DRUG REGULATORY AUTHORITY
OF PAKISTAN

Medical Devices Rules, 2017

GOVERNMENT OF PAKISTAN
MINISTRY OF NATIONAL HEALTH SERVICES, REGULATION AND COORDINATION
DRUG REGULATORY AUTHORITY OF PAKISTAN
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Islamabad, the 16th January, 2018.

NOTIFICATION

S.R.O.32(I)/2018.—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 the approval of the Federal Government, is pleased to make the following rules, namely:-

CHAPTERI
PRELIMINARY

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

(2) They shall come into force at once, unless specifically provided otherwise.

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, regulation in Asian and other regions;

(vii) "auditor" means an inspector or panel of inspectors nominated by the MDB or the Authority who shall perform functions and exercise powers under Schedule V of the DRAP Act in relation to 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) "clinical evaluation" means review of relevant scientific literature or the review and assessment of data collected through clinical investigation;

(xii) "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;

(xiii) "combinations products" mean and include-

(a) a product comprised of two or more regulated components, i.e., drug and device, biologic and device, drug and biologic, or drug and device and biologic, that are physically, chemically or otherwise combined or mixed and produced as a single entity; and

(b) two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;

(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) "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;

(xvi) "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;

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

(xviii) "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;

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

(xx) "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;

(xxi) "enlistment" means listing a medical device product in the medical device register by allocating thereto a proper number for the purpose of manufacturing and marketing authorization;

(xxii) "enlistment application" means an application in the prescribed form as specified in the forms annexed to these rules, accompanied with required information, attachments, data, evidence to support the claims made in the application and proper fee submitted under these rules by the manufacturer or importer or another eligible person to the Division of Medical Devices and Medicated Cosmetics;

(xxiii) "enlistment certificate" means a certificate on the format prescribed in Forms to the applicant containing an identification number allocated to product formulation in the medical device register which authorizes its

holders for manufacturing and marketing authorization subject to compliance to these rules and conditions for enlistment;

(xxiv) "enlistment certificate holder" means proprietor or owner of the company or firm to whom enlistment certificate of the product has been granted;

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

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

(xxvii) "establishment licence" means licence granted to any person under these rules for manufacturing, import, export, storage, distribution or sale of medical devices;

(xxviii) "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;

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

(xxx) "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;

(xxxi) "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;

(xxxii) " GDPMD" means Good Distribution Practices for medical devices;

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

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

(xxxv) "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;

(xxxvi) "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;

(xxxvii) "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 or animal 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;

(xxxviii) "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, namely

(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;

(xxxix) "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;

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

(xli) "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;

(xlii) "in-vitro diagnostic (IVD) medical device" 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 or animal 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;

(xliii) "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;

(xliv) "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 or animal life;

(xlv) "manufacturer" means any establishment which designs, manufactures, fabricates, make components, 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, [1][refurbishment], relabelling, remanufacturing, repacking or specification development and initial distributors of foreign entities performing these functions;

[1] Inserted vide S.R.O 559(I)/2022 dated 27.04.2022

(xlvi) "Medical Device Board" or "MDB" means a body responsible for enlistment or registration of medical devices, licensing of establishments and issuance of permits for export and import of medical devices and for the matters ancillary thereto;

(xlvii) "market authorization holder" means any person having marketing authorization, enlistment or registration in respect of medical device from the regulatory authority of the country of its origin;

(xlviii) "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;

(xlix) "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;

(l) "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;

(li) "NANDO" means New Approach Notified and Designated Organization information system of European Union for carrying out conformity assessment and regulation of conformity assessment bodies of medical devices;

(lii) "National Registry for Cardiac Stents" means an Information Technology (IT) based national registry for cardiac stent established by the Authority for monitoring, evaluation and data collection in respect of manufacturing, import, sale and utilization of cardiac stents;

(liii) "notified body" means a conformity assessment body;

(liv) "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;

(lv) "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;

(lvi) "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;

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

(lviii) "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;

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

[2][(lix-a) "refurbished medical device" means a medical device the whole or any part of which has been substantially rebuilt, reequipped or restored, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device that can be used for the purpose originally intended by the product owner of the original medical device, and without prejudice to the generality of the foregoing, a refurbishment of a medical device may involve any or all of the following actions, namely:—

(a) stripping a medical device into component parts or sub-assemblies;
(b) checking parts of the medical device for suitability for reuse;
(c) replacing component part or sub-assemblies of the medical device that are not suitable for reuse;
(d) assembly reclaim or replacement component parts of the medical device or another medical device;
(e) testing the assembled medical device against the specifications of the original medical device or, if the product owner of the original medical device has revised those specifications, the revised specifications; or
(f) identifying the reassembled medical device as a refurbished medical device.;

(lix-b) "refurbishment" means a systematic process that ensures safety and effectiveness of the medical device without significantly changing the device's performance, safety specifications or changing the purpose originally intended by the product owner of the original medical device;]

(lx) "registration certificate holder" in relation to a registered medical device, means a person or an organization who obtained registration certificate of a medical device;

(lxi) "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;

[2] Inserted vide S.R.O 559(I)/2022 dated 27.04.2022

(lxii) “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;

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

(lxiv) “Schedule” means a schedule to these rules;

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

(lxvi) “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;

(lxvii) "specifications" mean the specifications approved for the purpose of registration under these rules;

(lxviii) “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;

(lxix) "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) 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 be a medical device but is not truly that medical device or it does not contain the drug claimed for that medical device;

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

(lxxi) “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

(lxxii) “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 assigned to them in the DRAP Act and the Act.

CHAPTER II

ESTABLISHMENT LICENCE

3. 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 or imported on more than one premises, a separate licence shall be issued in respect of each such premises:

Provided that the said premises for which a licence is granted shall include the declared distribution godowns for stocking and storage purposes for medical devices located in Federal and Provincial capitals only.

4. 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-1 or Form-2, 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 63; and
(b) such documents or information as specified in Form-1 or Form-2, as the case may be.

(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 (3) and shall inform the applicant of its decision in writing with reasons of such decision.

5. Procedure for grant of establishment licence,—(1)Upon receipt of the application on Form-1 or Form-2 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.

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

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

(a) The applicant shall be in possession of such 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) [3][the manufacturing shall be conducted under the active supervision of competent technical staff, who shall be in-charge of production, a whole-time employee of the manufacturer and having relevant qualification and experience as deemed appropriate by the MDB;]

(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) [4][the incharge of quality control shall be a whole-time employee of the manufacturer and shall possess relevant qualification and experience as deemed appropriate by the MDB;]

(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 licensed 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;

[3] Substituted vide S.R.O 1500(I)/2021 dated 22nd November, 2021.
[4] Substituted vide S.R.O 1500(I)/2021 dated 22nd November, 2021.

(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; and

(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.

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

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

(b) the circumstances in which a licence was issued 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 subjected to and inform such licensee accordingly.

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

(a) the applicant shall be in possession of 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.

(d) the applicant shall comply with good distribution practices for medical devices (GDPMD); and

(e) the import, storage, distribution and sale shall be conducted under the active directions and personal supervision of at least one competent technical staff who shall be a whole-time employee and has from a university or institution recognized by Higher Education Commission -

(i) a degree in pharmacy, biomedical engineering, veterinary sciences, microbiology, biotechnology, biochemistry, medical physics, biophysics; or
(ii) B.Sc. (Hons) degree in medical laboratory technology; or
(iii) a degree in computer science or software technology along with basic background of pharmacy.

(5)Where a licence is granted to an establishment to import and sell 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 including appropriate handling and storage at all levels of its supply chain upto end user;

(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;

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

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

(b) the circumstances in which a licence was issued 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 subjected to and inform such licensee accordingly.

7. 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-1 or Form-2, as the case may be, and shall be accompanied by the following, namely:—

(a) application fee as specified in rule 63; and

(b) documents or information specified in Form-1 or Form-2, as the case may be.

(2) The MDB may reject an application if the establishment fails to deposit specified fee or 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.

(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, the applicant shall deposit an additional fee equivalent to applicable renewal fee for each month till one year of the expiry of the establishment licence and after one year the establishment licence shall cease to exist and the application shall be treated as a fresh application for grant of establishment licence.

(6) If an application for renewal is made before the expiry of the period of validity of licence or after expiry of the period of validity along-with depositing additional fee, the existing licence shall continue to be valid until orders are passed on such application.

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

(8) 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.

(9) Where the MDB decides to renew an existing establishment licence, the renewal of licence shall be granted on the format as set out in Form-3 or Form-4 for manufacturer or importer, as the case may be.

8. 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; or

(b) 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 inForm-1 or Form-2, as the case may be; and

(b) accompanied by the relevant application fee specified in rule 63.

(4) Upon receipt of the application under sub-rule (3), the MDB shall consider the proposed change and may inspect the establishment through a panel of experts or through Federal Inspector of Drug (FID) or any inspector or officer authorized by MDB 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.

9. 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.

10. 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 under sub-rule (1) 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 III
CLASSIFICATION AND GROUPING OF MEDICAL DEVICES

11. Classification and grouping of medical devices. — (1) For the purpose of registration and enlistment, the method of classification and grouping of medical devices shall be in accordance with Schedule A and B respectively, which the MDB as per GHTF or IMDRF guidelines may amend from time to time.

(2) In case of any dispute or uncertainty or combination product over classification of a medical device, the establishment may request in writing to the MDB to decide on the dispute and the MDB shall inform in writing of its decision.

CHAPTER IV
ENLISTMENT AND REGISTRATION OF MEDICAL DEVICES

12. Enlistment and registration of medical devices. — (1) The MDB shall enlist and 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; or
(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.

13. Classes of medical devices for enlistment and registration,—(1) The MDB shall issue following types of medical devices enlistment and registration, namely:**—**

(a) enlistment of Class A medical devices; and
(b) registration for Class B, C and D medical devices.

14. Procedure for enlistment and registration of medical devices,—(1) An application for enlistment or registration of 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 authorized representative in Pakistan having valid establishment licence.

(2) An application for enlistment or registration of medical devices under sub-rule (1) for local manufacture or import shall be made to the MDB on the format as set out in following forms, namely:-

(a) application as set out in Form-6 or Form-6A for enlistment of Class-A medical devices for local manufacturer or importer, as the case may be; and
(b) application as set out in Form-7 or Form-7A for registration of Class B,C or D medical devices for local manufacturer or importer, as the case may be.

(3) An application under sub-rule (1) to enlist or register medical devices shall be accompanied by the following, namely:—
(a) application fee as specified in rule 63 ; and
(b) information or documents or samples, where practicable, specified in Form-6 or Form-6A, Form-7 or Form-7A, 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 of medical devices shall conform to the principles of validation.

(6) Complete labelling and prescribing information of medical devices, where applicable, shall be same as approved in the country of origin or as approved in European Union, USA, Japan, Canada or Australia. Application for registration may be supported by relevant rules and certification from the manufacturer accordingly.

15. Procedure for grant of certificate for enlistment or registration of medical device,—(1) Upon receipt of the application on prescribed form under these rules, application fee and information, particulars, documents and samples, where practicable, of the medical device under these rules, 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, manufacturing capability, GDPMD and other requirements under these rules. For this purpose, the MDB may constitute a panel of experts which may include inspectors or auditors. However, such inspection shall be exempt for the countries as specified under sub-rule (2).

(2) MDB may grant certificate of enlistment or registration of medical devices if authorized by the stringent regulatory authorities as specified by the MDB for life-saving medical devices and registration by the MDB shall be based on registration of the medical devices registered by the regulatory authorities 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 or CE marked by conformity assessment bodies (CABs) notified in NANDO database under the relevant European directive for medical devices subject to evidence and supporting documents.

(3) If the MDB is satisfied with all requirements pertaining to the application for medical device's enlistment or registration, it shall enlist and register the medical device and enter it in the medical device register.

(4) The enlistment or registration of the medical device under sub-rule (3) shall be for a period of five years from the date of enlistment or registration, as the case may be, unless it is cancelled or suspended by the MDB before its expiry.

(5) The MDB shall assign an enlistment and registration number and issue a certificate of enlistment and registration on the format as set out in Form-8 or Form-8A for the medical device for local manufacture or import, as the case may be.

(6) In case the application for enlistment or registration under these rules is rejected by the MDB, it shall inform the applicant of its decision in writing with reasons of such decision.

16. Renewal of certificate for enlistment and registration of medical device,—(1) An application for renewal of a medical device's enlistment and registration for local manufacture or import shall be made on the format as set out in Form-6 or Form-6A, Form-7 or Form-7A, 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 63;

(b) information or documents or samples, where practicable, specified in Form-6 or Form-6A, Form-7 or Form-7A, as the case may be.

(2) The MDB may reject an application if the enlistment or 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 enlistment or 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). For this purpose, the MDB may constitute a panel of experts which may include inspectors or auditors.

(4) If the MDB is satisfied that all the requirements pertaining to the application for renewal of medical device's enlistment or registration have been fulfilled, it shall renew the enlistment or 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 enlistment or 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 enlistment or registration but within one year after expiry of the period of validity, the applicant shall pay an additional fee equivalent to applicable renewal fee for each month till one year and after one year, the enlistment or registration, as the case may be, shall cease to exist and the application shall be treated as a fresh application for grant of enlistment or registration.

(6) If an application for renewal is made before the expiry of the period of validity of enlistment or registration or within one year of the period of validity along with depositing additional fee, the enlistment or registration shall continue to be valid until orders are passed on such application.

(7) If an application for renewal is made after one year 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.

(8) In case the application for renewal of enlistment or registration of a medical device is rejected by the MDB, it shall, after providing to applicant an opportunity of being heard, inform the applicant of its decision in writing with reasons of such decision.

(9) Where the MDB decides to renew an existing enlistment or registration certificate, the renewal of certificate shall be granted on the format as set out in Form-8 or Form-8A for enlistment or registration, as the case may be.

17. Changes concerning enlisted or registered medical device,—(1) The enlistment or registration certificate holder shall apply to the MDB for prior approval, if any change is proposed regarding the particulars provided in relation to the enlistment or 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 particulars of certificate for enlistment or registration of medical device for local manufacture or import shall be —

(a) made on the format as set out in Form-6 or Form-6A or Form-7 or Form-7A, as the case may be; and

(b) accompanied by the relevant application fee specified in rule 63.

(3) Upon receipt of the application for change relating to an enlisted or 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 enlistment or registration holder under sub-rule (2) and the enlistment or 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 enlistment or registration holder contravenes sub-rule (1) or sub-rule (3), its enlistment or registration may be cancelled or suspended as the MDB may deem fit after giving to the enlistment or registration holder the opportunity of being heard.

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

(a) the approval of change in any particular of enlistment or registration of the medical device was obtained by fraud or misrepresentation; or
(b) the circumstances in which the change in any particular of enlistment or 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 enlistment or registration holder an opportunity of showing cause against the action proposed to be taken, cancel or suspend the enlistment or registration or specify any further conditions to which the enlistment or registration shall be subject and inform the establishment accordingly.

18. Certificate of enlistment or registration of medical device,—(1) A certificate of enlistment or 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 an enlistment or registration holder assigns or transfers his enlistment or registration of the medical device to any other person or classes of persons without the prior written approval of the MDB, the MDB may cancel or suspend the enlistment or registration of medical device as it may deem fit, after giving to the enlistment or registration holder the opportunity of being heard.

(3) A certificate of enlistment or registration issued for a medical device shall without demand be surrendered to the MDB within fourteen days after the enlistment or registration of the medical device is cancelled by the MDB under sub-rule (2).

