is/are hereby permitted to import into Pakistan from----------the medical devices or components or raw material specified below for the purpose of clinical investigation, examination, test or analysis at----------

Name(s) of medical device or component or raw material with quantities which may be imported:

(i) ……
(ii) ……
(iii) ……

2. This permit is subject to the conditions prescribed in the rules.

3. This permit shall, unless, previously suspended or cancelled, be in force for a period of three years from the date specified below:

Date---------- Name, signature and stamp of Import Permitting Authority----------

FORM 14
[See rule 101(1)(b)]

INTIMATION OF ARRIVAL OF CONSIGNMENTS OF IMPORTED MEDICAL DEVICES OR COMPONENTS OR RAW MATERIAL, OTHER THAN THOSE IMPORTED FOR PERSONAL USE.

(i) Name and address of importer:
(ii) Status (whether commercial importer or industrial consumer) :
(iii) Establishment licence No:
(iv) Import permit No :
(v) Import Policy Order applicable:
(vi) Name and address of exporter and manufacturer:

S.No	Name of medical device / component / raw material	Registration No.	Rate (for C & F/F.O.B.)	Packing	Quantity	Total Value
(1)	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**	**(7)**

DECLARATION

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to action to be taken by the MDB under the DRAP Act, the Act and the rules made there under.

Date…….. **Signature…….**

Name and address of establishment with stamp:

FORM 15
[See rule 104(3)]

APPLICATION FORM FOR EXPORT PERMIT OF MEDICAL DEVICE

I/We ..... hereby apply with the following for permission to export the medical device manufactured by M/s ..... ……..to…….

(a) Name of medical devices:
(i) …….
(ii) ……
(iii) **……**

(b) I undertake that—

(i) I shall comply with all the conditions of the permit;
(ii) I declare that I am carrying on the manufacture of medical device mentioned above at the premises specified below and I shall, from time to time, report any change of premises on which the manufacture will be carried on and, in cases where manufacture is carried on in more than one factory, any change in the distributions between the factories;
(iii) every medical device manufactured by us for export under licence shall conform with the provisions of the DRAP Act and rules made there under.

(c) Particulars of the premises where manufacture is carried on: ----------

2. In view of above, necessary export permit of the said medical devices may be granted.

DECLARATION

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to action to be taken by the MDB under the DRAP Act, the Act and the rules made there under.

Establishment licence No. and address. : ----------

Director or authorized person name and signature: ----------

Date: ----------

FORM 16
[See rule 105(1)]

EXPORT PERMIT FOR MEDICAL DEVICE

Permit No.....

M/s.....of.....is hereby permitted to export the medical device specified below during the period for which this permit is in force manufactured by.....: —

(i) ……..
(ii) …….
(iii) …….

2. This permit is subject to the conditions prescribed in the rules and shall be in force for a period of three years from the date stated below unless earlier suspended or cancelled under the rules.

Dated..... Name, signature and stamp of Export Permitting Authority

FORM 17
[see rule 106 (1)]
APPLICATION FOR EXPORT OF SMALL QUANTITIES OF MEDICAL DEVICES FOR THE PURPOSE OF CLINICAL INVESTIGATIONS, EXAMINATION, TEST OR ANALYSIS

l/We ..... of ..... hereby apply for permission to export the medical devices specified below manufactured by M/s ..... to……..for the purpose of clinical investigations or examination or test or analysis: —

Name (s) and quantities of medical devices:

(i) ……..
(ii) ……..
(iii) ……..

2. In view of above, necessary export permit of the said medical devices may be granted.

DECLARATION

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to action to be taken by the MDB under the DRAP Act, the Act and the rules made there under.

Date..... Signature----------

Name with stamp and address of applicant:

FORM 18
[see rule 106(3)]
EXPORT PERMIT FOR SMALL QUANTITIES OF MEDICAL DEVICES FOR THE PURPOSE OF CLINICAL INVESTIGATIONS, EXAMINATION, TEST OR ANALYSIS

Permit No.....

M/s.....of.....is hereby permitted to export, during the period for which this permit is in force, the medical devices specified below and manufactured by.....

Name (s) of medical devices with quantity:

(i) ……..
(ii) ……..
(iii) ……..

2. This permit is subject to the conditions prescribed in the rules and shall be in force for a period of three years from the date stated below unless earlier suspended or cancelled under the rules.

Dated..... Name, signature and stamp of Export Permitting Authority

FORM-19
(see rule 137)

MEDICAL DEVICE REGISTER

S.No	Name of Licensed Establishment or registered conformity assessment body or medical device	License No or Registration No	Particulars	Validity	Decision of MDB
(1)	(2)	(3)	(4)	(5)	(6)

FORM-20
[See rule 140 (1)]
APPLICATION FOR APPROVAL OF ADVERTISMENT OF A MEDICAL DEVICE

I.....of M/s……. hereby apply for permission to advertise the following medical device through …… (specify name of media)

(a) Name of medical device:
(b) Registration number:
(c) Class of medical device:
(d) Name and complete address of manufacturer:
(e) intended uses of the medical device:
(f) indications that the medical device will diagnose, treat, prevent, cure or mitigate:
(g) instructions for use:
(h) contraindications:
(i) warnings to inform on specific risk or hazard that a user needs to know before using the medical device:
(j) precautions to exercise special care necessary for the safe and effective use of the medical device:
(k) potential adverse effects or side effects:

2. The required fee, information and documents have been attached and therefore requested to grant permission.

DECLARATION

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to action to be taken by the MDB under the DRAP Act, the Act and the rules made there under.

Date.....

Signature----------

Name, address and stamp of applicant:

FORM-21
[see rule 140(3)**]**

F.No……..
DRUGS REGULATORY AUTHORITY OF PAKISTAN

Islamabad, the dated……..

M/s……..

PERMISSION TO ADVERTISE A MEDICAL DEVICE

You are hereby permitted to advertise following medical device through ……

(a) Name of medical device:
(b) Manufactured by:

2. This permission shall be subject to the conditions specified in the DRAP Act, 2012 and Medical Devices Rules, 2015.

3. This permission shall be valid for a period of two years from the date of issue unless earlier suspended or cancelled.

Secretary
Medical Device Board
Seal:

DR. NOOR MUHAMMAD SHAH
Director, Medical Devices and Medicated Cosmetics Division
Drug Regulatory Authority of Pakistan
