

Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
Drug Regulatory Authority of Pakistan
❦❦❦❦❦❦

Islamabad, the 20th July, 2026.

NOTIFICATION

No. F. 1-1/2026/DD-MDMC.— The following draft of the Medical Devices (Refurbishment) Regulations, 2026, which is proposed to be made by the Drug Regulatory Authority of Pakistan, with the approval of the Policy Board, in exercise of the powers conferred by section 24 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), read with rule 76 of the Medical Devices Rules, 2017, is hereby published for the information of all persons likely to be affected thereby and notice is hereby given that objections or suggestions thereon, if any, may, for consideration of the Authority, be sent within seven days of the publication of this Notification.

Any objections or suggestions which may be received from any person in respect of the said draft before expiry of the aforesaid period shall be taken into consideration by the Authority.

DRAFT MEDICAL DEVICES (REFURBISHMENT) REGULATIONS, 2026

1. Short title and commencement.— (1) These Regulations shall be called the Medical Devices (Refurbishment) Regulations, 2026.

(2) They shall come into force at once.

2. Definitions.— (1) In these Regulations, unless there is anything repugnant to the subject or context:

- (a) “Act” means the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012);
- (b) “Applicant” means a manufacturer or authorized representative;
- (c) “intended use” means the overall purpose or function of a device, encompassing its specified indications for use;
- (d) “performance specifications” means the performance characteristics of a device established by the original equipment manufacturer (OEM) for the device to perform as intended, including those listed in device labeling or in finished product release specifications. Examples include measurement accuracy, output accuracy, energy output level, and stability criteria;
- (e) “rebuild” or “recondition” or “refurbish” means restoring a medical device to the OEM’s original or current specifications without significantly changing its performance, safety specifications, or intended use. These activities include

repair of components, installation of OEM-provided updates and upgrades, and replacement of worn parts;

- (f) “refurbisher” means a person who undertakes the refurbishment of a medical device. For regulatory purposes, refurbishers may be classified into two categories:
 - (i) manufacturer; and
 - (ii) third party refurbisher;
- (g) “refurbishment certificate” means a certificate confirming that the medical device has been refurbished in accordance with Good Refurbishment Practices for Medical Devices (GRPMD) and that the refurbishment process does not significantly alter the finished device’s intended use, safety, or performance specifications;
- (h) “remanufacture” means any process, condition, renovation, repackaging, restoration, or any other act done to a finished device that significantly changes the finished device’s performance or safety specifications or intended use. Remanufacturing is not covered under the scope of these regulations;
- (i) “repair” means a type of servicing that returns a component to the OEM’s original specifications, including replacing non-working components or parts outside of preventive or routine maintenance;
- (j) “rules” means the Medical Devices Rules, 2017, as amended from time to time;
- (k) “service” means repair and/or preventive or routine maintenance of one or more parts in a finished device, after distribution, for purposes of returning it to the safety and performance specifications established by the OEM and to meet its original intended use. Servicing excludes activities that significantly change the finished device’s safety or performance specifications, or intended use;
- (l) “third party refurbisher” means any person who is authorized by the manufacturer to refurbish a medical device. If a third party refurbisher places a refurbished medical device in the market under its own name, he shall be considered a manufacturer as defined in the Medical Devices Rules, 2017;
- (m) “third party servicers and independent service organizations (ISOs)” means entities, other than the OEM or healthcare delivery organizations, that maintain, restore, refurbish, repair, or service a finished device after distribution, for purposes of returning it to the OEM’s original safety and performance specifications and to meet its original intended use; and
- (n) “used medical device” means a medical device that has been in service, taken out of service and is put back into service usually at another location.

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

3. Enlistment and registration of refurbished medical devices.— (1) The MDB shall enlist and register refurbished medical devices as defined in clause (lix-a) and (lix-b) of sub-rule (1) of rule 2 of the rules.

(2) An application for enlistment or registration of a refurbished medical device shall be made by —

- (a) an establishment having valid licence to manufacture medical devices, which may be a third party refurbisher authorized by the foreign principle for refurbishment; or
- (b) an importer in his capacity as authorized representative in Pakistan having valid establishment licence:

Provided that indenting of refurbishment of medical devices is not allowed under these regulations. Single-use and disposable medical devices shall not be refurbished. The MDB may, from time to time, adopt or issue guidelines specifying additional categories of medical devices that are prohibited from refurbishment (negative list).