19. Conditions of enlistment or registration of medical device,—(1) An enlistment or registration holder shall comply with all conditions for the grant of certificate of enlistment or registration of medical device provided for in these rules.

(2) The import, manufacture and sale of medical devices shall be in accordance with the provisions of these rules.

(3) Each medical device shall be made available in sufficient quantity so as to ensure its regular and adequate supply in the market.

(4) The labelling information including licence number, registration number, maximum retail price (MRP) etc, as have been approved for the purpose of enlistment or registration of a medical device shall be clearly specified in the labelling.

(5) The manufacture or import of any medical device shall not, without prior approval of the MDB, be discontinued for such period which may result in its shortage:

Provided that in circumstances beyond control of a manufacturer or importer of a medical device, which may lead to reduction in production or import of that medical device, the circumstances may be intimated to the MDB. In case of failure to comply, the enlistment or registration holder, as the case may be, shall be held responsible for creating willful shortage leading to its black marketing and the enlistment or registration may be suspended or cancelled as the MDB may deem fit, after giving to the enlistment or 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 enlistment or 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 there from 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 in 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 in 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 enlistment or 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 inform the MDB within thirty days of such an information having come to his knowledge and shall take appropriate action within the shortest possible time.

(11) If a clinical information for a medical device is approved by a regulatory authority in any of the countries specified under rule 67, the same clinical information shall be considered as approved for medical device's enlistment or 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 enlistment or registration, is reported in any of the countries specified under rule 67, 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 an enlistment or registration holder contravenes these rules, he shall, after being heard by the MDB, be liable for suspension or cancellation of his enlistment or registration of medical device without prejudice to any punishment under the any other law for the time being in force.

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

(a) the enlistment or registration of a medical device was procured by fraud or

misrepresentation; or

(b) the circumstances in which a medical device was enlisted or registered no longer exist; or

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

the MDB may, after affording to the enlistment or registration holder, as the case may be, an opportunity of showing cause against the action proposed to be taken, cancel or suspend the enlistment or registration or specify any further conditions to which the enlistment or registration shall be subject and inform the establishment accordingly.

20. Cancellation or suspension of enlistment or registration of medical device,—(1) Before suspension or cancellation of enlistment or registration of a medical device, the MDB shall issue a show cause notice to the establishment for suspension or cancellation of enlistment or registration due to non-compliance of any of the conditions of enlistment or 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 under sub-rule (1).

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

(4) The MDB shall inform the establishment, in writing, on the cancellation or suspension of the enlistment or registration of a medical device under sub-rule (3).

(5) Where an enlistment or 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 without demand the certificate of enlistment or registration to the MDB.

CHAPTER V
IMPORT AND EXPORT

21. Import of medical devices,—A medical device may be imported subject to the condition that the importer shall possess valid medical device establishment licence and medical device enlistment or registration and have premises under his possession for proper storage to preserve its properties.

22. Import of small quantities of medical devices, components or raw materials for clinical investigation or sample for evaluation, etc. — (1) An application on the format as set out in Form-9 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 Director, Medical Devices and Medicated Cosmetics of the Authority alongwith a fee as specified in rule 63.

(2) Permit 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-10.

23. Conditions of a permit to import small quantities of medical devices, components or raw materials for clinical investigation or sample for evaluation, etc. — [5][(1)] A permit to import small quantities of medical devices, components or raw materials thereof including those, the import of which is otherwise without enlistment or registration, 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

[5] Inserted vide S.R.O 559 (I)/2022 dated 27.04.2022

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.

[6][(2) If the MDB, on the basis of information received or on an inquiry conducted by it, is of the 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 exists; or
(c) it is necessary in the public interest to do so;

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 to and inform accordingly.]

24. Import of medical devices for personal and hospital's patient's use. — Small quantities of medical devices, including those the import of which is otherwise without enlistment or registration prohibited under the DRAP Act and the rules made thereunder, may be imported for personal and hospital's patient's 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) 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;

(d) any medical device, the import of which is otherwise prohibited on account of non-enlistment or non-registration, may be imported for patients in hospital (public or private) subject to prior approval of MDB or any officer authorized by it in this behalf as per following conditions, namely:-

    (i) the medical device shall not be sold or distributed in the market;
    (ii) the medical device shall be on free sale in the country of origin;
    (iii) the medical device shall be used in the hospital or institution only and not for the purpose of clinical trial, examination, test or analysis;
    (iv) clearance certificate must be obtained from assistant director, or officer authorized, of the Authority, at the time of arrival of shipment, before customs clearance. Consumption or utilization record must be maintained by the importer, under the supervision of qualified technical staff as specified in these rules; and
    (v) the medical device is not enlisted or registered or available in Pakistan.

[7][**24A. Import of medical devices for donation.—**Medical devices, including those the import of which is otherwise prohibited without enlistment or registration under the Drug Regulatory

[6] Inserted vide S.R.O 559(I)/2022 dated 27.04.2022
[7] Inserted vide S.R.O 559(I)/2022 dated 27.04.2022

Authority of Pakistan Act, 2012 and these rules, may be imported for the purpose of donation, except products included in Schedule D and classes C and D, subject to the following conditions, namely:—

(a) the medical device shall not be sold or distributed in the market;
(b) documentary evidence or confirmation from website for free sale in the country of origin provided that in case of non-availability of such evidence, the importer shall be responsible for safety and performance of medical devices.
(c) the medical device shall not be used for the purpose of clinical trial, examination, test or analysis;
(d) clearance certificate must be obtained from the Assistant Director of the relevant field office or officer authorized of the Authority at the time of arrival of shipment. Consumption of utilization record must be obtained by the importer under the supervision of qualified technical staff as specified in these rules; and
(e) the medical device, where applicable, shall be preferably has six months of expiry or fifty percent of shelf life, whichever is less:

Provided that medical devices included in Schedule D and classes C and D may be imported for donation with the approval of the MDB or an officer authorized by it in this behalf.]

25. [8]**[.....]**

26. 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 by DRAP in this behalf.

(2) If the Collector of Customs or an officer authorized by DRAP in this behalf has reason to suspect that any medical device, raw material and component does not comply with the provisions of the DRAP Act or these rules, he may refer the matter to Director Medical Devices and Medicated Cosmetics, DRAP for appropriate action:

Provided that if the importer gives a written undertaking, endorsed by MDB or an officer authorized by DRAP in this behalf, not to dispose of the medical device or the component or the raw material without the consent of the MDB and to return the consignment or such portion thereof to the Collector of Customs as may be required by the MDB, the Collector of Customs may hand 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.

[9][**27. No objection certificate for export**.— No objection certificate for export shall be issued to;

(i) the registered medical devices manufactured by the licensed manufacturers under the rule; or
(ii) the medical devices applied for registration by the licensed manufacturer under the rules.]

28. [10][....]

29. 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 without enlistment or registration prohibited

[8] Omitted vide S.R.O 559(I)/2022 dated 27.04.2022
[9] Substituted vide S.R.O 559(I)/2022 dated 27.04.2022
[10] Omitted vide S.R.O 559(I)/2022 dated 27.04.2022

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 or an officer authorized in this behalf on the format as set out in Form-14 alongwith fee as specified in rule 63.

(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 liable for action under the DRAP Act and these rules without prejudice to any other action that may be taken under any other law for the time being in force.

(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-15.

30. Duration of permit to export medical devices,—A permit to export medical devices issued under these rules, unless earlier suspended or cancelled, shall be valid for three years:

Provided that if application for renewal of the permit is made three months before the expiry of the existing permit issued under these rules, the current permit shall continue to be valid until orders are passed on such application.

31. 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 MDB from every batch or lot, as the MDB 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 MDB 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 MDB;

(c) the permit holder shall, on being informed by the MDB 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; and

(d) the permit holder shall, in respect of each batch or lot of medical devices, maintain a record of all exports made by him.

(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.

32. 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 by MDB 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 by MDB in this behalf.

33. Procedure at customs port,—(1) If the Collector of Customs or an officer authorized by customs authorities in this behalf or if requested by an officer authorized for this purpose by the MDB has reason to suspect that any medical device does not comply with the provisions of the DRAP Act or these rules, the said officer authorized by the MDB may take samples with the approval of MDB, 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 duly endorsed by MDB or an officer authorized by the MDB in this behalf 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 hand 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's reports provided to the Collector of Customs show that the samples of any medical device in a consignment which does 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 devices 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's reports provided to the Collector of Customs show 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.

34. Export of medical devices for personal use,—Small quantities of medical devices, including those the export of which is otherwise prohibited without enlistment or registration 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; and

(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.

[11][34A. **Export of medical devices for donation.—** Medical devices, manufactured by licensed manufacturers, including those the export of which is otherwise prohibited without enlistment or registration under the Drug Regulatory Authority of Pakistan Act, 2012 and these rules, may be exported for the purpose of donation subject to issuance of NOC by the Assistant Director of relevant field office as per procedure and conditions determined by the MDB.]

35. 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.

36. Suspension or cancellation of export-permit ,—If the export-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 and 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.

37. No right to claim title on fraudulent enlistment, registration, licence, permit, etc,—Where a certificate of enlistment or registration, establishment-licence, permit, etc, as the case may be, is issued fraudulently without any application or decision of the MDB under these rules, such certificate, licence or permit, as the case may be, shall not be deemed to have been granted under these rules and the certificate-holder and the persons who connived in such act of fraud, shall be liable to punishment as specified in the DRAP Act and the rules made thereunder without prejudice to any other penal action that may be taken under any other law for the time being in force.

CHAPTER VI
LABELLING OF MEDICAL DEVICES

38. General provisions of labelling of medical devices,— (1) No person shall—

(a) place any medical device in the market unless it has been appropriately labeled including information of establishment-licence's details, enlistment or registration number, MRP; 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) Where a medical device has either not been appropriately labeled, or partially labeled as mentioned in sub-rule (1), the importer on his request in this behalf may be allowed by MDB to comply with these rules relating to labelling by printing the information of establishment-licence's details, enlistment or registration number, MRP or any other information which may be required by MDB at establishment's licensed premises.

[11] Inserted vide S.R.O 559(I)/2022 dated 27.04.2022

(3) The importer may, in special cases where the strict application of the labelling requirements is impracticable or may adversely impact the quality and safety of the medical device, obtain exemption from MDB from the labelling requirements as provided in these rules.

(4) The label of a medical device shall be legible, permanent and prominent.

39. 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 it be 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.

40. Format of labelling of medical devices,—(1) The format of labelling shall be in accordance with the international standards for medical device's 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.

41. 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.

42. 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, enlistment or registration number, date of manufacturing, date of expiry and maximum retail price (MRP) 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.

43. Specific contents of labelling of medical devices,—Where a medical device requires specific contents of labelling, the following specific contents shall be required in the labelling in addition to general contents under rule 42, 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 re-usable medical device, information and instruction for cleaning, disinfecting, packaging and, where appropriate, the method of re-sterilization and any restriction on the number of re-use;

(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 it as required it 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.

44. 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 drug 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.

45. 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 VII
RESPONSIBILITIES AND OBLIGATIONS

46. General responsibilities and obligations of licensees and enlistment or registration holders,—(1)Licensees and enlistment or registration holders shall conduct their

operation in accordance with the provisions of these rules and shall comply with all the conditions of the licence and enlistment or registration issued by the MDB and on being required by the MDB or its authorized officer, the licensee and enlistment or registration holder shall—

(a) produce his licence, certificate of enlistment or registration or permit, as the case may be, to the MDB or the authorized officer for inspection; and

(b) produce 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 enlistment 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 enlistment or registration holder shall be signed by the proprietor or chief executive officer or managing director or 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 letter of his authorization from the said persons.

47. Responsibilities 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, enlistment or 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 [12][representatives] in Pakistan on its behalf relating to any matter as specified in sub-rule (1).

(3) A manufacturer or [13][its 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 enlistment or registration, be guilty of an offence and shall on conviction be punished as specified in the DRAP Act.

48. Responsibilities and obligations of importer or authorized representative,—(1) An importer being [14][...] authorized representative shall—

(a) obtain an appropriate authorization from manufacturer or the authorized representative, as the case may be;

(b) import and distribute in the market only enlisted or 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;

[12] Substituted vide S.R.O 559(I)/2022 dated 27.04.2022
[13] Substituted vide S.R.O 559(I)/2022 dated 27.04.2022
[14] Omitted vide S.R.O 559(I)/2022 dated 27.04.2022

(e) ensure the compliance of the conditions of licence, enlistment or 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 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 enlistment or registration, as the case may be, be guilty of an offence and shall on conviction be punished as specified in the DRAP Act.

49. 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 to the MDB or an authorized officer any record which is false or misleading, his licence or enlistment 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.

50. 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.

51. Analysis by quality control laboratories,—(1) The Authority shall, by notification in the official Gazette, establish one or more laboratories for testing the quality, safety and performance of the medical devices:

[15][Provided that till establishment of a laboratory of the Authority, the Authority may, for the purpose of test and analysis, notify any other laboratory of repute and specify scope thereof.]

(2) An Inspector may, where he thinks so to do, send a sample of a medical device to a quality control laboratory specified under sub-rule (1) for the purpose of test, analysis and report of the sample of a medical device. The Inspector shall ensure maintenance of integrity of samples thus obtained and sent for test, analysis and report.

[15] Substituted vide S.R.O 559(I)/2022 dated 27.04.2022

(3) The Authority, by notification in the official Gazette, shall specify the detailed procedure for sampling and analysis of medical devices.

CHAPTER VIII
EXEMPTIONS, PROHIBITIONS AND SAMPLING

52. Exemption from operation of the rules,—[16][(1) The medical devices specified in column (2) of the Table below shall, in terms of section 36 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) and from commencement of these rules, be exempted from the operation of these rules for a period as specified in column (3) thereof, namely: —

TABLE

S.No.	Class of medical device	Exemption period
(1)	(2)	(3)
1.	Class D medical devices	Till the 31st day of March, 2022
2.	Class C medical devices	Till the 30th day of June, 2022
3.	Class B medical devices	Till the 30th day of September, 2022
4.	Class A medical devices	Till the 31st day of December, 2022

Provided that the exemptions shall be applicable only to the establishment license holders either as importer or local manufacturer under these rules:

Provided further that the imported consignments of the devices and raw materials of above mentioned licensed importers and manufacturers may be released by Pakistan Custom till the validity of exemption period after ensuring the submission of following documents, namely:-

(i) For clearance of class A medical device from Pakistan Customs, it is mandatory for importer to submit notarized ISO 13485 and notarized letter of authorization from manufacturer abroad along with any of the following documents, namely;-

a. Notarized free sale certificate from country of origin; or

b. Notarized declaration of conformity from manufacturer abroad; or

c. Notarized production or full quality assurance certificate (CE-marking certificate) from conformity assessment body CAB);

(ii) For clearance of class B, C or D medical device from Pakistan Customs, it is mandatory for importer to submit notarized ISO 13485 and notarized letter of authorization from manufacturer abroad along with any of the following documents, namely:-

a. Notarized free sale certificate from country of origin along with declaration of conformity, full quality assurance certificate (CE-marking certificate) from CAB. However, for class D medical

[16] Substituted vide S.R.O 526(I)/2021 dated 30.04. 2021

device, design examination certificate shall be mandatory; or

b. Notarized free sale certificate from any of the reference countries i.e., USA, Japan, Australia, Canada, Austria, Belgium, Denmark, France, Germany, Ireland, Italy, Netherlands, Norway, Spain, Sweden, Switzerland, United Kingdom; or
c. Notarized free sale certificate from country of origin along with WHO prequalification status; and

(iii) For clearance of raw materials for local manufacturing of medical device from Pakistan Customs, a valid establishment license to manufacture medical devices locally issued under these rules.

