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:	
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)	Detail of manufacturing and quality control processes.	
(vii)	Class of medical device or accessory or component whether Class B, Class C or Class D	
(viii)	Shelf life supported with stability studies:	
(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 from 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.	
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 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 with intended use;	
(x)	Specimen of Label as approved in country of origin	
(xi)	Essential principle of safety and performance.	
(xii)	Declaration of conformity (DoC):—Please attach the complete, signed and attested DoC. The DoC need to be printed on the manufacturer's letterhead, filled and signed by the responsible person.	
(xiii)	Description of the medical device with intended use;	
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 Medical Devices Rules, 2017.		
6.	**Technical Information**	
(i)	Complete description of the medical device with intended use;	
(ii)	Explanation of novel features, if any;	
(iii)	Indications that the device will diagnose, treat, prevent, cure or mitigate;	
(iv)	Contraindications;	
(v)	Warnings to inform on specific risk or hazard that a user needs to know before using the medical device;	
(vi)	**sample of labels on the medical device and its packaging;**	
(vii)	Instructions for installation and maintenance, if applicable;	
(viii)	Any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform, if applicable. And	
(ix)	Promotional material and product brochures.	
(x)	Sample of labels on the medical device and its packaging;	
(xi)	Information on validation for medical devices with sterile or with measuring function, where applicable:	
(xii)	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)	Information on validation for medical devices with sterile or with measuring function, where applicable:	
(vi)	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	
(vii)	Attach the report or certification containing information on the objectives, methodology, results, discussion and conclusions of the pre-clinical physical tests conducted on the medical device,	
(viii)	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.