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

Islamabad, the 1st September, 2026.

NOTIFICATION

S.R.O. 1450(I)/2026.– 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, the Drug Regulatory Authority of Pakistan, with the prior approval of the Policy Board, is pleased to make the following Regulations, namely:-

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) "applicant" means a licensed manufacturer or importer who is a designated Authorized Representative in Pakistan acting on behalf of an accredited foreign legal refurbisher;

(b) "end-of-service-life (EOSL)" means the official declaration issued by an Original Equipment Manufacturer (OEM) or qualified entity defining the date after which technical support, original spare parts, or safety updates are no longer guaranteed for a specific device model;

(c) "Good Refurbishment Practices for Medical Devices (GRPMD)" means the quality assurance system and operational guidelines, aligning with relevant international standards as adopted by the Authority;

(d) "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;

(e) "remanufacture" means any process, renovation, re-design, or modification done to a finished device that significantly alters its original performance, safety

specifications, clinical mechanism, structural design, or intended use. Remanufacturing falls outside the scope of these regulations and shall be governed under the general manufacturing provisions of the rules;

(f) "rules" means the Medical Devices Rules, 2017, as amended from time to time;

(g) "third party refurbisher" means any person who is authorized by the manufacturer to refurbish a medical device in accordance with GRPMD; and

(h) "used medical device" means a medical device that has been previously commissioned, placed into clinical service, and subsequently decommissioned or taken out of service for restoration prior to being put back into clinical use and is not a refurbished medical device under the rules and regulations.

(2) The words and expressions used but not defined herein shall have the same meanings as assigned to them in the DRAP 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 manufacturer or OEM for refurbishment; or

(b) an importer in his capacity as authorized representative in Pakistan having valid establishment licence:

Provided that single-use, implantable and disposable medical devices shall not be refurbished. The Authority 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-regulation (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-1R or Form-2R for enlistment of Class-A refurbished medical devices for local manufacture or import, as the case may be; or

(b) application as set out in Form-3R or Form-4R for registration of Class B, C or D refurbished medical devices for local manufacture or import, as the case may be.

(4) The procedure for enlistment or registration or renewal or change concerning the enlisted or registered refurbished medical device shall be in accordance with the rules and regulations. However, the application forms specified in sub-regulation (3) shall be used for submission of application for enlistment or registration or renewal or changes concerning thereto. Furthermore, the certificate for enlistment or registration of refurbished medical devices shall be issued in the format specified in Form-5R or Form-6R of the regulations for local manufacture or import, as the case may be.

4. General conditions of enlistment or registration of refurbished medical device.— (1) An establishment license holder shall comply with all conditions prescribed herein and under the rules:

(a) the refurbishing facility shall maintain an established Quality Management System certified under relevant international standards as adopted by the Authority covering "Refurbishment of Medical Devices" within its scope;

(b) the refurbisher shall comply with guidelines for Good Refurbishment Practices for Medical Devices (GRPMD);

(c) the labelling of a refurbished medical device shall comply with the requirements of the rules, and shall prominently include the term "Refurbished" on the medical device. The device shall be printed with new distinct catalogue/code number on the label depicting the device as refurbished medical device. The label shall state the name and address of the legal refurbisher, establishment license number, the original manufacturing date, the refurbishment date, ensuring full unit traceability;

(d) a Technical File for each refurbished product model shall be established and maintained including but not limited to OEM intended use and performance baseline documentation, Risk Management File, Software verification and validation report for active software components (if applicable), Traceability records of all replaced sub-assemblies and critical parts, Essential Principles / General Safety and Performance Requirements (GSPR), etc.;

(e) a declaration of conformity shall be produced 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;

(f) a test or analysis report or certificate of analysis (CoA) shall be submitted, demonstrating conformity with the international standards, and the general safety and performance requirements;

(g) all radiation-emitting locally refurbished medical devices shall undergo radiological calibration by the Pakistan Nuclear Regulatory Authority (PNRA before final Quality Control (QC) batch release file by the local refurbisher.

(h) in the case of a third-party refurbisher or manufacturer operating in Pakistan, the foreign manufacturer or legal manufacturer shall designate and appoint them an Authorized Representative in Pakistan for refurbishment;

(i) all refurbished medical devices shall conform to the age profiling as per guidelines issued by the Authority; and

(j) a refurbishment certificate issued by the refurbisher 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 local 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 DRAP Act and 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) The enlistment or registration under these regulation may be suspended or cancelled by the MDB due to reasons including but not limited to the following:

(a) the refurbished medical device is unsafe to patients or users; or

(b) the situation has changed and the benefits no longer outweigh the risks; or

(c) the MDB is of the opinion that the enlistment or registration holder is not complying these regulations and applicable conditions; or

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

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

(f) it is necessary in the public interest to do so.