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(2) The exemptions in sub-rule (1) shall not be applicable to the life-saving or life-sustaining medical devices specified in Schedule-D and Schedule-E.]

53. 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 non-enlisted or unregistered medical device shall not apply in the case where the non-enlisted or unregistered medical device is a custom-made medical device.

(4) Any person who contravenes sub-rules (1) or (2) shall be guilty of an offence punishable under the DRAP Act.

54. 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 enlisted or registered medical devices be sent for appropriate 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 IX
USAGE, OPERATION, MAINTENANCE, ETC.

55. 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 enlisted or 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 upto 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.

56. 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 implanted device was placed into the body of that person and name and signature of the operator or surgeon of the procedure, as the case may be;

(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, without prejudice to any action that may be taken under any other law for the time being in force.

(3) The establishment licence-holder shall compulsorily provide his manufacturing or import and sale data on the IT based National Registry for Cardiac Stent, provided at the DRAP website. Similarly, Cath laboratories registered by the Federal or Provincial healthcare commission shall enter the data for utilization of cardiac stents implanted to patients in the National Registry for Cardiac Stents.

57. 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.

58. 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) a person installing, testing, commissioning, maintaining or calibrating a medical device shall be trained by the manufacturer or authorized representative or a competent trainer, as the case may be, 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 X
MEDICAL DEVICE BOARD (MDB)

59. Medical Device Board,—(1)There shall be a Medical Device Board (MDB), responsible for enlistment or registration of 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	Chairman
(b)	Additional Director, Medical Devices and Medicated Cosmetics, Drug Regulatory Authority of Pakistan	Member-cum-Secretary
(c)	Director General Health or his nominee not below BS-19, of each province;	Member
(d)	one urologist or nephrologists having relevant experience of not less than five years, to be nominated by the Authority;	Member
(e)	two pharmacists having relevant experience of not less than five years in manufacturing or quality control of therapeutic goods preferably in medical devices to be nominated by the Authority;	Member
(f)	one biomedical engineer having relevant experience of not less than five years, to be nominated by the Authority;	Member
(g)	one radiologist having relevant experience of not less than five years, to be nominated by the Authority;	Member
(h)	one software or electromechanical engineer having relevant experience of not less than five years, to be nominated by the Authority;	Member
(i)	one general or orthopedic surgeon having relevant experience of not less than five years, to be nominated by the Authority;	Member
(j)	one cardiovascular surgeon or interventional cardiologist having relevant experience of not less than	Member

	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;	Member
(l)	one pathologist or medical technologist having relevant experience of not less than five years, to be nominated by the Authority;	Member

(3) The MDB may co-opt any other person who is expert of any specialty for the disposal of relevant cases.

(4) The MDB may include one representative each from association of manufacturers and importers (Healthcare Devices Association of Pakistan or Pakistan Chemists and Druggists Association or Pharma Bureau) as observers as and when required.

(5) The members of the MDB, other than its *ex-officio* members, shall hold office for two years and shall be eligible for re-nomination.

(6) A member, other than its *ex-officio* member, may resign by writing under his hand addressed to the Authority.

(7) No person who is a member of the Appellate Board or the Policy Board shall be a member of the MDB.

(8) The Chairman himself or on the directions of the Authority may call meeting of the MDB.

(9) In the absence of Chairman from a meeting, the MDB members may elect one of the members to preside over at meeting.

(10) Where the MDB requires examination or evaluation of applications for the grant of licence, enlistment, 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.

(11) The quorum to conduct a meeting shall be one-half of the total members including the Chairman of the MDB.

(12) The MDB shall follow policy guidelines issued by the Policy Board of the Authority.

(13) 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.

(14) The MDB shall, for the purpose of these rules, fix responsibility of offences before referring a case to the Court.

(15) 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 enlistment or registration certificate.

(16) The MDB may appoint a panel of experts or inspectors for inspection of any establishment to submit its report to the MDB.

(17) The MDB may appoint a panel of experts or inspectors for inspection of any establishment for enlistment or registration of medical devices within the country or abroad to submit its report to the MDB and the MDB may evaluate the report and subsequently approve, reject or suspend the application for enlistment or registration of medical device after giving to the applicant the opportunity of being heard.

(18) 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.

(19) 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.

(20) 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.

(21) The MDB shall issue recall notices for withdrawal of stock from the market, if any medical device is declared by the notified laboratory to be unsafe and of sub-standard. Likewise, the marketing authorization holder shall inform the MDB for the recalls within thirty days after the identification of problem.

(22) The MDB may direct the Inspector for investigation of cases and implementation of recall notices effectively.

(23) 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 XI
APPEAL

60. Appeal against decision of the MDB ,—The aggrieved person or party may prefer appeal before the Appellate Board of the Authority against the decision of MDB within a period of sixty days.

61. Analysis by appellate laboratory ,—(1) Authority shall, by notification in the official Gazette, establish one or more appellate laboratories for the purposes of ascertaining the validity or authenticity of a report and analysis generated by any quality control laboratory under these rules.

(2) The Authority, by notification in the official Gazette, shall specify the detailed procedure for ascertaining the validity or authenticity of a report and analysis of medical devices under sub-rule (1).

(3) The Authority shall, on receipt under rule 60, forward the appeal to the MDB and the MDB shall, for ascertaining the validity or authenticity of the impugned report and analysis, send to the appellate laboratory the portion of sample of the medical device lying with it. The result and report of such appellate laboratory on the impugned report and analysis shall be conclusive evidence of the facts stated therein.

CHAPTER XII
MEDICAL DEVICE REGISTER

62. Register of medical devices,—The MDB shall maintain separate registers on the format as set out in Form-16 in respect of medical devices enlisted or registered, establishments licensed and decisions of the MDB taken for cancellation or suspension of enlistment or registration of medical devices and licences of establishments.

CHAPTER XIII
FEE

63. Fee for various activities and amendment of Schedules,— (1) The fee specified in column (4) of the Table in Schedule C shall be payable in respect of an activity specified in column (3) thereof against the subject specified in column (2) of that Table.

(2) The Authority may, with the approval of Policy Board, amend Schedule C so as to omit any entry there from, add any entry thereto or amend any entry therein.

(3) The Authority may, on the recommendation of MDB, amend Schedules A,B and D and the Forms so as to omit any [17][form or] entry there from, add any entry thereto or amend any entry therein.

CHAPTER XIV
ADVERTISMENT OF MEDICAL DEVICES

64. 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..

65. 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-17.

(2) An application for advertisement shall be accompanied with the following, namely:—

(a) application fee as prescribed in rule 63; and

(b) documents or information as specified in Form-17.

(3) The permission for advertisement shall be issued on the format as set out in Form-18.

(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). Before rejection of the application for advertisement the MDB shall provide to applicant an opportunity of being heard and inform the applicant of its decision in writing with reasons of such decision.

66. 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:

[17] Inserted vide S.R.O 1500(I)/2021 dated 22nd November, 2021

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 enlisted or registered.

(4) Where the information in an advertisement on intended use is provided, the advertisement material shall also 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) 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 XV
MISCELLANEOUS

67. Outsourcing,— (1) Out sourcing of manufacturing of medical devices may be allowed subject to fulfilment of the following conditions, namely: —

(a) the establishment for manufacturing medical device being contract giver, intending to outsource, has been licensed and its medical device enlisted or registered by the MDB or 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 or CE marked by manufacturer whose conformity assessment is performed by conformity assessment bodies notified in NANDO database under the relevant European directive for medical devices subject to evidence and supporting document;

(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.

[18][(2) Outsourcing of manufacturing processes or analysis of medical devices may be allowed subject to the conditions laid down in Schedule F and for this purpose:—

(a) the licensed manufacturers of medical devices or the applicant of establishment license for manufacturing of medical devices shall apply to the MDB;

(b) the MDB shall issue following types of certificates of permission to local manufacturers of medical devices, namely:—

(i) certificate to outsource manufacturing processes of medical devices; and
(ii) certificate to outsource for analysis of medical devices.

(c) the application for certificate under sub-rule (2) shall be made on Form-1(A) or Form-1(B), as the case may be, to the Secretary or Chairman MDB and the outsourcing permission certificate shall be issued on Form-3(A) and Form-3(B);

(d) an application for certificate under sub-rule (2) shall be accompanied with the following, namely:—

(i) application fee as specified in Schedule C; and
(ii) all documents or information as specified in Form-1(A) or Form-1(B), as the case may be.

(e) an application for certificate of permission shall comply with the requirements as specified in these rules;

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

Provided that the Authority may, on the recommendations of the MDB, amend the Schedule F so as to omit any entry therefrom, add any entry thereto or amend any entry therein.]

(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.

68. Standards of testing. —The standards for testing of medical devices shall be in accordance with the international standards.

69. Fee to be non-refundable. — Any fee specified under rule 63 and deposited in

[18] Substituted vide S.R.O 559(I)/2022 dated 27.04.2022

respect of any activity shall be non-refundable.

70. 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, without prejudice to any punishment provided for in any other law for the time being in force.

71. Inspection of manufacturer abroad. — (1) No medical device of class B, C or D manufactured abroad shall be registered or registration thereof renewed or post registration variation in case of any critical change at manufacturing site allowed under these rules, unless the manufacturing unit of such medical device is inspected.

(2) A medical device shall be exempt from inspection under sub-rule (1) where the medical device is approved by regulatory authorities of the countries specified in rule 67 irrespective of the fact that the manufacturing unit is not located in these countries.

(3) The medical devices pre-qualified by the World Health Organization [19][or CE marked by conformity assessment bodies (CABs) notified in NANDO database under the relevant European directive for medical devices subject to evidence and supporting documents] shall be exempt from inspection of manufacturing units abroad under sub-rule (1).

(4) Where registration of a medical device is cancelled or suspended by the exporting country or, as the case may be, cancellation of pre-qualification by the WHO, the registration holder of such medical device in Pakistan shall be bound to inform the MDB about the cancellation or suspension within fifteen days of such cancellation or suspension and in case of non- compliance the MDB shall take action against the importer, which may also lead to suspension or cancellation of registration of that medical device and punishment under the DRAP Act without prejudice to any other action that may be taken under any other law for the time being in force.

72. Indenting of Medical Devices. — (1) The [20][registered] medical devices may be imported [21][commercially] through [22][indenting under conditions to be determined by the MDB].

(2) Where an institute, hospital, a registered charitable trust or institution intends to import medical devices through an indenter, the MDB may allow such indenting subject to the condition that such medical devices imported through indenting shall not be sold for commercial purpose in the open market.

73. Technical ambiguities:- Where a question arises in respect of technical ambiguities of a medical device, the matter shall be placed before the MDB for decision..

74. Repeal. — The Medical Devices Rules, 2015 and all other rules, notifications, orders and such other instruments made under the Act or the DRAP Act so far as they regulate medical devices and the activities covered under these rules, except notification No.F.5-11/2017-SO (Admn) dated 15th March, 2017, are hereby repealed.

75. [23][Emergency use authorization.— The MDB may grant emergency use authorization to medical devices in public health emergency, national disaster, natural calamity or pandemic, as the case may be, subject to such procedure, conditions and validity, as may be

[19] Inserted vide S.R.O 599(I)/2022 dated 27.04.2022
[20] Inserted vide S.R.O 599(I)/2022 dated 27.04.2022
[21] Inserted vide S.R.O 599(I)/2022 dated 27.04.2022
[22] Substituted vide S.R.O 599(I)/2022 dated 27.04.2022
[23] Added vide S.R.O 599(I)/2022 dated 27.04.2022

determined by the Authority on the recommendations of the MDB.]

76. [24]**[Regulation for refurbished medical devices.—**Refurbished medical devices shall be regulated as per procedure and standards as may be prescribed by the regulations.]

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[24] Added vide S.R.O 599(I)/2022 dated 27.04.2022

DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-1
[*see rule 4(2), 5(1), and 6(2)]*

APPLICATION FORM FOR GRANT OR RENEWAL OF AN ESTABLISHMENT LICENCE TO MANUFACTURE MEDICAL DEVICES

I/WE
……..……
…..... (1)…….. (2)……. (attach list of partners)
Holder (s) of CNIC No. ……..……Owner of M/S …… hereby apply for Establishment Licence of my firm/company established under company/partnership Act ..... Having NTN ……. located at the premises as under ……

Sr. No.	Description	Particular
1.	**Purpose of application, whether;**	**Please select appropriate column**
(i)	Fresh/New Application	
(ii)	For renewal of establishment licence to manufacture medical devices	
	(i) Licence number and date:	
	(ii) Validity date:	
	(iii) Last renewal date and its validity:	
	(iv) Attach certificate of licence and last renewal:	
(iii)	Proposed change of any particular of a licensed establishment (in case of any proposed change, please mention details of change	
2.	**Establishment details**	**Please provide detail against each where applicable**
(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)	Details of premises (please provide triplicate detail layout plan with dimension):	
(viii)	Details of section wise equipments and machinery for manufacturing and instruments for quality control :	

Sr.No.	Name of Equipment	Make	Model	Capacity
(1)	(2)	(3)	(4)	(5)

3.	**Detail Of Qualified technical Person (Attached copies of CNIC, Photographs, Degrees , Experience Certificate and Certificate of Concerned council)**	
(a)	Names of production incharge for supervising manufacturing processes	

	Qualifications of production incharge	
(b)	Names and qualifications of quality control incharge for supervising quality control department	
	Qualifications of quality control incharge for supervising quality control department	
(c)	Other technical staff working in these departments:	
4.	**Proof of fee deposited:**	
5.	**Details of medical devices intended to be manufactured:**	
6.	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 legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under. This certificate must be on stamp paper duly notarized and signed and stamped by Proprietor, Chief Executive, Managing Director or an authorized officer. In case of an authorized officer authority letter from the owner of the establishment shall be provided.

Name(s)……..
Designations……..
Signature(s)……..
Stamp……..
Date…….

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.
- Provide readable softcopy along with application in USB/CD.