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

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

(4) An application for renewal, cancellation or suspension, changes concerning the refurbished or enlisted refurbished medical device and the applicable conditions, requirements, procedures, and all other related provisions shall be applicable as specified in rules. However, the application forms specified in sub-rule (3) shall be used for submission of applications for registration/ enlistment, renewal, changes concerning thereto. Additionally, the certificate for enlistment or registration of refurbished medical devices shall be issued in the format specified in Form-8R or Form-8AR of the rules, for locally manufactured or imported refurbished medical devices, respectively under these regulations.

4. General conditions of enlistment or registration of refurbished medical device.— (1) An enlistment or registration holder shall comply with all conditions prescribed herein for the grant of certificate of enlistment or registration of refurbished medical devices, including those prescribed under the rules:

- (a) refurbishment activities shall be included in the scope of quality management system for the manufacture of medical device;

- (b) refurbishment activities shall comply with guidelines for Good Refurbishment Practices for Medical Devices (GRPMD) issued by the Authority;
- (c) each medical device shall undergo conformity assessment by Conformity Assessment Body (CAB) or may be conducted by the Authority;
- (d) labelling of a refurbished medical devices shall comply with the requirements of the rules, and shall prominently include the term "Refurbished" together with a distinct catalogue number bearing the suffix "[R]";
- (e) a Technical File shall be established and maintained, providing evidence of compliance with the Act and the rules;
- (f) a Declaration of Conformity shall be signed, confirming that the device complies with the requirements of the Act, the rules, and the laws of the country of origin (in case of import), and that refurbishment does not significantly change the finished device's performance, safety specifications, or intended use;
- (g) a technical risk assessment shall be conducted, with the final report duly signed by the relevant qualified technical person;
- (h) a test analysis report or certificate of analysis (CoA) shall be submitted, demonstrating conformity with the Act, the rules, relevant ISO standards, and the general safety and performance requirements;
- (i) local manufacturers or third-party refurbishers shall conduct a clinical evaluation and performance study for high-risk refurbished medical devices;
- (j) radiation-emitting medical devices, including X-ray machines, refurbished locally or by third-party refurbishers, shall undergo assessment by the Pakistan Nuclear Regulatory Authority (PNRA). The applicant shall submit the relevant certificate or evaluation report issued by PNRA;
- (k) in the case of a third-party refurbisher or manufacturer operating in Pakistan, the foreign principal or legal manufacturer shall designate and appoint them an Authorized Representative in Pakistan;
- (l) the manufacturing date of the main equipment intended for refurbishment shall not be more than ten (10) years prior to the date of import; and
- (m) a refurbishment certificate shall be submitted, confirming that the medical device has been refurbished in accordance with Good Refurbishment Practices for Medical Devices (GRPMD), and that the refurbishment process does not significantly alter the device's intended use, safety, or performance specifications. The certificate shall further confirm compliance with the Act, the rules, applicable ISO/IEC standards, and the General Safety and Performance Requirements (GSPR).

(2) The refurbisher shall:

- (a) employ suitably qualified, competent, and adequately trained technical personnel appropriate to the modality or type of medical device being refurbished;
- (b) establish and maintain adequate service workshops and possess calibrated testing instruments, tools, and equipment necessary for installation, preventive maintenance, calibration, and performance verification of the medical devices; and
- (c) maintain the capability to provide effective after-sales service, including technical support, maintenance, repair services, and the long-term availability of spare parts and components.

(3) An enlistment or registration holder shall also comply with any other condition which the MDB or the Authority may prescribe in the public interest.

5. Cancellation or Suspension of Refurbished Medical Devices.- (1) Before suspension or cancellation of enlistment or registration of a refurbished medical device, the MDB shall issue a show cause notice to the enlistment or registration holder of refurbished medical devices 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 the Act, rules or these regulations.

(2) The enlistment or registration holder of refurbished medical devices shall submit, in writing, reply to the show cause notice within fifteen days from the date of issuance of the notice under sub-regulation (1).

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

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

(5) Where an enlistment or registration is cancelled by the MDB pursuant to sub-regulation (4), the enlistment or registration holder of refurbished medical devices shall within fourteen days after being informed in writing of the cancellation return without demand the certificate of enlistment or registration to the MDB.

(6) A letter of cancellation shall be issued by MDB if new information is brought to the attention of the MDB indicating any of the following:

- (a) the device is unsafe to patients or users;
- (b) the situation has changed so that the benefits no longer outweigh the risks;
- (c) the MDB has reasonable grounds to believe that the applicant is using the

refurbished equipment to circumvent licensing requirements; and

- (d) the device is no longer needed to treat the patient, or the licensee refuses to supply the authorized medical device.

6. Fee for various activities. — (1) The fee as notified by the Authority under the Drug Regulatory Authority of Pakistan (Fee and Levy) Rules, 2022 shall be payable in respect of an activity performed under these regulations.