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

(2) The Authority may, on the recommendation of MDB, add or omit any Form or amend Forms so as to omit any entry therefrom, add any entry thereto or amend any entry therein.



DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-1R
[See regulation 3(3)(a)]

APPLICATION FORM FOR ENLISTMENT OR RENEWAL OF REFURBISHED CLASS A MEDICAL DEVICE 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 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)	For Refurbished Class A medical device	
(ii)	For renewal of medical device	
(iii)	Proposed change of any particular of an enlisted medical device (in case of any proposed change, please mention details of change	
(iv)	Name and address of the legal entity that would be responsible for the refurbishment of medical device.	
(v)	Establishment license number	
(vi)	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)	Brief description of the device,	
(ii)	Intended use of the device	
(iii)	Indication of the particular type of the device (general or in-vitro diagnostic), and of the class under the risk-based classification	
(iv)	Name and address of the original equipment manufacturer?	
(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)	GMDN or HS Codes if any.	

(x)	Date of manufacturing of the original medical device	
(xi)	The service life of the original medical device.	
(xii)	Refurbishment date.	
(xiii)	New Shelf life/ Service life of the refurbished medical device:	
(xiv)	The label of the device indicating refurbishment	
(xv)	Proposed MRP of medical device :	
(xvi)	Storage condition:	
(xvii)	Is the medical device for export only?	
(xviii	Proof of fee deposited:	
(xix)	Complete description of the medical device	
(xx)	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;	
(xxi)	Description or complete list of the various configurations of the medical device to be registered	
(xxii)	Complete description of the key functional elements, its formulation, its composition and its functionality;	
(xxiii	Contraindications;	
(xxiv	Warnings to inform on specific risk or hazard that a user needs to know before using the medical device;	
(xxv)	Attach Notarized letter of authorization (LOA) from legal manufacturer/ foreign principal for the purpose of refurbishment.	
(xxvi	Old catalogue/ code/model number of the original medical device	
(xxvi	New catalogue/ code/model number assigned to the device by the refurbisher .	
(xxvi	Refurbishment certificate	
(xxix	Declaration of conformity (DOC) as mentioned in the regulation	
(xxx)	PNRA report/ certificate in case of radiation emitting device.	
(xxxi	Technical File as mentioned in the regulations as applicable.	
(xxxi	Information on the grouping of the device in accordance with the Medical Device Rules	
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……..

DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-2R
[See regulation 3(3)(a)]

APPLICATION FORM FOR ENLISTMENT OR RENEWAL OF REFURBISHED CLASS A MEDICAL DEVICE 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 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 for enlistment	
(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)	Date of manufacturing of the original medical device	
	The service life of the original medical device.	
	Refurbishment date.	
	New Shelf life/ Service life of the refurbished medical device supported with stability studies, where applicable::	
	The label of the device indicating refurbishment	
	Name and address of the original equipment manufacturer?	
(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/ duly notarized from the country of origin.	
(xi) *	Free sale certificate in the country of origin duly attested by Embassy of Pakistan/ Apostille.	
(xii) *	In case of life saving/ life sustaining / sterile medical device/ measuring medical device Free Sale certificate of reference countries [as mentioned in rule 15(2) of the MDR 2017] duly attested by Embassy of Pakistan/ Apostille OR WHO prequalified, then WHO prequalification report/evidence OR CE certificate/ Production Quality Assurance certificate/ Full quality assurance 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 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)	Essential principle of safety and performance.	
(viii) *	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.	
(ix)	Old catalogue/ code/model number of the original medical device	
(x)	New catalogue/ code/model number assigned to the device by the refurbisher .	
(xi)	Refurbishment certificate	
(xii)	Technical File as mentioned in the regulations as applicable.	
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.....

DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-3R
[See regulation 3(3)(b)]

APPLICATION FORM FOR REGISTRATION OR RENEWAL OF REFURBISED CLASS B, C& D MEDICAL DEVICE 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 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)	For Refurbished Class B,C or D medical device	
(ii)	For renewal of registration	
(iii)	Proposed change of any particular of an enlisted medical device (in case of any proposed change, please mention details of change	
(iv)	Name and address of the legal entity that would be responsible for the refurbishment of medical device.	
(v)	Establishment license number	
(vi)	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)	Brief description of the device,	
(ii)	Intended use of the device	
(iii)	Indication of the particular type of the device (general or in-vitro diagnostic), and of the class under the risk-based classification	
(iv)	Name and address of the original equipment manufacturer?	
(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)	GMDN or HS Codes if any.	