[25][DRUG REGULATORY AUTHORITY OF PAKISTAN

FORM-1(A)

[See rule 67(2)]

APPLICATION FORM FOR GRANT OR RENEWAL OF CERTIFICATE TO OUTSOURCE MANUFACTURING PROCESSES OF MEDICAL DEVICES

I/WE……..…… (1)…….. (2)……..…(attach list of partners/directors) holder(s) of CNIC Nos ….……..…… Owner/ Managing Director/ CEO) of M/s …… having valid ELM……..or applied on Form-1 vide DRAP diary No.……..… dated……..hereby apply for certificate to outsource manufacturing process(es) of medical device(s) to ……(name of contract acceptor) for the following activities (1)…….(2)……

Sr.	Description	Particular
1.	**Purpose of application, whether;**	**Please select appropriate column**
(i)	Fresh/New Application	
(ii)	For renewal of permission certificate to outsource manufacturing processes of medical devices	
	a. Certificate number and date of issue:	
	b. Validity date:	
	c. Last renewal date and its validity:	
	d. Attach copy of certificate and last renewal:	
(iii)	Proposed change in any particular of the certificate (in case of any proposed change, please mention details of change)	
2.	**Proof of fee deposited:**	
3.	**Contract** between contract giver and contract acceptor (provide on stamp paper duly signed by both)	
4.	**Contract giver details**	**Please provide detail against each where applicable**
(i)	Establishment name, address, contact information; (Attach copy of ELM or DRAP Diary No. of Form-1 application)	
(ii)	Details of medical device(s) for which outsourcing is intended to be performed	
(iii)	Details of manufacturing process(es) of each device(s) for which outsourcing is intended to be performed	
5.	**Contract acceptor details**	
(i)	Establishment name, address, contact information	
(ii)	(Type of ownership i.e proprietorship, partnership, public or private limited In case of proprietorship, provide: NTN, Online FBR certification In case of partnership, provide: NTN, online FBR certification, Partnership deed, Certificate of registrar of firms In case of public & private limited, provide: NTN, SECP Form 21, Form-29)	

[25] Inserted vide S.R.O 559(I)/2022 dated 27.04.2022

(iii)	Names of proprietor/partners/directors; (Also attach readable copies of CNIC)			
(iv)	Residential addresses of partners/proprietors/directors			
(v)	Details of procedure for performing the outsourcing step(s),			
(vi)	Materials to be used			
(vii)	Standards applied (if any).			
(viii)	Copy of quality certificates such as ISO13485 etc (if any)			
(ix)	Details of equipment and machinery for manufacturing and instruments for quality control;			
Sr.No.	Name of Equipment	Make	Model	Capacity
(1)	(2)	(3)	(4)	(5)
(x)	In case manufacturing involves biological material then provide the list of all materials of animal, human, microbial or recombinant origin used in product and in the manufacturing process, which includes animal or human cells, tissues or derivatives, rendered non-viable cells, tissues or derivatives of microbial or recombinant origin; the details concerning selection of sources/ donors; harvesting, processing, preservation, testing and handling of tissues, cells and substances;			
(xi)	Expertise available, their qualification and experience (provide names, CNIC(s), degree/certificate, experience letter(s) etc)			
6.	Any other relevant information that may be required by the MDB.			

DECLARATION

Certified that the documents and information provided herein to outsource the activity as mentioned in the Form are genuine and correct; and if found at any stage to be misrepresenting or incorrect it shall lead to legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under.

This certificate must be on stamp paper to be provided by contract giver and contract acceptor duly notarized and signed and stamped by Proprietor/ Partner/Chief Executive/Managing Director

Name(s)……..
Designations……..
Signature(s)……..
Stamp……..
Date…….

Note:

- This form shall also be used if change is proposed regarding the particulars provided in relation to the permission certificate to outsource manufacturing processes of medical devices. For this purpose, provision of relative information is mandatory.

- Provide readable softcopy along with application in USB/CD.]

[26][DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-1(B)
[See rule 67(2)]
APPLICATION FORM FOR GRANT OR RENEWAL OF PERMISSION CERTIFICATE TO OUTSOURCE ANALYSIS OF MEDICAL DEVICES

I/We ……..…… (1)…….. (2)…….…(attach list of partners/directors) holder(s) of CNIC Nos ….…….…… Owner/ Managing Director/ CEO) of M/s ……, having valid ELM……..or applied on Form-1 vide DRAP diary No.……..…dated……...…….....hereby apply for certificate to outsource analysis of medical device(s) to ……(name of contract acceptor) for the following activities(1)…….(2) ……..

Sr.	Description	Particular
1.	**Purpose of application, whether;**	**Please select appropriate column**
(i)	Fresh/New Application	
(ii)	For renewal of permission certificate to outsource manufacturing processes of medical devices	
	e. Certificate number and date of issue:	
	f. Validity date:	
	g. Last renewal date and its validity:	
	h. Attach copy of certificate and last renewal:	
(iii)	Proposed change in any particular of the certificate (in case of any proposed change, please mention details of change)	
2.	**Proof of fee deposited:**	
3.	**Contract** between contract giver and contract acceptor (provide on stamp paper duly signed by both)	
4.	**Contract giver details**	**Please provide detail against each where applicable**
(i)	Establishment name, address, contact information; (Attach copy of ELM or DRAP Diary No. of Form-1 application)	
(ii)	Details of medical device(s) for which outsourcing is intended to be performed	
(iii)	Details of analysis processes of each device(s) for which outsourcing is intended to be performed	
5.	**Contract acceptor details**	
(i)	Establishment name, address, contact information	
(ii)	Type of ownership i.e proprietorship, partnership, public or private limited (In case of proprietorship, provide: NTN, Online FBR certification In case of partnership, provide: NTN, online FBR certification, Partnership deed, Certificate of registrar of firms In case of public & private limited, provide: NTN, SECP Form 21, Form-29)	
(iii)	Names of proprietor/partners/directors; (Also attach readable copies	

[26] Inserted vide S.R.O 559(I)/2022 dated 27.04.2022

	of CNIC)	
(iv)	Residential addresses of partners/proprietors/directors	
(v)	Details of procedure for performing the outsourcing step(s),	
(vi)	Details of all the tests to be performed including acceptance limit/criteria	
(vii)	Materials to be used	
(viii)	Standards applied (attach copies of standards)	
(ix)	Analysis/testing protocols to be used (software validation protocol in case of active medical device testing),	
(x)	Copy of quality certificates such as ISO13485 etc (if any)	
(xi)	Details of equipment/facility for performing the tests;	

Sr.No.	Name of Equipment	Make	Model	Capacity
(1)	(2)	(3)	(4)	(5)

(xii)	Sample report/certificate that will be provided to contract giver upon completion of analysis
(xiii)	Expertise available, their qualification and experience (provide names, CNIC(s), degree/certificate, experience letter(s) etc)
6.	Any other relevant information that may be required by the MDB.

DECLARATION

Certified that the documents and information provided herein to outsource the activity as mentioned in the Form are genuine and correct; and if found at any stage to be misrepresenting or incorrect it shall lead to legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under.

This certificate must be on stamp paper to be provided by contract giver and contract acceptor duly notarized and signed and stamped by Proprietor/ Partner/Chief Executive/Managing Director

Name(s)……..
Designations……..
Signature(s)……..
Stamp……..
Date…….

Note:

- This form shall also be used if change is proposed regarding the particulars provided in relation to the permission certificate to outsource manufacturing processes of medical devices. For this purpose, provision of relative information is mandatory.
- Provide readable softcopy along with application in USB/CD.]

DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-2
[see rule 4(2), 5(1), 6(3) and 8(3)(a)]

APPLICATION FORM FOR GRANT OR RENEWAL OF AN ESTABLISHMENT LICENCE TO IMPORT MEDICAL DEVICES

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 establishment licence to import medical devices at the premises situated at …….

Sr. No.	Description	Particular
1.	**Purpose of application, whether;**	**Please select appropriate column**
(i)	Fresh/New Application	
(ii)	For renewal of establishment licence to import medical devices	
	(i) Licence number and date:	
	(ii) Validity date:	
	(iii) Last renewal date and its validity:	
	(iv) Attach certificate of licence and last renewal:	
(iii)	Proposed change of any particular of a licensed establishment (in case of any proposed change, please mention details of change	
2.	**Establishment details**	**Please provide detail against each, where applicable**
(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:	
	[27][…..]	
(iv)	Names of partners/proprietors/directors:	
(v)	Addresses of partners/proprietors/directors:	
(vi)	Date of establishment:	
	[28][…..]	
(vii)	Details of equipments and machinery for Storage and Handling of Medical Devices:	

Sr.No.	Name of Equipment	Make	Model	Capacity
(1)	(2)	(3)	(4)	(5)

[27] Omitted vide Notification No. F. 10-1/2020-MD dated 4th June, 2021, Before omission, the aforesaid Rules, in Form-2 the entries in column (2) at sub-serial number (iv) read as under:
"(iv) Drug Sale License issued by Provincial Government"
[28] Omitted vide Notification No. F. 10-1/2020-MD dated 4th June, 2021, Before omission, the aforesaid Rules, in Form-2 the entries in column (2) at sub-serial number (viii) read as under:
" (viii) Drug Sale License issued by Provincial Governments;"

3.	**Detail Of Qualified technical Person (Attached copies of CNIC, Photographs, Degrees , Experience Certificate and Certificate of Concerned council)**	
(a)	Names of Qualified Technical Person for supervising sale, distribution or wholesale of medical devices	
	Qualifications of Qualified technical person	
(b)	Other technical staff working in these departments:	
4.	**Proof of fee deposited:**	
5.	**Details of medical devices intended to be Imported:**	
6.	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 legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under. This certificate must be on stamp paper duly notarized and signed and stamped by Proprietor, Chief Executive, Managing Director or an authorized officer. In case of an authorized officer authority letter from the owner of the establishment shall be provided.

UNDERTAKING

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.

Name(s)……..
Designations……..
Signature(s)……..
Stamp……..
Date…….

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.
- Provide readable softcopy along with application in USB/CD.

DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-3
[*see rule 5(2)****]***
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 following medical devices …….

3. This licence shall, in addition to the conditions specified in the Medical Devices Rules, 2017made 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 qualified technical staff.

..... Production Incharge	..... Quality Control Incharge

Renewal Date: _____-

Secretary
Medical Device Board
Seal:

[29]**[DRUG REGULATORY AUTHORITY OF PAKISTAN**
FORM-3(A)
[See rule 67(2)]

OUTSOURCING PERMISSION CERTIFICATE FOR MANUFACTURING PROCESSES OF MEDICAL DEVICES

Certificate No. _____
ELM No. _____
Date of issue: _____
File No. _____

M/s…….……..….(name and address) is hereby certified to outsource manufacturing process(es) of medical device(s) at the following premises……..…….(name and address)

2. This certificate permit the outsourcing of manufacturing process(es) namely…….. of following medical device(s) ……

3. This certificate shall, in addition to the conditions specified in the Medical Devices Rules, 2017 made under the DRAP Act, 2012, be subject to the following conditions namely:—

(a) The certificate shall be in force for a period of five years from the date of issue unless earlier suspended or cancelled.

(b) The final release of the finished medical device shall be issued by the establishment license holder.

Renewal Date: _____

Secretary,
Medical Device Board
Seal:]

[29] Inserted vide S.R.O 559(I)/2022 dated 27.04.2022

[30][DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-3(B)
[See rule 67(2)]

OUTSOURCING PERMISSION CERTIFICATE FOR ANALYSIS OF MEDICAL DEVICES

Certificate No: _____
ELM No: _____
Date of issue: _____
File No. _____

M/s…….(name and address) is hereby certified to outsource analysis of medical device(s) at the following premises……..…….(name and address)

2. This certificate permit the outsourcing of analysis namely…….. (name of tests) of following medical device(s) ……

3. This certificate shall, in addition to the conditions specified in the Medical Devices Rules, 2017 made under the Drug Regulatory Authority of Pakistan Act, 2012, be subject to the following conditions namely:—

(a) The certificate shall be in force for a period of five years from the date of issue unless earlier suspended or cancelled.

(b) The final release of the finished medical device shall be issued by the establishment license holder.

Renewal Date: _____

Secretary,
Medical Device Board
Seal:]

[30] Inserted vide S.R.O 559(I)/2022 dated 27.04.2022

DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-4
[*see rule 5(2)****]***
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. Name(s) of proprietor(s) along with the residential address and CNIC Number(s)
   (i) ……..
   (ii) …….

3. 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) …….

4. Addresses of godowns , if any, where medical devices shall be stored……

5. The licence will be in force for a period of five years from the date of issue unless earlier suspended or cancelled.

6. This licence shall, in addition to the conditions specified in the Medical Devices Rules, 2017made 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.
   (iv) Importer shall be responsible for labeling requirements as per Medical Devices Rules, 2017including Importer Licence details, Products Registration Numbers and MRP.

Renewal Date:_____

Secretary
Medical Device Board
Seal:

FORM-5

[*see rule 6(2)(i), 6(5)(b), 19(7) and 48(1)(i)****]***

Warranty under Medical Devices Rules, 2017

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 or accessories or components	Batch or lot No	Expiry date	Rate per Unit
(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:

DRUG REGULATORY AUTHORITY OF PAKISTAN

FORM-6

[*see rule 14(2)(a), 16(1), and 17(2)****]***

APPLICATION FORM FOR ENLISTMENT OR RENEWAL OF CLASS-A MEDICAL DEVICE OR ACCESSORY OR COMPONENT FOR LOCAL MANUFACTURE.

I (name and designation)……..of M/s……..hereby apply for enlistment or renewal of enlistment or proposed change of any particular of enlisted Class A medical device or accessory or component for local manufacture, namely ……,details of which are mentioned below along with enclosures.

Sr. No.	Description	Particular to be filled by applicant
1.	**Purpose of application, whether;**	
(i)	Fresh/New Application	
(ii)	For renewal of enlistment to manufacture Class A medical device or accessory or component	
	(i) Licence number and date:	
	(ii) Validity date:	
	(iii) Last renewal date and its validity:	
	(iv) Attach certificate of enlistment and last renewal:	
(iii)	Proposed change of any particular of an enlisted medical device(in case of any proposed change, please mention details of change	
2.	**Product Detail details**	**Please provide detail against each where applicable**
(i)	Medical device brand name:	
(ii)	Medical device generic name:	
(iii)	Does the medical device contain any active ingredient, poison or drug?	
(iv)	HS code for the medical device, if applicable:	
(v)	GMDN code for the medical device, if applicable:	
(vi)	Shelf life:	
(vii)	Proposed MRP of medical device:	
(viii)	Storage condition:	
(ix)	Is the medical device for export only?	
(x)	Proof of fee deposited:	
(xi)	Complete description of the medical device with intended use;	
(xii)	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, where applicable;	
(xiii)	Description or complete list of the various configurations of the medical device to be registered	
(xiv)	Complete description of the key functional elements, its formulation, its composition and its functionality;	
(xv)	Explanation of novel features, if any;	
(xvi)	Indications that the device will diagnose, treat,	

	prevent, cure or mitigate;	
(xvii)	Contraindications;	
(xviii)	Warnings to inform on specific risk or hazard that a user needs to know before using the medical device;	
3.	**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.**	(only for those active medical devices or devices to be used with active medical devices)
4.	**Sample of labels on the medical device and its packaging;**	
(i)	Instructions for installation and maintenance, if applicable;	
(ii)	Promotional material and product brochures. If any	
(iii)	Sample of labels on the medical device and its packaging;	
(iv)	Provide complete documentation related to the manufacturing and quality control processes.	
5.	**Grouping of medical device :**	
	Specify medical device grouping applicable to the medical device :	
	List the constituent-components or medical devices that are grouped together:	
6.	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 legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under. This certificate must be on stamp paper duly notarized and signed and stamped by Proprietor, Chief Executive, Managing Director or an authorized officer. In case of an authorized officer authority letter from the owner of the establishment shall be provided.

Name(s)……..
Designations……..
Signature(s)……..
Stamp……..
Date…….

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.

- Provide readable softcopy along with application in USB/CD.

[31][DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-6A
[See rule 14(2)(a), 16(1) and 17(2)]

APPLICATION FORM FOR ENLISTMENT OR RENEWAL OF CLASS A MEDICAL DEVICE OR ACCESSORY OR COMPONENT FOR IMPORT

I [name and designation]……of M/s……hereby apply for enlistment or renewal of enlistment or proposed change of any particular of enlisted Class A medical device or accessory or component for import, namely ……, manufactured by M/s …… located at …… details of which are mentioned below along with enclosures.

