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;**	
(i)	Instructions for installation and maintenance and usage, if applicable;	
(ii)	Information on validation for medical devices with sterile or with measuring function, where applicable:	
(iii)	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.