(x)	Date of manufacturing of the original medical device	
(xi)	The service life of the original medical device.	
(xii)	Refurbishment date.	
(xiii)	New Shelf life/ Service life of the refurbished medical device:	
(xiv)	The label of the device indicating refurbishment	
(xv)	Proposed MRP of medical device :	
(xvi)	Storage condition:	
(xvii)	Is the medical device for export only?	
(xviii	Proof of fee deposited:	
(xix)	Complete description of the medical device	
(xx)	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;	
(xxi)	Description or complete list of the various configurations of the medical device to be registered	
(xxii)	Complete description of the key functional elements, its formulation, its composition and its functionality;	
(xxiii	Contraindications;	
(xxiv	Warnings to inform on specific risk or hazard that a user needs to know before using the medical device;	
(xxv)	Attach Notarized letter of authorization (LOA) from legal manufacturer/ foreign principal for the purpose of refurbishment.	
(xxvi	Old catalogue/ code/model number of the original medical device	
(xxvi	New catalogue/ code/model number assigned to the device by the refurbisher .	
(xxvi	Refurbishment certificate	
(xxix	Declaration of conformity (DOC) as mentioned in the regulation	
(xxx)	PNRA report/ certificate in case of radiation emitting device.	
(xxxi	Technical File as mentioned in the regulations as applicable.	
(xxxi	Information on the grouping of the device in accordance with the Medical Device Rules	
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……

DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-4R
[See regulation 3(3)(b)]

APPLICATION FORM FOR REGISTRATION OR RENEWAL OF REFURBISHED CLASS B, C & D MEDICAL DEVICE 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 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 for registration	
(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 / refurbisher 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)	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 whether Class B, Class C or Class D	
(viii)	Proposed MRP of medical device:	
(ix)	Storage condition:	
(x)	Is the medical device for export only?	
(xi)	Proof of fee deposited:	
(xii)	Date of manufacturing of the original medical device	
(xiii)	The service life of the original medical device.	
(xiv)	Refurbishment date.	
(xv)	New Shelf life/ Service life of the refurbished medical device supported with stability studies, where applicable::	
(xvi)	Name and address of the original equipment manufacturer?	
(xvii)	Old catalogue/ code/model number of the original medical device	
(xviii)	New catalogue/ code/model number assigned to the device by the refurbisher .	
(xix)	Refurbishment certificate	
(xx)	Technical File as mentioned in the regulations as applicable.	
For Class B & C Medical Devices		
(xxi) *	Agency agreement/Letter of Authorization from legal manufacturer/ OEM duly notarized from the country of origin.	
(xxii) *	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 [**as mentioned in rule 15(2) of the MDR** 2017] duly attested by Embassy of Pakistan/ Apostille where applicable.	
(xxiii) *	Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized in the country of origin:	
For Class D		

(xxiv) *	Agency agreement/Letter of Authorization from legal manufacturer/ OEM duly notarized from the country of origin.	
(xxv) *	Free sale certificate in the country of origin	
(xxvi) *	Free sale certificate in reference countries [**as mentioned in rule 15(2) of the MDR** 2017] duly attested by Embassy of Pakistan/ Apostille or CE Certificate (Design Examination Certificate) / **EU Technical documentation assessment certificate duly notarized** in the country of origin	
(xxvii) *	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 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 indicating refurbishment, brochure and its packaging;	
(viii)	Essential principle of safety and performance.	
(ix)	Description of the medical device with intended use, indications, contraindications; novel features, if any. Provide instructions for use / manual;	
(x) *	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.	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……



DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-5R
[See regulation 3(4)]

CERTIFICATE OF ENLISTMENT OR REGISTRATION OF A REFURBISHED MEDICAL DEVICE FOR LOCAL MANUFACTURE

Licence No. _____
Date of issue: _____

M/s……..

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

Enlistment/ Registration No.	Name of medical device along with model/code number	Brief description	Class	Shelf life/ service 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 and regulations made there-under.

Secretary
Medical Device Board
Seal

DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-6R
[See regulation 3(4)]

CERTIFICATE OF ENLISTMENT OR REGISTRATION OF A REFURBISHED MEDICAL DEVICE FOR IMPORT

Licence No. _____
Date of issue: _____

M/s……..

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

Enlistment or Registration No.	Name of medical device along with model/code number	Brief description	Class	Shelf life/ service 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 and regulations made there-under.

Secretary
Medical Device Board
Seal

[No. F.13-3/2026-LA]

AAMAR LATIF,
Director (Legal Affairs).

The Manager,
Printing Corporation of Pakistan Press,
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