Sr. No.	Description	Particular to be filled by applicant
1.	**Purpose of application, whether;**	
(i)	Fresh/New Application	
(ii) *	For renewal of enlistment to import Class A medical device or accessory or component	
	(i) Enlistment number and date:	
	(ii) Validity date:	
	(iii)Last renewal date and its validity:	
	(iv)Attach certificate of enlistment and last renewal:	
(iii)	Proposed change of any particular of an enlisted medical device (in case of any proposed change, please mention details of change)	
2. *	**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:	
3.	**Manufacturer Detail:**	
(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 ofsub-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:	
4.	**Product details**	**Please provide detail against each**

[31] Substituted vide S.R.O 430(I)/2022 dated 18th March, 2022.

		where applicable
(i) *	Medical device brand name:	
(ii) *	Medical device generic name:	
(iii)	HS code for the medical device, if applicable:	
(iv)	GMDN code for the medical device, if applicable:	
(v)	Shelf life supported with stability studies, where applicable:	
(vi)	Proposed MRP of medical device:	
(vii)	Storage condition:	
(viii)	Is the medical device for export only?	
(ix) *	Proof of fee deposited:	
(x) *	Original Agency agreement/Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin.	
(xi) *	Free sale certificate in the country of origin duly attested by Embassy of Pakistan.	
(xii) *	Is the product available on Free Sale in reference countries provided in rule 67 of Medical Devices Rules, 2017? If so, then provide original Free Sale Certificate duly attested by Embassy of Pakistan OR if the product is WHO prequalified, then provide WHO prequalification report/evidence.	
5.	**Grouping of medical devices:**	
(i)	Specify medical device grouping applicable to the medical device:	
	Single **Set** **Family** **System** **Kit** **Cluster**	
	Note: Grouping shall be accepted as per Schedule-B-II of the Medical Devices Rules, 2017.	
(ii)	List the constituent-components or medical devices that are grouped together:	
(iii)	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;	
(iv)	Description or complete list of the various configurations of the medical device to be registered using the format under these rules	
(v)	Complete description of the key functional elements, its formulation, its composition and its functionality;	
(vi) *	Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized in the country of origin:	
(vii)	Full Quality assurance certificate or equivalent as applicable duly notarized in the country of origin:	
(viii)	Essential principle of safety and performance.	
(ix) *	Declaration of conformity (DoC):- Please attach the complete DoC. The DoC need to be printed on the manufacturer‘s letterhead, filled and signed by the responsible person.	
6.	**Technical Information**	
(i)	Complete description of the medical device with intended	

	use, indications, contraindications; Provide instructions for use / manual.	
(ii)	Explanation of novel features, if any;	
(iii)	Provide manufacturing flow chart and quality control tests performed on the medical device	
(iv)	Sample of labels of the medical device, brochure and its packaging;	
7.	Any other relevant information that may be required by the MDB.	
NOTE: For renewal application, only fields marked with (*) are required along with an affidavit that all the other technical details remains unchanged and in case of any change, these details will be provided for evaluation and approval.		

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 legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under. This certificate must be on stamp paper duly notarized and signed and stamped by Proprietor, Chief Executive, Managing Director or an authorized officer. In case of an authorized officer authority letter from the owner of the establishment shall be provided.

Name(s)…….
Designations……...
Signature(s)……
Stamp……..
Date……

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.
- Provide readable softcopy along with application in USB/CD.]

DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-7
[see rule 14(2)(b), 16(1), and 17(2)**]**

APPLICATION FORM FOR REGISTRATION OR RENEWAL OF CLASS B, C & D MEDICAL DEVICE OR ACCESSORY OR COMPONENT FOR LOCAL MANUFACTURE.

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 or accessory or component for local manufacture, namely ……,details of which are mentioned below along with enclosures.

Sr. No.	Description	Particular to be filled by applicant
1.	**Purpose of application, whether;**	
(i)	Fresh/New Application	
(ii)	For renewal of registration to manufacture medical devices or accessory or component	
	(i) Licence number and date:	
	(ii) Validity date:	
	(iii) Last renewal date and its validity:	
	(iv) Attach certificate of registration and last renewal:	
(iii)	Proposed change of any particular of an registered medical device(in case of any proposed change, please mention details of change)	
2.	**Product Detail details**	**Please Provide Detail against each where applicable**
(i)	Medical device brand name:	
(ii)	Medical device generic name:	
(iii)	Does the medical device contain any active ingredient, poison or drug?	
(iv)	Class of medical device or accessory or component whether Class B, Class C or Class D	
(v)	HS code for the medical device, if applicable:	
(vi)	GMDN code for the medical device, if applicable:	
(vii)	Shelf life:	
(viii)	Proposed MRP of medical device:	
(ix)	Storage condition:	
(x)	Is the medical device for export only?	
(xi)	Proof of fee deposited:	
(xii)	Complete description of the medical device with intended use;	
(xiii)	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;	
(xiv)	Description or complete list of the various configurations of the medical device to be registered .	
(xv)	Complete description of the key functional elements, its formulation, its composition and its functionality;	

(xvi)	Explanation of novel features, if any;	
(xvii)	Indications that the device will diagnose, treat, prevent, cure or mitigate;	
3.	**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.**	(only for those active medical devices or devices to be used with active medical devices)
4.	**As applicable, following information to be provided on medical devices containing biological material:**	(only for those medical devices containing biological material)
(i)	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;	
(ii)	Detailed information concerning the selection of sources or donors;	
(iii)	Detailed information on the harvesting, processing, preservation, testing and handling of tissues, cells and substances;	
(iv)	Process full description of the system for record keeping allowing traceability from sources to the finished medical device.	
5.	**sample of labels on the medical device and its packaging;**	
(v)	Instructions for installation and maintenance and usage, if applicable;	
(vi)	Information on validation for medical devices with sterile or with measuring function, where applicable:	
(vii)	Provide complete documentation related to the manufacturing and quality control processes.	
6.	**Grouping of medical device :**	
	Specify medical device grouping applicable to the medical device :	
	List the constituent-components or medical devices that are grouped together:	
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 legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under. This certificate must be on stamp paper duly notarized and signed and stamped by Proprietor, Chief Executive, Managing Director or an authorized officer. In case of an authorized officer authority letter from the owner of the establishment shall be provided.

Name(s)……..
Designations……..
Signature(s)……..
Stamp……..
Date…….

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.

- Provide readable softcopy along with application in USB/CD.

[32][**DRUG REGULATORY AUTHORITY OF PAKISTAN**

FORM-7A

[See rule 14(2)(b), 16(1) and 17(2)]

APPLICATION FORM FOR REGISTRATION OR RENEWAL OF CLASS B, C& D MEDICAL DEVICE OR ACCESSORY OR COMPONENT FOR IMPORT

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 or accessory or component for import, namely …… manufactured by M/s …… located at …… details of which are mentioned below along with enclosures.

Sr. No.	**Description**	**Particular to be filled by applicant**
1.	**Purpose of application, whether;**	
(i)	Fresh/New Application	
(ii) *	For renewal of registration to import medical devices or accessories or components	
	(i) Licence number and date:	
	(ii) Validity date:	
	(iii)Last renewal date and its validity:	
	(iv)Attach certificate of registration and last renewal:	
(iii)	Proposed change of any particular of a registered medical device or accessory or component (in case of any proposed change, please mention details of change)	
2. *	**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:	
3.	**Manufacturer Detail:**	
(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 duly notarized in the country of origin:	

[32] Substituted vide S.R.O 430(I)/2022 dated 18th March, 2022.

4.	**Product details**	**Please Provide Detail against each where applicable**
(i) *	Medical device brand name:	
(ii) *	Medical device generic name:	
(iii)	HS code for the medical device, if applicable:	
(iv)	GMDN code for the medical device, if applicable:	
(v)	Does the medical device contain any active ingredient, poison or drug?	
(vi)	Provide manufacturing flow chart and quality control tests performed on the medical device	
(vii)	Class of medical device or accessory or component whether Class B, Class C or Class D	
(viii)	Shelf life supported with stability studies where applicable:	
(ix)	Proposed MRP of medical device:	
(x)	Storage condition:	
(xi)	Is the medical device for export only?	
(xii)	Proof of fee deposited:	
(xiii) *	Original Agency agreement/Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin.	
(xiv) *	Free sale certificate in the country of origin duly attested by Embassy of Pakistan.	
(xv) *	Whether the product is available on free sale in reference countries provided in rule 67 of Medical Devices Rules, 2017. Please attach original and valid free sale certificate duly attested by Embassy of Pakistan OR provide WHO prequalification report/evidence.	
5.	**Grouping of medical devices :**	
(i)	Specify medical device grouping applicable to the medical device :	
	Single **Set** **Family** **System** **Kit** **Cluster**	
	Note: Grouping shall be accepted as per Schedule-B-II of the Medical Devices Rules, 2017.	
(ii)	List the constituent-components or medical devices that are grouped together:	
(iii)	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;	
(iv)	Description or complete list of the various configurations of the medical device to be registered using the format under these rules	
(v)	Complete description of the key functional elements, its formulation, its composition and its functionality;	
(vi)*	Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized in the country of origin:	
(vii) *	Full Quality Assurance Certificate or equivalent as applicable duly notarized in the country of origin:	

(viii) *	Design Examination certificate, as applicable duly notarized in the country of origin;	
(ix)	Brief Description of the Medical Device	
(x)	Sample of labels of the medical device, brochure and its packaging;	
(xi)	Essential principle of safety and performance.	
(xii) *	Declaration of conformity (DoC):— Please attach the complete DoC. The DoC need to be printed on the manufacturer‘s letterhead, filled and signed by the responsible person.	
(xiii)	Description of the medical device with intended use, indications, contraindications; novel features, if any. Provide instructions for use / manual;	
From this section onward, information is only applicable for those medical devices not approved or allowed for free sale in reference countries mentioned in rule 67 of the Medical Devices Rules, 2017 or not CE marked or not WHO Prequalified.		
6.	**Technical Information**	
(i)	Instructions for installation and maintenance, if applicable;	
(ii)	Any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform, if applicable.	
(iii)	Promotional material.	
(iv)	Information on validation for medical devices with sterile or with measuring function, where applicable:	
(v)	Provide complete documentation related to the manufacturing and quality control processes.	
7.	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.	(only for those active medical devices or devices to be used with active medical devices)
8.	As applicable, following information to be provided on medical devices containing biological material:	(only for those medical devices containing biological material)
(i)	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;	
(ii)	Detailed information concerning the selection of sources or donors;	
(iii)	Detailed information on the harvesting, processing, preservation, testing and handling of tissues, cells and substances;	
(iv)	Process full description of the system for record keeping	

	allowing traceability from sources to the finished medical device.	
(v)	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	
(vi)	Attach the report or certification containing information on the objectives, methodology, results, discussion and conclusions of the pre-clinical tests, clinical studies conducted on the medical device,	
9.	Any other relevant information that may be required by the MDB.	
NOTE: For renewal application, only fields marked with (*) are required along with an affidavit that all the other technical details remains unchanged and in case of any change, these details will be provided for evaluation and approval.		

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 legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under. This certificate must be on stamp paper duly notarized and signed and stamped by Proprietor, Chief Executive, Managing Director or an authorized officer. In case of an authorized officer authority letter from the owner of the establishment shall be provided.

Name(s)……..
Designations……..
Signature(s)……
Stamp…….
Date……

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.
- Provide readable softcopy along with application in USB/CD.]

DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-8
[see rule 15(5)]
CERTIFICATE OF ENLISTMENT OR REGISTRATION OF A MEDICAL DEVICE OR ACCESSORY OR COMPONENT FOR LOCAL MANUFACTURE

Licence No. _____
Islamabad, Date of issue: _____
F.No : _____

M/s……..

The medical device as per details given below has been registered or enlisted under the DRAP Act, 2012 and the rules made there-under subject to the conditions appearing hereinafter:

Enlistment/ Registration No.	Name of medical device or accessory or component	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 enlistment/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 enlisted/registered medical device.

4. This enlistment/registration is subject to the conditions specified in the DRAP Act, 2012 and the rules made there-under.

Secretary
Medical Device Board
Seal:

DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-8A
[*see rule 15(5)****]***
CERTIFICATE OF ENLISTMENT OR REGISTRATION OF A MEDICAL DEVICE OR ACCESSORY OR COMPONENT FOR IMPORT

Licence No. _____
Islamabad, Date of issue: _____
F.No : _____

M/s……..

The medical device as per details given below has been registered/enlisted under the DRAP Act and the rules made there-under subject to the conditions appearing hereinafter:

Enlistment or Registration No.	Name of medical device or accessory or component	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 enlistment/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 enlisted/registered medical device.
4. This enlistment/registration is subject to the conditions specified in the DRAP Act, 2012 and the rules made there-under.

Secretary
Medical Device Board
Seal:

FORM 9
[See rule 22(1)]
APPLICATION FOR PERMIT TO IMPORT MEDICAL DEVICE(S) OR ACCESSORIES OR COMPONENT(S) 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, accessories, 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:
(i) …….
(ii) …….
(iii) …….

Quantities:
……..
……..

Manufactured by----------

2. In view of above, necessary permit to the said medical devices or accessories 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 10

[See rule 22(2)]

PERMIT TO IMPORT MEDICAL DEVICES OR ACCESSORIES 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 accessories or components or raw material specified below for the purpose of clinical investigation, examination, test or analysis at----------

Name(s) of medical device or accessory 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 11

[See rule 25(1)(c)]

INTIMATION OF ARRIVAL OF CONSIGNMENTS OF IMPORTED MEDICAL DEVICES OR ACCOSSORIES 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 /accessory / component / raw	Registration No.	Rate (for C & F/F.O.B.)	Packing	Quantity	Total Value

	material					
(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 12

[See rule 27(3)]

APPLICATION FORM FOR EXPORT PERMIT OF MEDICAL DEVICE OR ACCESSORY OR COMPONENT

I/We ..... hereby apply with the following for permission to export the medical device or accessory or component manufactured by M/s ..... ……..to…….

(a) Name of medical devices or accessory or component:
- (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 or accessory or component 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 or accessory or component manufactured by us for export under licence shall conform to 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 or accessories or components 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 13

[See rule 28(1)]

EXPORT PERMIT FOR MEDICAL DEVICE OR ACCESSORIES OR COMPONENTS

Permit No.....

M/s.....of.....is hereby permitted to export the medical device or accessories or components 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 14

[see rule 29(1)]

APPLICATION FOR EXPORT OF SMALL QUANTITIES OF MEDICAL DEVICES OR ACCESSORIES OR COMPONENTS FOR THE PURPOSE OF CLINICAL INVESTIGATIONS, EXAMINATION, TEST OR ANALYSIS

l/We ..... of ..... hereby apply for permission to export the medical devices or accessories or components 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 or accessories or components:

(i) ……..
(ii) ……..
(iii) ……..

2. In view of above, necessary export permit of the said medical devices or accessories or components 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 15

[see rule 29(3)]

EXPORT PERMIT FOR SMALL QUANTITIES OF MEDICAL DEVICES OR ACCESSORIES OR COMPONENTS 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 or accessories or components specified below and manufactured by.....

Name (s) of medical devices or accessories or components 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.

Name, signature and stamp of
Dated..... Export Permitting Authority

FORM-16
(see rule 62)

MEDICAL DEVICE REGISTER

S.No	Name of Licensed Establishment or Enlisted/ registered medical device	License No or Enlistment No or Registration No	Validity	Particulars	Decision of MDB
(1)	(2)	(3)	(5)	(6)	(7)

FORM-17
[See rule 65(1)]

APPLICATION FOR APPROVAL OF ADVERTISMENT OF A MEDICAL DEVICE

I.....of M/s……. hereby apply for permission to advertise the following medical device or accessory or component through …… (specify name of media)

(a) Name of medical device or accessory or component:
(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:

DRUG REGULATORY AUTHORITY OF PAKISTAN

FORM-18

[*see rule 65(3)****]***

PERMISSION TO ADVERTISE A MEDICAL DEVICE OR ACCESSORY OR COMPONENT

Islamabad, the dated……..

