DRUG REGULATORY AUTHORITY OF PAKISTAN

[Form-7 rule 14(2)(b), 16(1), and 17(2)]

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

Sr.#	DESCRIPTION	SELECT (YES/NO/NA)
1.	**Application on Form-7** (Duly signed & stamped)	
i	New Application	
ii	For renewal (copy of registration letter and last renewal attached)	
iii	Provided the Change of any particular of a registration (in case of any proposed change).	
2.	**Proof of fee deposited:** (endorsed by Statistical officer.)	
3.	Attach copy of valid establishment license to manufacture MD.	
4.	**Product Detail:**	
i	Provided the Medical device brand & generic name.	
ii	Provided the MD contain any active ingredient/poison/drug;	
iii	Provided the class of MD with relevant rules;	
iv	Provided the HS code/ GMDN code.	
v	Provided the shelf-life & storage conditions, i.e., justified with stability studies:	
vi	Provide complete details of manufacturing and QC processes.	
vii	Provided the Proposed MRP of medical device:	
viii	Provided the medical device is for export or to be placed only in local market?	
ix	Provided the complete description with intended use, Key functional elements, formulation & composition with functionality:	
x	Provided the Description of the accessories, other MD and other products that are not medical devices, intended to be used in combination with:	
xi	Provided the complete list of various configurations to be registered;	
xii	Provided the Explanation of novel features, if any;	
xiii	Provided the Contraindications & Warnings to use medical device;	
xiv	Attached the documentation on software validation studies to verify the correctness of software, shall include the results of all verification, validation and testing performed prior to final release. (Active medical devices.)	
5.	**Following info. to be provided for MD containing biological material:**	
i	Provided the list of all materials of animal, human, microbial or recombinant origin used in the MD 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	Provided the details concerning the selection of sources or donors;	
iii	Provided the details of the harvesting, processing, preservation, testing and handling of tissues, cells and substances;	
iv	Provided the full description of the system for record keeping allowing traceability from sources to the finished medical device.	
6.	**Sample of labels on the medical device and its packaging;**	
i	Provided the Instructions for installation and maintenance and usage;	
ii	Provided the Information on validation for medical devices with sterile or with measuring function, where applicable:	
iii	Provided the Grouping of medical devices:	
iv	Provided list of MDs/ constituents-components that are grouped together:	
7.	Provided the DECLARATION (on stamp paper) as per Form-7.	
8.	Provide readable softcopy along with application in USB/CD.	