- (2) Any fee deposited shall in no case be refunded.

7. Application of the rules.— These regulations shall apply in addition to, and not in derogation of, the rules. Unless otherwise provided, the definitions, procedures, requirements, and provisions of the rules shall apply *mutatis mutandis* to the refurbished medical devices.



DRUG REGULATORY AUTHORITY OF PAKISTAN

FORM-6B

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

APPLICATION FORM FOR REGISTRATION OR RENEWAL OF REFURBISHED CLASS A MEDICAL DEVICE OR ACCESSORY 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 local manufacture, namelydetails of which are mentioned below along with enclosures.

Sr. No.	Description	Particular to be filled by applicant
1.	Purpose of application, whether;	
(i)	For Refurbished Class A medical device or accessory	
(ii)	Proposed change of any particular of an enlisted medical device (in case of any proposed change, please mention details of change	
(iii)	Name of the legal entity that would be responsible for the refurbishment of medical device	
(iv)	Full Address of the legal entity that would be responsible for the refurbishment of medical device	
(v)	Type of an applicant (the particular role),	
(vi)	Establishment license number	
(vii)	Name of the particular responsible person, his/her designation and contact details (phone number and email address),	
2.	Product Details	Please provide detail against each where applicable
(i)	Names of the device and the brand as indicated in the labeling (the appropriate table should be filled in case if several devices are included in one submission),	
(ii)	Brief description of the device,	
(iii)	Intended use of the device as initially defined by the manufacturer	
(iv)	Indication of the particular type of the device (general or in-vitro diagnostic), and of the class under the risk-based classification	
(v)	Medical device brand name:	
(vi)	Medical device generic name:	
(vii)	Does the medical device contain any active ingredient, poison or drug?	
(viii)	HS code for the medical device, if applicable:	
(ix)	Codes in accordance with the Medical Device Nomenclature (e.g. GMDN, HS, UMDNS or other codes),	
(x)	Shelf life:	
(xi)	Proposed MRP of medical device:	

(xii)	Storage condition:	
(xiii)	Is the medical device for export only?	
(xiv)	Proof of fee deposited:	
(xv)	Complete description of the medical device with intended use;	
(xvi)	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;	
(xvii)	Description or complete list of the various configurations of the medical device to be registered	
(xviii)	Complete description of the key functional elements, its formulation, its composition and its functionality;	
(xix)	Indications that the device will diagnose, treat, prevent, cure or mitigate;	
(xx)	Contraindications;	
(xxi)	Warnings to inform on specific risk or hazard that a user needs to know before using the medical device;	
(xxii)	How old is the equipment?	
(xxiii)	Who is the original manufacturer?	
(xxiv)	Name of the foreign principle / manufacture. Attach Notarized LOA	
(xxv)	Indication of the number of medical devices available	
(xxvi)	New lot/batch number assigned to the device by the entity performing the refurbishment	
(xxvii)	Information on the grouping of the device in accordance with the Medical Device Regulation	
3.	As applicable, attach documentation on software validation studies to verify that the device works as intended previously. (correctness of software in medical device). The document shall include the results of all verification, validation and testing performed prior to final release.	
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 soft copy along with application in USB/CD.
- Catalogs or other printed materials containing the information regarding the initial intended purpose of the device, and also the general description of the device itself and the way it operates
- The label of the device indicating that it has been refurbished and the refurbishment date,
- Implementation Good Refurbishment Practices and Maintenance management system, audited through DRAP inspectors



DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-7C

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

**APPLICATION FORM FOR REGISTRATION OR RENEWAL OF
REFURBISHED CLASS B, C & D MEDICAL DEVICE OR ACCESSORY 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	
	(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:	
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:		
For Class B & C Medical Devices			
(xiii)	*	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/any European Country duly attested by Embassy of Pakistan/ Apostille where applicable and CE certificate/ Production Quality Assurance certificate/ Full quality assurance certificate duly notarized in the country of origin. OR FSC from reference countries [<u>as mentioned in rule 15(2) of the MDR 2017</u>] duly attested by Embassy of Pakistan/ Apostille where applicable.	
(xv)	*	Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized in the country of origin:	
For Class D			
(xvi)	*	Agency agreement/Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin	
(xvii)	*	Free sale certificate in the country of origin	
(xviii)	*	Free sale certificate in reference countries [<u>as mentioned in rule 15(2) of the MDR 2017</u>] duly attested by Embassy of Pakistan/ Apostille or CE Certificate (Design Examination Certificate) / <u>EU Technical documentation assessment certificate duly notarized</u> in the country of origin	
(xix)	*	Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized in the country of origin:	
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)	Brief Description of the Medical Device	
(vii)	Sample of labels of the medical device, brochure and its packaging;	
(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.	
(x)	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.
- Catalogs or other printed materials containing the information regarding the initial intended purpose of the device, and also the general description of the device itself and the way it operates



DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-6C

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

**APPLICATION FORM FOR REGISTRATION OR RENEWAL OF
REFURBISHED CLASS B, C & D MEDICAL DEVICE OR ACCESSORY
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
2.	Purpose of application, whether;	
(viii)	For Refurbished Class A medical device or accessory	
(ix)	Proposed change of any particular of an enlisted medical device (in case of any proposed change, please mention details of change)	
(x)	Name of the legal entity that would be responsible for the refurbished medical device	
(xi)	Full Address of the legal entity that would be responsible for the refurbished medical device	
(xii)	Type of an applicant (the particular role),	
(xiii)	Establishment license number	
(xiv)	Name of the particular responsible person, his/her designation and contact details (phone number and email address),	
7.	Product Details	Please provide detail against each where applicable
(xxvii)	Names of the device and the brand as indicated in the labeling (the appropriate table should be filled in case if several devices are included in one submission),	
(xxix)	Brief description of the device,	
(xxx)	Intended use of the device as initially defined by the manufacturer	
(xxxi)	Indication of the particular type of the device (general or in-vitro diagnostic), and of the class under the risk-based classification	
(xxxii)	Medical device brand name:	
(xxxii)	Medical device generic name:	
(xxxiv)	Does the medical device contain any active ingredient, poison or drug?	
(xxxv)	HS code for the medical device, if applicable:	
(xxxv)	Codes in accordance with the Medical Device Nomenclature (e.g. GMDN, HS, UMDNS or other codes),	
(xxxv)	Shelf life:	
(xxxv)	Proposed MRP of medical device:	

(xxxix)	Storage condition:	
(xl)	Is the medical device for export only?	
(xli)	Proof of fee deposited:	
(xlii)	Complete description of the medical device with intended use;	
(xliii)	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;	
(xliv)	Description or complete list of the various configurations of the medical device to be registered	
(xlv)	Complete description of the key functional elements, its formulation, its composition and its functionality;	
(xlvi)	Indications that the device will diagnose, treat, prevent, cure or mitigate;	
(xlvii)	Contraindications;	
(xlviii)	Warnings to inform on specific risk or hazard that a user needs to know before using the medical device;	
(xlix)	How old is the equipment?	
(l)	Who is the original manufacturer?	
(li)	Name of the foreign principle / manufacture. Attach Notarized LOA	
(lii)	Indication of the number of medical devices available	
(liii)	New lot/batch number assigned to the device by the entity performing the refurbishment	
(liv)	Information on the grouping of the device in accordance with the Medical Device Regulation	
8.	As applicable, attach documentation on software validation studies to verify that the device works as intended previously. (correctness of software in medical device). The document shall include the results of all verification, validation and testing performed prior to final release.	
9.	Sample of labels on the medical device and its packaging;	
(v)	Instructions for installation and maintenance, if applicable;	
(vi)	Promotional material and product brochures. If any	
(vii)	Sample of labels on the medical device and its packaging;	
(viii)	Provide complete documentation related to the manufacturing and quality control processes.	
10.	Grouping of medical device:	
	Specify medical device grouping applicable to the medical device:	
	List the constituent-components or medical devices that are grouped together:	
11.	Any other relevant information that may be required by the MDB.	

DECLARATION

Certified that the documents and information provided herein are genuine and correct and if found at any stage to be misrepresenting or incorrect it shall lead to 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
- Catalogs or other printed materials containing the information regarding the initial intended purpose of the device, and also the general description of the device itself and the way it operates



DRUG REGULATORY AUTHORITY OF PAKISTAN

FORM-7B

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

APPLICATION FORM FOR ENLISTMENT OR RENEWAL OF REFURBISHMENT OF CLASS A MEDICAL DEVICE OR ACCESSORY 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 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:	
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)	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) *	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/ Apostilled .							
(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:							
	<table border="1"> <tr> <td>Single</td> <td>Set</td> <td>Family</td> <td>System</td> <td>Kit</td> <td>Cluster</td> </tr> </table>	Single	Set	Family	System	Kit	Cluster	
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.
- Catalogs or other printed materials containing the information regarding the initial intended purpose of the device, and also the general description of the device itself and the way it operates

[No. F. 1-1/2026/DD-MDMC]

AAMAR LATIF,
Director (Legal Affairs).