F.No……..

M/s……..

You are hereby permitted to advertise following medical device or accessory or component 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, 2017.

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:

DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-19
[*see rule 52****]***

APPLICATION FORM FOR GRANT OF PROVISIONAL ESTABLISHMENT CERTIFICATE TO IMPORT MEDICAL DEVICES PROVIDED IN SCHEDULE D

I/We ……..of M/s……..hereby apply for grant of provisional establishment certificate to import medical devices provided in Schedule D at the premises situated at …….

S. No.	Descriptions	To be filled by applicant
(1)	(2)	**(3)**
1.	Establishment name and address including godown address:	
2.	Type of ownership and copy of business registration as issued by the Registrar of Companies, Security Exchange Commission of Pakistan or any other authorized body (Proprietorship, partnership, private limited, public limited, etc)	
3.	Names and address of partners/proprietors/directors (attached 4 photographs and CNIC of each)	
4.	Name, qualification, registration No, CNIC No. and address of qualified technical person(s) for supervising import, sale and distribution (attach 4 photographs, CNIC and copy of degree and Registration certificate)	
5.	Copy of drug sale licence issued by provincial government	
6.	Original bank deposit slip	
7.	Original and valid authorized agency agreement from market authorization holder duly notarized in the country of origin.	

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 legal action under the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under. This certificate must be on stamp paper duly notarized and signed and stamped by Proprietor, Chief Executive, Managing Director or an authorized officer. In case of an authorized officer authority letter from the owner of the establishment shall be provided.

UNDERTAKING

I/we also undertake that I/we;

(a) shall comply with the provisions of Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under;
(b) shall not sell or stock any expired, spurious, substandard, unregistered, misbranded, counterfeit or any medical device in violation of the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under.

Name(s) of partners/proprietors/directors/ authorized person……

Designations……..
Signature(s)……..
Stamp……..
Date…….

DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-20
[*see rule 52****]***
PROVISIONAL ESTABLISHMENT CERTIFICATE TO IMPORT MEDICAL DEVICES PROVIDED IN SCHEDULE "D"

Provisional Establishment Certificate No.
Date of issue:

M/s……..situated at……is hereby entitled to hold Provisional Establishment Certificate as importer of medical devices provided in schedule D and being authorized agent of manufacturer(s) M/s……..

2. This Provisional Establishment Certificate permits the import and distribution through wholesale of medical devices provided in Schedule D subject to compliance of Medical Devices Rules, 2017.

3. Name(s) of partners/proprietor(s)/director(s)/ MD/CEO along with CNIC Number(s)
(i) ……..
(ii) …….

4. Name(s) of the qualified technical person(s) in-charge who will personally supervise the import and sale of medical devices by way of wholesale along with registration No. and CNIC No.
(i) ……..
(ii) …….

5. Addresses of godowns (licensed premises) where medical devices shall be stored ……

6. This certificate will be in force till the expiry of exemption for establishment licence from the date of issue unless earlier suspended or cancelled.

7. This provisional certificate, in addition to the conditions specified in the Medical Devices Rules, 2017 made under the DRAP Act, 2012, shall be subject to regulatory conditions including the following conditions, namely:-

(a) 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.
(b) The importer shall be responsible for the quality, efficacy and safety of all the medical devices imported and sold by him.
(c) He shall abide by all the provisions of the Drug Regulatory Authority of Pakistan Act, (XXI) of 2012 and the rules made thereunder.
(d) He shall immediately recall the defected and unsafe medical devices within 15 days after intimation to him and report the compliance to the Authority.
(e) Provisional Establishment Certificate shall be surrendered to the Authority within 7days if it is suspended, revoked or its holder winds up his business.
(f) The importer shall print MRP on the label of medical devices for patient information.
(g) Any other relevant condition imposed by the Authority in future.

Secretary
Medical Device Board
Seal:

DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-21
[see rule 52]
APPLICATION FORM FOR PROVISIONAL REGISTRATIONOF A MEDICAL DEVICE FOR IMPORT PROVIDED IN SCHEDULE D

I/We (name(s) and designation)……..of M/s……..hereby apply for Provisional Registration of medical device for import provided in schedule D, namely ……, details of which are mentioned below along with enclosures.

S.No	Requirements	To be filled by the applicant
(1)	(2)	(3)
1.	Details of importer: (a) Name of establishment: (b) Complete address and contact information as telephone numbers, fax numbers, email addresses, official websites, etc : (c) Provisional Establishment Certificate number and date of issuance (attach copy of Provisional Establishment Certificate):	
2.	General Information: (a) Medical device brand name, (b) non-proprietary generic name (GMDN/UMDNS: (c) Classification of Medical Device: (d) Brief description of medical device: (e) Original and valid Free sale certificate from regulatory authorities of reference countries mentioned in rule 67 of the Medical Devices Rules, 2017 (f) valid CE mark from the conformity assessment body (CAB) notified by European Union under the directives concerning medical devices. (g) Copy of valid authorized agency agreement with manufacturer abroad: (h) Original Bank deposit slip:	
3.	Name and Address of Manufacturer aboard as per free sale certificate:	

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 legal action under the Drug Regulatory

Authority of Pakistan Act, 2012 and the rules made there under. This certificate must be on stamp paper duly notarized and signed and stamped by Proprietor, Chief Executive, Managing Director or an authorized officer. In case of an authorized officer authority letter from the owner of the establishment shall be provided.

UNDERTAKING

I/we also undertake that I/we;

(a) shall comply with the provisions of Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under,

(b) shall not sell or stock any expired, spurious, substandard, unregistered, misbranded, counterfeit or any medical device in violation of the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under.

Name(s) of partners/proprietors/directors/ authorized person……

Designation…….

Signature……..

Stamp…….

Date…….

Note: Incomplete application shall not be entertained and shall not be considered as submitted.

DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-22
[see rule 52]
PROVISIONAL CERTIFICATE OF ENLISTMENT OR REGISTRATION OF A MEDICAL DEVICE OR ACCESSORY

Provisional enlistment or registration No. _____
Islamabad, Date of issue: _____
F.No : _____

M/s……..

The medical device as per details given below has been enlisted or registered under the DRAP Act, 2012 and the rules made there-under subject to the conditions appearing hereinafter:-

Provisional Enlistment/ Registration No.	Name of medical device	Class of medical device
(1)	(2)	(4)

(a) Name and complete address of manufacturer:
(b) Names and complete addresses of manufacturing sites:

2. This provisional enlistment or registration certificate shall be valid till expiry of exemption provided in rule 52 from the date mentioned above unless earlier suspended or cancelled.
3. The name shall be changed in case it has resemblance with already enlisted or registered medical device.
4. This provisional certificate, in addition to the conditions specified in the Medical Devices Rules, 2017 made under the DRAP Act, 2012, shall subject to regulatory conditions including the following conditions, namely:-

(a) 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.
(b) The importer shall be responsible for the quality, efficacy and safety of all the medical devices imported and sold by him.
(c) He shall abide by all the provisions of the Drug Regulatory Authority of Pakistan Act, (XXI) of 2012 and the rules made thereunder.
(d) He shall immediately recall the defected and unsafe medical devices within 15 days after intimation to him and report the compliance to the Authority.
(e) Provisional Establishment Certificate shall be surrendered to the Authority within 7days if it is suspended, revoked or its holder winds up his business.
(f) The importer shall print MRP on the label of medical devices for patient information.
(g) Any other relevant condition imposed by the Authority in future.

Secretary
Medical Device Board
Seal:

SCHEDULE A

[see rule 11]

CLASSIFICATION SYSTEM FOR MEDICAL DEVICES

Structure of the Classification Rules:

(a) MDB should establish a device classification system consisting of four classes where Class A represents the lowest hazard and Class D the highest.

(b) The determination of class should be based on rules derived from the potential of a medical device to cause harm to a patient or user (i.e. the hazard it presents) and thereby on its intended use and the technology/ies it utilizes.

(c) These rules should allow a manufacturer or importer to readily identify the class of its particular medical device subject, where appropriate, to the MDB resolving any matters of interpretation.

(d) The rules should be capable of accommodating future technological developments.

(e) The manufacturer should document its justification for placing its product into a particular class, including the resolution of any matters of interpretation where it has asked a MDB for a ruling.

(f) An accessory to a medical device maybe classified separately using the classification rules in this guidance document.

(g) If, based on the manufacturer's intended use, two or more classification rules apply to the device, the device is allocated the highest level of classification indicated.

(h) Where one medical device is intended to be used together with a different medical device, that may or may not be from the same manufacturer, (e.g. a pulse oximeter and a replaceable sensor sourced from a different manufacturer, or a general purpose syringe and a syringe driver), the classification rules should apply separately to each of the devices.

(i) Classification of an assemblage of medical devices that individually comply with all regulatory requirements depends on the manufacturer's purpose in packaging and marketing such a combination of separate devices. For example:

(I) If the combination results in a product that is intended by the manufacturer to meet a purpose different from that of the individual medical devices that make it up, the combination is a new medical device in its own right and should be classified according to the new intended use.

(II) If the combination is for the convenience of the user but does not change the intended uses of the individual medical devices that make it up (e.g. a customised kit that provides all the devices necessary to carry out a particular surgical procedure), the classification allocated to the assemblage for the purpose of a Declaration of Conformity is at the level of the highest classified device included within it.

(j) Classification of an assemblage of medical devices where one or more of the medical devices that is in the assemblage has yet to comply with all the relevant regulatory requirements, should be for the combination as a whole according to its intended use.

(k) While most software is incorporated into the medical device itself, some is not. Provided such standalone software falls within the scope of the definition for a 'medical device', it is deemed to be an active device and should be classified as follows:

(i) Where it drives or influences the use of a separate medical device, it should be classified according to the intended use of the combination.

(ii) Where it is independent of any other medical device, it is classified in its own right using the rules in this document.

(l) The historical experience of a MDB may require a particular type of medical device to be allotted a different classification from that assigned through the application of these classification rules.

Tabular Representation of the Classification System

CLASS	LEVEL	DEVICE EXAMPLES
A	Low Hazard	tongue depressors/ disposable masks
B	Low-moderate Hazard	Hypodermic Needles / suction equipment
C	Moderate-high Hazard	Lung ventilator / bone fixation plate
D	High Hazard	Heart valves / implantable defibrillator

Manufacturer's Determination of Device Class

The manufacturer should:

a) Refer to the IMDRF guidance document entitled *Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'* to confirm the product concerned is a medical device.

b) Document the intended use of the medical device.

c) Take into consideration all the rules that follow in order to establish the proper classification for the device, noting that **where a medical device has features that place it into more than one class, classification should be based on the highest class indicated.**

d) Determine if the device is subject to special national rules that apply within a particular jurisdiction and whether this affects the device class.

e) Ask the MDB to resolve any matter of interpretation, if such exists.

Classification Rules

The actual classification of each device depends on the claims made by the manufacturer for its intended use and the technology/ies it utilises. As an aid to interpreting the purpose of each rule, illustrative examples of medical devices that should conform to the rule have been provided in the table below. However, it must be emphasised that a manufacturer of such a device should not rely on it appearing as an example but should instead make an independent decision on classification taking account of its particular design and intended use.

Manufacturers and MDB are advised to refer to the definitions in rule 2 of these rules for a proper understanding of the terms used within these rules.

Non-Invasive Devices

RULE	ILLUSTRATIVE EXAMPLES
Rule 1. All non-invasive devices which come into contact with injured skin:	Devices covered by this rule are extremely claim sensitive.
- are in Class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates only, i.e. they heal by primary intent;	Examples: cotton wool.
- are in Class B if they are intended to be used principally with wounds which have breached the dermis, including devices principally intended to manage the microenvironment of a wound.	Example: non-medicated impregnated gauze dressings.
unless they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, in which case they are in Class C.	Devices used to treat wounds where the subcutaneous tissue is as least partially exposed and the edges of the wound are not sufficiently close to be pulled together. To close the wound, new tissue must be formed within the wound prior to external closure. The device manufacturer claims that they promote healing through physical methods other than 'primary intent'. Examples: dressings for chronic ulcerated wounds; dressings for severe burns.
Rule 2(i). All non-invasive devices intended for channeling or storing • liquids, or • gases for the purpose of eventual infusion, administration or introduction into the body are in Class A,	Such devices are 'indirectly invasive' in that they channel or store liquids that will eventually be delivered into the body. Examples: administration sets for gravity infusion; syringes without needles.
unless they may be connected to an active medical device in Class B or a higher class, in which case they are Class B;	Examples: syringes and administration sets for infusion pumps; anesthesia breathing circuits. **NOTE:** "Connection" to an active device covers those circumstances where the safety and performance of the active device is influenced by the non-active device and *vice versa*.
Rule 2(ii). All non-invasive devices intended to be used for • channeling blood, or • storing or channeling other body liquids, or • storing organs, parts of organs or	Examples: tubes used for blood transfusion, organ storage containers.

RULE	ILLUSTRATIVE EXAMPLES
body tissues, for the purpose of eventual infusion, administration or introduction into the body are Class B.	
unless they are blood bags, in which case they are Class C.	Example: Blood bags that do not incorporate an anti-coagulant. **NOTE:** In some jurisdictions, blood bags have a special rule that places them within a different class.
Rule 3. All non-invasive devices intended for modifying the biological or chemical composition of • blood, • other body liquids, or • other liquids, intended for infusion into the body are in Class C,	Such devices are 'indirectly invasive' in that they treat or modify substances that will eventually be delivered into the body. They are normally used in conjunction with an active device within the scope of either Rule 9 or 11. Examples: haemodializers; devices to remove white blood cells from whole blood. **NOTE**: For the purpose of this part of the rule, 'modification' does not include simple, mechanical filtration or centrifuging which are covered below.
unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class B.	Examples: devices to remove carbon dioxide; particulate filters in an extracorporeal circulation system.
Rule 4. All other non-invasive devices are in Class A.	These devices either do not touch the patient or contact intact skin only. Examples: urine collection bottles; compression hosiery; non-invasive electrodes, hospital beds.

Invasive Devices

RULE	ILLUSTRATIVE EXAMPLES
Rule 5. All invasive devices with respect to body orifices (other than those which are surgically invasive) and which: • are not intended for connection to an active medical device, or • are intended for connection to a Class A medical device only.	Such devices are invasive in body orifices and are not surgically invasive (refer to definition in Section 4). Devices tend to be diagnostic and therapeutic instruments used in ENT, ophthalmology, dentistry, proctology, urology and gynaecology. Classification depends on the duration of use and the sensitivity (or vulnerability) of the orifice to such invasion.
- are in Class A if they are intended for transient use;	Examples: examination gloves; enema devices.
- are in Class B if they are intended for	Examples: urinary catheters, tracheal tubes.

RULE	ILLUSTRATIVE EXAMPLES
short-term use;	
unless they are intended for short-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class A,	Examples: dressings for nose bleeds.
- are in Class C if they are intended for long-term use;	Example: urethral stent; contact lenses for long-term continuous use (for this device, removal of the lens for cleaning is considered as part of the continuous use).
unless they are intended for long-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear-drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class B.	Examples: orthodontic materials, removable dental prosthesis.
All invasive devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to an active medical device in Class B or a higher class, are in Class B.	Examples: tracheal tubes connected to a ventilator; suction catheters for stomach drainage; dental aspirator tips. **NOTE:** Independent of the time for which they are invasive.
Rule 6. All surgically invasive devices intended for **transient use** are in Class B,	A majority of such devices fall into several major groups: those that create a conduit through the skin (e.g. syringe needles; lancets), surgical instruments (e.g. single-use scalpels; surgical staplers; single-use aortic punch); surgical gloves; and various types of catheter/sucker etc.
unless they are reusable surgical instruments, in which case they are in Class A; or	Examples: Manually operated surgical drill bits and saws. **NOTE**: A surgical instrument connected to an active device is in a higher class than A.
unless intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or	Example: catheter containing sealed radioisotopes.
unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class C; or	**NOTES**: (a) The 'biological effect' referred to is an intended one rather than unintentional. The term 'absorption' refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body. (b) This part of the rule does not apply to those substances that are excreted without modification from the body.

RULE	ILLUSTRATIVE EXAMPLES
	Example: Insufflation gases for the abdominal cavity.
unless intended to administer medicinal products by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class C; or	Example: insulin pen for self-administration. **NOTE**: The term 'administration of medicines' implies storage and/or influencing the rate/volume of medicine delivered not just channeling. The term 'potentially hazardous manner' refers to the characteristics of the device and not the competence of the user.
unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D; or	Example**:** spinal needle.
unless intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.	Examples: angioplasty balloon catheters and related guide wires; dedicated disposable cardiovascular surgical instruments.
Rule 7. All surgically invasive devices intended for **short-term use** are in Class B,	Such devices are mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types. Examples: infusion cannula; temporary filling materials; non-absorbable skin closure devices; tissue stabilizers used in cardiac surgery. **NOTE:** Includes devices that are used during cardiac surgery but do not monitor or correct a defect.
unless they are intended to administer medicinal products, in which case they are in Class C; or	**NOTE**: The term 'administration of medicines' implies storage and/or influencing the rate/volume of medicine delivered not just channeling.
unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class C; or	Example: surgical adhesive.
unless they are intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or	Example: brachytherapy device.
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or	Example: biological adhesive. **NOTE**: The 'biological effect' referred to is an intended one rather than unintentional. The term 'absorption' refers to the degradation of a material within the body and the metabolic elimination of the

RULE	ILLUSTRATIVE EXAMPLES
	resulting degradation products from the body.
unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D;	Example: neurological catheter.
unless they are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.	Examples: cardiovascular catheters; temporary pacemaker leads; carotid artery shunts.
Rule 8. All implantable devices, and **long-term surgically invasive** devices, are in Class C,	Most of the devices covered by this rule are implants used in the orthopedic, dental, ophthalmic, and cardiovascular fields. Example: maxilla-facial implants; bone plates and screws; bone cement; posts to secure teeth to the mandibula bone (without a bioactive coating).
unless they are intended to be placed into the teeth or on prepared tooth structure, in which case they are in Class B; or	Examples: materials for inlays, crowns, and bridges; dental filling materials.
unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D; or	Examples: prosthetic heart valves; cardiovascular stents; pacemaker leads and electrodes; deep brain stimulation electrodes; cerebrospinal catheter.
unless they are intended to be life supporting or life sustaining, in which case they are in Class D; or	
unless they are intended to be active implantable medical devices, in which case they are Class D; or	Example: pacemakers; implantable defibrillators.
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or	Example: implants claimed to be bioactive. **NOTE**: Hydroxy-apatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer.
unless they are intended to administer medicinal products, in which case they are in Class D; or	Example: subcutaneous infusion ports for long-term use.
unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class D; or	Example: surgical adhesives intended for long term use. **NOTE**: Bone cement is not within the scope of the term 'chemical change in the body' since any change

RULE	ILLUSTRATIVE EXAMPLES
	takes place in the short rather than long term.
unless they are breast implants, in which case they are in Class D.	

Active Devices

RULE	ILLUSTRATIVE EXAMPLES
Rule 9(i). All active therapeutic devices intended to administer or exchange energy are in Class B,	Such devices are mostly electrically powered equipment used in surgery; devices for specialized treatment and some stimulators. Examples: muscle stimulators; powered dental hand pieces; hearing aids; neonatal phototherapy equipment; ultrasound equipment for physiotherapy.
unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionizing radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class C.	Examples: lung ventilators; baby incubators; electrosurgical generators; external pacemakers and defibrillators; surgical lasers; lithotripters; therapeutic X-ray and other sources of ionizing radiation. **NOTE**: The term 'potentially hazardous' refers to the type of technology involved and the intended application.
Rule 9(ii). All active devices intended to control or monitor the performance of active therapeutic devices in Class C, or intended directly to influence the performance of such devices, are in Class C.	Examples: external feedback systems for active therapeutic devices.
Rule 10(i). Active devices intended for diagnosis are in Class B:	Such devices include equipment for ultrasonic diagnosis/imaging, capture of physiological signals.
- if they are intended to supply energy which will be absorbed by the human body (except for devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, in which case they are Class A), or	Examples: magnetic resonance equipment; diagnostic ultrasound in non-critical applications; evoked response stimulators.
- if they are intended to image *in vivo* distribution of radiopharmaceuticals, or	Example: gamma/nuclear cameras.
- if they are intended to allow direct diagnosis or monitoring of vital physiologi-	Example: electronic thermometers, stethoscopes and blood pressure monitors; electrocardiographs.

RULE	ILLUSTRATIVE EXAMPLES
cal processes, **unless** they are specifically intended for: a) 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, or b) diagnosing in clinical situations where the patient is in immediate danger, in which case they are in Class C.	 Example: monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors. Example: ultrasound equipment for use in interventional cardiac procedures.
Rule 10(ii). Active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including devices which control or monitor such devices, or those which directly influence their performance, are in Class C.	Example: devices for the control, monitoring or influencing of the emission of ionizing radiation.
Rule 11. All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are in Class B, **unless** this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode and route of administration, in which case they are in Class C.	Such devices are mostly drug delivery systems or anaesthesia equipment. Examples: suction equipment; feeding pumps; jet injectors for vaccination; nebulizer to be used on conscious and spontaneously breathing patients where failure to deliver the appropriate dosage characteristics is not potentially hazardous. Examples: infusion pumps; anaesthesia equipment; dialysis equipment; hyperbaric chambers; nebulizer where the failure to deliver the appropriate dosage characteristics could be hazardous.
Rule 12. All other active devices are in Class A.	Examples: examination lamps; surgical microscopes; powered hospital beds & wheelchairs; powered equipment for the recording, processing, viewing of diagnostic images; dental curing lights.

Additional Rules

RULE	ILLUSTRATIVE EXAMPLES

RULE	ILLUSTRATIVE EXAMPLES
Rule 13. All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices, are in Class D.	These medical devices incorporate medicinal substances in an ancillary role. Examples: antibiotic bone cements; heparin-coated catheters; wound dressings incorporating antimicrobial agents to provide ancillary action on the wound; blood bags incorporating an anti-coagulant. **NOTE:**In some jurisdictions such products: - are considered to be outside the scope of the medical device definition; - may be subject to different controls.
Rule 14. All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are in Class D,	Example: porcine heart valves. **NOTE:** In some jurisdictions such products: - are considered to be outside the scope of the medical device definition; - may be subject to different controls.
unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only in which case they are in Class A.	Examples: leather components of orthopaedic appliances.
Rule 15. All devices intended specifically to be used for sterilizing or disinfecting medical devices are in Class B.	Example: desk-top sterilisers for use with dental instruments.
unless they are disinfectant solutions or washer-disinfectors intended specifically for invasive medical devices, as the end point of processing, in which case they are in Class C; or	Examples: solutions intended to be used for the disinfection of medical devices without further processing (for example in a steriliser) including those where the infective agent is a prion; washer-disinfector equipment specifically for disinfecting an endoscope or another invasive device.
unless they are intended to clean medical devices by means of physical action only, in which case they are in Class A.	

RULE	ILLUSTRATIVE EXAMPLES
Rule 16. All devices that are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class C.	**NOTE:** In some jurisdictions such products: - are considered to be outside the scope of the medical device definition; - may be subject to different controls.
Rule 17. All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class C,	Examples: condoms; contraceptive diaphragms.
unless they are implantable or long-term invasive devices, in which case they are in Class D.	Example: intrauterine contraceptive device.

Rationale for the inclusion of the Additional Rules within this document

There are a small number of products that fall within the scope of the definition of a medical device and which may need to be classified to take account of factors other than those covered by the general rules (Rules 1 to 12). While IMDRF continues to support and encourage regulatory harmonisation, it recognises that a particular Regulatory Authorities may have to reflect different local needs or social considerations when it introduces regulations on the classification of a minority of medical devices. Additional rules 13 to 17 provide examples of where this may occur.

For the understanding of those countries that are not Founding Members of IMDRF, it is felt important to offer guidance on the classification of such devices. Therefore, five Additional Rules are provided (Rules 13 to 17).

Matters that may need to be considered are: -

Rule 13:	Devices incorporating a medicinal substance • The regulations applying to medicinal products require different acceptance procedures to those for medical devices. • The behavior of a medicinal substance used in conjunction with a medical device may differ from that covered by its approved use as a medicinal product alone.
Rule 14:	Devices incorporating animal or human tissues • There is an absence of global regulatory controls for such devices. • Classification needs to acknowledge the diversity of opinions on such devices, globally. • The possible transmission of infectious agents to human beings by the use of devices incorporating animal or human tissues (e.g. Bovine Spongiform Encephalopathies (BSE) and Creutzfeldt-Jacob disease (CJD)) demands classification at a higher level.
Rule 15:	Disinfection as the end point of processing • Classification of disinfection solutions and washer-disinfector

	equipment intended for the treatment of invasive devices **as the end point of processing** rather than as an intermediate step before sterilization.
Rule 16:	Fluids used with contact lenses • The particular concerns relating to disinfectant solutions and other fluids that are used with contact lenses, due to sensitivity and vulnerability of the eye.
Rule 17:	Contraceptive devices • The hazard associated with unwanted pregnancy if caused by mechanical failure of the device. • The need to safeguard public health through the use of condoms to reduce the prevalence of sexually transmitted diseases. • User expectation that contraceptive devices are perfectly reliable and safe despite published data to the contrary.

Reclassification of Medical Devices

Once a rules-based system has been adopted, modifications may occasionally be required. For example, where post-market experience with a particular device type suggests the classification rule recommended through this guidance document is no longer appropriate. In such a circumstance, consideration should be given to a change to the classification of the device type by a change to the rules.

Current IMDRF procedures require that all IMDRF documents be reviewed at regular intervals. Such a review of this document will provide an opportunity to change the classification of a particular device type by a changing the appropriate rule

SCHEDULE B
[see rules 11],

GROUPING OF MEDICAL DEVICES

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-vitrocluster.

(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.

Methods of grouping,—

Single Medical Device:

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.

Family

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;

Permissible Variant

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 labeling, instructions-for-use, brochures or catalogues for each constituent-component state that the constituent-component is intended for use with the system.

Set

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 labeled with that set name. Individual medical devices in the set may contain additional descriptive

phrases.

IVD-KIT

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 labeling, 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.

CLUSTER

(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 1
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/glycatedhaemoglobin; 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	Cytochemical staining; embedding, fixing,

		reagents	mounting media; stain solutions; immuno histology kits
4.	Microbiology - culture (i) cytochemical staining (ii) embedding, fixing, mounting media (iii) stain solutions (iv) immunohistology kits	Culture media	Dehydrated culture media (DCM); additives for DCM; prepared media (tubes, bottles, 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, shigellaetc.)
		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

SCHEDULE C

[see rule 63]

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.	ENLISTMENT / REGISTRATION OF MEDICAL DEVICES	Fee for enlistment of Class A medical devicefor local manufacture or importer.	5,000
		Fee for renewal of enlistment of Class A medical device for local manufacture or importer.	5, 000
		Fee for registration of Class B,C & D medical device for local manufacture.	20,000
		Fee for renewal of registration of Class B,C & D medical for local manufacture.	10, 000
		Fee for registration of Class B medical device or accessory or component for importer.	25,000
		Fee for renewal of registration of Class B medical for importer.	12,500
		Fee for registration of Class C & D medical device or accessory or component for importer.	50,000
		Fee for renewal of registration of Class C & D medical for importer.	25,000
		Fee for enlistment or registration of accessory or component for local manufacture.	5,000
		Fee for renewal enlistment or registration of accessory or component for local manufacture.	5,000
		Fee for post enlistment or registration variation	5,000
		Fee for change in particulars of enlisted or registered medical device shall be fifty percent of the registration fee.	
3.	ESTABLISHMENT LICENCES	Fee for establishment licence to manufacture medical devices.	100,000
		Fee for establishment licence to import medical devices.	20,000
		Fee for renewal of establishment licence to	50,000

		manufacture medical devices.	
		Fee for renewal of establishment 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
[33][9.	OUTSOURCING	Fee for certificate to outsource manufacturing processes of medical devices for each contract acceptor	50,000
		Fee for certificate to outsource analysis of medical devices for each contract acceptor.	50,000
		Fee for renewal of certificate to outsource manufacturing processes of medical devices for each contract acceptor	25,000
		Fee for renewal of certificate to outsource analysis of medical devices for each contract acceptor.	25,000
		Note: Fee for change in particulars of certificate shall be fifty percent of the initial fee of certificate.]	

[33] Added vide S.R.O 599(I)/2022 dated 27.04.2022

SCHEDULE D

[See Rule 52]

LIST OF LIFE SAVEING OR LIFE SUSTAINING MEDICAL DEVICES

1. CARDIOVASCULAR AND ALLIEDMEDICAL DEVICES

Sr.No	NAME OF MEDICAL DEVICE
(1)	(2)
	ELECTRO PHYSIOLOGY ITEMS
1)	PPM SINGLE & DUAL CHAMBER (COMPLETE SET) (ALL TYPE)
2)	RF Ablation Catheter (All Types)
3)	Diagnostic Catheter Quadipolar (All Type)
4)	Diagnostic Catheter Decapolar (All Type)
5)	ICD single & Dual Chamber (Complete set) (All Type)
6)	CRT (Biventricular Device) (ALL TYPE)
7)	CRT-D (Biventricular Device) (ALL Type)
8)	TPM Lead (All Type)
9)	TPM Generator (All TYPE)
10)	Cryo-Ablation Balloon and System for AFablation procedure (All Type)
11)	Mapping system for Arrhythmias (All Type)
	PEDIATRIC CARDIOLOGY
12)	ASD Device with Delivery System (All Type)
13)	PDA Device with Delivery system (All Type)
14)	VSD Device with Delivery System (All Type)
15)	PFO Device wit Delivery system (All Type)
16)	Bib Balloon (All Type)
17)	Valvoplasty Balloon including high pressure (All Type)
18)	Valvoplasty Balloon (All Type)
19)	Steptostomy Catheter (All Type)
20)	CP Stent covered and bare metal with Delivery System (All Type)
21)	CP Stent Open cell design (All Type)
22)	Sizing Balloon (All Type)
23)	Embolization coil (All Type)
24)	PVC Embolization Particles(All Type)
25)	Vascular Plug with delivery system (All Type)
26)	Glide Wire (All Type)
27)	Amplatz Wire super stiff guide wire (All Type)
28)	Amplatz Wires Extra Stiff guide wire (All Type)
29)	Snare Catheter (All Type)
30)	Noodle wire (All Type)
31)	Wedge Pressure Catheter (All Type)
	CARDIAC SURGERY & ANESTHESIA DISPOSABLES
32)	Aortic Cannula Adult/ Paed (All Types/All Sizes)
33)	Cardioplegia Retrograde & Antegrade Cannula (All Type)
34)	Arterial catheter (All Types)
35)	Central Venous Catheter (All Sizes/ Types)
36)	LV Vent Catheter (All Types)
37)	Venous Cannula Single Stage (All Sizes)

38)	Venous Cannula Two Stage (All sizes)
39)	Intra Aortic Balloon Catheter (All Type)
40)	Coronary Ostial Cannula (All Type)
41)	Coronary Ostial Cannula (All Type)
42)	Heart Valve Mechanical, Tissue, Combo & Bovine / Contegra (All Type)
43)	Oxygenator with tubing Adult/ peads/ Small Adult /Neonate (All Type)
44)	Intra Coronary Shunt (All Type)
45)	Pericardial sump Adult & Paeds (All Type)
46)	Suction Catheters (All Sizes)
47)	Annuloplasty Ring (All Type)
48)	Aortic Punch (All Type)
49)	Bone Wax (All Type)
50)	Chest Tube All Sizes (All Type)
51)	Embolectomy Catheter (All Type)
52)	Liga Clip (All Type)
53)	Octopus Heart Stabilizer (All Type)
54)	Plastic Bull dog (All Type)
55)	Surgicel (All Type)
56)	Teflon Pledget (All Type)
57)	VSD PRXH(All Type)
58)	Arterial Cascular Graft (All Type)
59)	Cardioplegia Delivery System /adult and Paed (All Type)
60)	Cardioplegiamultiperfusion adaptor (All type)
61)	Cardioplegia Y adaptor (All Type)
62)	Customized Tubing Pack All Sizes for Oxygenators with arterial filter
63)	Femoral Arterial Cannula all sizes wire reinforced (All Type)
64)	Haemofilter All sizes (All Type)
65)	Safety Suction Devices (All Type)
66)	Epicardial pacing wire with connector (All Type)
67)	Manometer Line (All Type)
68)	Heat and Moisture Exchanger (HME) Filter (All Type)
69)	Itra Cardiac Vent (All Type)
70)	Mitral Annuloplasty rings All sizes & types
ANGIOGRAPHY & ANGIOPLASTY	
71)	Femoral Radial Sheath Introducer sets with haemostatic Valve (All Type)
72)	Femoral and Radial Closure Device (All Type)
73)	Angiography Wire (All Type)
74)	PTCA Guide Wire (All Type)
75)	Pressure Wire (All Type)
76)	PTMC Balloon (All Type)
77)	Valvuloplasty Balloon (All Type)
78)	Aspiration Catheter (All Type)
79)	Diagnostic & Guiding Catheters (All Type)
80)	PTCA Guide Extension Catheter (All Type)
81)	Micro Catheter (All Type)
82)	IVUS Catheter (All Type)
83)	Broken Brough Beedle (All Type)
84)	Catheter foe ;VAD (All Type)
85)	Impella Catheter (All Type)
86)	Angiography Control Syringe (All Type)

87)	Rota Blator wire (All Type)
88)	Rota Burr (All Type)
89)	Rota Links Plus (All Type)
90)	Inflation Device (All Type)
91)	Coronary Snare (All Type)
92)	Intra aortic Balloon (All Type)
93)	IVC Filter (All Type)
94)	ACT Cartridges (All Type)
95)	Injector Syringes (All Type)
96)	Puncture Needles (All Type)
97)	Distal Protection Device (All Type)
98)	High pressure manifold (All Type)
99)	Pressure line flexible (All Type)
100)	Mullen Sheath Introducer set (All Type)
101)	Micro Puncture set (All Type)
102)	Arterial intoducer Sheaths (All Type)
103)	Peripheral Diagnostic & Guiding Catheters All sizes and All Types
104)	Peripheral angioplasty Guide Wires all sizes & all Types
105)	Peripheral Angiograpy Balloons (All Types)
106)	Peripheral Stents (All types)
107)	Coils (All Type)
108)	PVA particles (All Type)
109)	High Pressure Balloon (All Type)
110)	PTCA Balloon Semi NC (All Type)
111)	Cutting Balloon (All Type)
112)	Drug Eluting Balloon (All Type)
113)	Bare Metal Stent (All Type)
114)	Covered Stent cardiovascular (All Type)
115)	Drug Eluting Stent (DES) (All Type)
116)	Bioresorbable Stent (All Type)
117)	Bronchial stents with / without delivery system (All Type)
118)	Aortic Stent with/without delivery system (all Type)
119)	OCT / OFDI Catheters (All Type)
120)	Perfusion Balloon (all Type)
121)	Transcutaneous Pace Makers (External) (All Type)
122)	Automated CPR Devices (All Type)
123)	Thrombus Aspiration device (All Type)
124)	Intracoronary Imaging Device (All Type)
125)	Aortic Vaue for TAVI Self Expanding / Balloon expandable with accessories (All Type)
126)	Mitra Clip Device (All Type)
127)	Pulmonary artery catheter (All Type)
128)	ECMO Circuit (All Type)
129)	Pulmonary Valved Conduits (All Type)
130)	Aortic Valved Conduits (All Type)
131)	Hemostatic Glue/Powder
132)	Bovine Pericardial Pateh (All Type)
133)	TEFLON Hemostatic sheet (All Type)
134)	Hemodialysis Catheters(All Type)

[34][SCHEDULE- E

[see rule 52]

LIST OF MEDICAL DEVICES WHICH WERE PREVIOUSLY DEFINED OR DECLARED AS DRUGS UNDER THE DRUGS ACT, 1976

1. Auto-disable and disposable syringe;
2. Cannula;
3. Disposable sets for collection or transfusion of blood or giving any infusion;
4. Catheter;
5. Butterfly needle;
6. Stent;
7. Abortive and contraceptive device;
8. Surgical ligature;
9. Suture;
10. Bandage; and
11. Absorbent cotton.]

[35][SCHEDULE F

1. The Contract.--A contract shall be a written agreement which should be drawn up and accepted between the contract giver and the contract acceptor specifying their respective responsibilities relating to the manufacture and/or analysis as under:-

(a) technical aspects of the contract should be drawn up;

(b) all arrangements for manufacture and/or analysis must be in accordance with the conditions of registration or enlistment granted by MDB and agreed by both parties;

(c) the contract should specify the way that each batch has been manufactured and/or analyzed for compliance with the requirements of registration or enlistment;

(d) the contract should describe clearly who is responsible for purchasing materials, testing and releasing materials;

(e) in the case of contract analysis, the contract should state whether or not the contract acceptor should take samples at the premises of the manufacturer;

(f) manufacturing, analytical and distribution records, and reference samples should be kept by or be available to the contract giver. In the event of complaint or suspected defect, any record relevant to assessing the quality of a product must be accessible and specified in the recall procedure of the contract giver; and

(g) the contract should permit the contract giver to visit the facility of the contract acceptor.

2. Contract Acceptor.--The contract acceptor shall be a person performing manufacturing processes and/or analysis outsourced by the establishment licence holder and is responsible for the following, namely:-

(a) to successfully carry out the work outsourced under the contract by the contract giver;

(b) to have adequate premises and equipment, knowledge and experience, and competent personnel to satisfactorily carry out the work given by the contract giver;

[34] Added vide S.R.O No. 526(I)/2021 dated 30.04.2021
[35] Added vide S.R.O No. 599(I)/2022 dated 30.04.2022

(c) to ensure that all products or materials delivered to him are suitable for their intended purpose; and

(d) not to pass any of the work entrusted to him under the contract to a third party and to refrain from any activity which may adversely affect the quality of the product manufactured or analyzed for the contract giver.

3. Contract Giver.--The contract giver shall be a person possessing establishment licence and is responsible for the following, namely:-

(a) to assess the competence of the contract acceptor to successfully carry out the work assigned under the contract;

(b) to provide the contract acceptor with all the information necessary to carry out the contracted operations correctly in accordance with the requirements of registration or enlistment and legal requirements;

(c) to ensure that the contract acceptor is fully aware of challenges associated with the product or the work which might pose a hazard to his premises, equipment, personnel, other materials or other products;

(d) to ensure that all processed products and materials delivered to him by the contract acceptor comply with their specifications;

(e) to undertake major steps of production as determined by MDB, including but not limited to the final assembling and packing;

(f) to perform in-process controls;

(g) to keep samples for reference and analysis, if required;

(h) to keep records relevant to assessing the quality of a product in an event of complaint or a suspected defect or recall;

(i) to recall the expired, spurious, substandard, misbranded, counterfeit medical devices as defined by these rules; and

(j) to release the product for marketing upon the test/analysis results carried out by the contract issue final quality control report depending upon the test/analysis results carried out by the contract acceptor in case of outsourcing of analysis.

4. Outsourcing Permission Certificate.--Outsourcing Permission Certificate means a certificate issued by MDB under sub-rule (2) of rule 67.

5. Procedure for grant of certificate.--(1) Upon receipt of an application on Form-1(A) or Form-1(B) for certificate, the MDB shall consider the application and shall inspect the premises of outsourced facility to verify any information, particulars, documents and other requirements under these rules. For this purpose, the MDB may also constitute a panel of experts, which may include inspector or auditors;

(2) If satisfied with all requirements under sub-rule (2) of rule 67, including satisfactory inspection report of the premises, the MDB shall issue a certificate to outsource manufacturing processes of medical devices and/or certificate to outsource analysis of medical devices in Form-3(A) or Form-3(B), as the case may be.

(3) A certificate issued under these rules shall, unless earlier suspended or cancelled, be valid for a period of five years from the date of issuance.

(4) Contract giver shall comply with conditions of certificate.

(5) Contract acceptor shall comply with relevant conditions of certificate.

(6) If contract acceptor and/or contract giver does not comply with sub-rule (2) of rule 67, the certificate may be cancelled or suspended as the MDB may deem fit after providing the certificate holder an opportunity of being heard.

(7) The certificate 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.

(8) An application for renewal of certificate shall, sixty days before its expiry, be made to the MDB on Form-1(A) or Form-1(B), as the case may be, and shall be accompanied by the following, namely:—

(a) application fee as specified in Schedule C; and
(b) documents or information specified in Form-1(A) or Form-1(B), as the case may be.

(9) The MDB may reject an application if the contract giver fails to deposit specified fee or provide information, particulars or documents as required under sub-rule (2) of rule 67.

(10) Upon receipt of the application for renewal of certificate, the MDB shall consider the application and may inspect the premises as it considers necessary to verify information, particulars, documents and other requirements under these rules. For this purpose, the MDB may also constitute a panel of experts which may include inspectors or auditors.

(11) If satisfied with all the requirements including satisfactory inspection report of contract acceptor, the MDB may approve renewal of certificate for a further period of five years from the date of expiry of previous certificate unless earlier cancelled or suspended by the MDB.

(12) If an application for renewal is made after expiry of the period of validity of certificate, the applicant shall deposit an additional fee equivalent to applicable renewal fee for each month till one year of the expiry of the certificate and after one year the certificate shall cease to exist and the application shall be treated as a fresh application for issuance of certificate.

(13) If an application for renewal is made before the expiry of the period of validity of certificate or after expiry of the period of validity along with additional fee, the existing certificate shall continue to be valid until orders are passed on such application.

(14) If an application for renewal is made after one year of expiry of the period of validity, the contract giver and contract acceptor shall be responsible for all the illegal operations carried out during that period.

(15) In case the application for renewal of certificate is rejected by the MDB as per procedure laid down under sub-rule (3) of rule 67, it shall inform the applicant of its decision in writing with reasons of such decision.

(16) Where the MDB decides to renew an existing certificate, the renewal of certificate shall be granted on Form-3(A) or Form-3(B), as the case may be.

6.Conditions for issuance of certificate.— The following shall be conditions for issuance of certificate, namely:—

(a) the contract acceptor shall be in possession of such premises which shall be suitable for intended use in size and construction and shall be located in an appropriate area;
(b) the contract acceptor shall provide adequate space, plant and equipment for the manufacturing operations and the analysis facilities including equipment, instruments, space and documentation, as the case may be;
(c) the manufacturing and/or analysis by the contract acceptor shall be conducted under the active directions and personal supervision of competent technical staff as determined by the MDB;

(d) the contract giver shall establish an independent quality control department and maintain separate staff and adequate laboratory equipment for carrying out tests, partial or full, as the case may be;

(e) the contract giver and acceptor shall have an appropriate system of quality assurance for the intended medical devices;

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

(g) the contract acceptor shall provide,—

(i) adequate facilities for first aid and firefighting;

(ii) medical inspection of workers at the time of employment and periodical checkup 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;

(h) a contract acceptor 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;

(i) any change in the expert staff or significant alteration in the premises allowed as contract acceptor or equipment or instrument shall take place in accordance with these rules;

(j) the certificate holder 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;

(k) the certificate along with the licence and the legal agreement shall be kept in the certified premises and shall be produced on the request of any member of the MDB or the concerned Inspector;

(l) the contract acceptor shall allow any member of the MDB or an Inspector to enter the premises and to inspect the plant and the process of manufacture and /or analysis and the means employed in either of the processes and to take samples, where applicable, for test and analysis;

(m) the contract giver and acceptor shall on being informed by the MDB that any part of any batch or lot of a medical device has been found non-conforming with the requirements of these rules, withdraw the remainder of the batch or lot of such device from sale and, as the case be practicable, recall and dispose of all issues already made from that batch or lot in such manner as may be directed by the MDB;

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

(o) the contract acceptor 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.

7.Extent of Outsourcing.—(1) In case of manufacturing, thecontract giver will undertake major steps of production as determined by MDB but not limited to the final assembling and packing; and

(2) In case of analysis, the contract giver will perform in-process controls and performance evaluation, as determined by MDB.

8. Changes concerning certificate.—(1) Certificate holder shall apply to MDB for prior approval, if any change is proposed regarding the particulars provided in the certificate.

(2) Application under sub-rule (2) of rule 67 for change in particulars made on Form-1(A) or Form-1(B), as the case may be; and accompanied by the relevant application fee specified in Schedule C.

(3) Upon receipt of the application under sub-rule (2) of rule 67, the MDB shall consider the proposed change and may inspect the establishment through a panel of experts or any inspector or officer authorized by the MDB 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.

9. General Responsibilities and Obligations.— (1) Contract giver and contract acceptor shall conduct their operation in accordance with the provisions of these rules and shall comply with the conditions of enlistment or registration issued by MDB and if required by the MDB or its authorized officer, the licensee and enlistment or registration holder shall—

(a) produce the certificate, licence, certificate of enlistment or registration, as the case may be, and

(b) produce such information, documents or samples, in relation to the compliance with the requirements of these rules.

(2) A contract giver who contravenes sub-rule (2) of rule 67 shall, without prejudice to the power of the MDB to suspend or cancel his licence or enlistment or registration, is also guilty of an offence and shall on conviction be punishable under the Drug Regulatory Authority of Pakistan Act, 2012.

(3) Any letter written to the Authority or MDB by the licensee, certificate holder, enlistment or registration holder shall be signed by the proprietor or chief executive officer or managing director or director of the contract giver or firm or organization, including the name, designation and complete address with stamp and, in case of authorized officer in this behalf, shall also be accompanied by the letter of his authorization.]

[F.NO.10-1/2016-MD]