DRUG REGULATORY AUTHORITY OF PAKISTAN

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

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

Sr.#	DESCRIPTION	SELECT (YES/NO/NA)
1.	**Application on Form-7A** (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 registered MD (in case of any proposed change).	
2.	**Proof of fee deposited:** (endorsed by Statistical officer.)	
3.	**Details of importer:** (Attach copy of valid establishment license)	
(i)	Provided the Name & particulars of responsible persons:	
(ii)	Provided the details of any change in establishment licence:	
4.	**Manufacturer Detail:**	
(i)	Provided the details of the manufacturer, that include complete address, telephone number, fax number, official website etc.:	
(ii)	Provided the manufacturing process of a MD consists of number of sub-assembly processes at different manufacturing sites with details:	
(iii)	Provided the multiple sites manufacture the same product, details of each sites including design and manufacturing activities:	
(iv)	Provided the credentials of manufacturer abroad duly notarized from the country of origin.	
5.	**Product details**	
(i)	Provided the Medical device brand & generic name.	
(ii)	Provided the HS code/ GMDN code.	
(iii)	Provided that the MD contain any active ingredient, poison or drug;	
(iv)	Provided the details of manufacturing and quality control processes.	
(v)	Provided the class of MD with relevant rules;	
(vi)	Provided the shelf-life & storage conditions, i.e., justified with stability studies:	
(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 Original Agency agreement or letter of authorization from manufacturer (legal) / owner or market authorization holder (MAH) or its authorised distributer, containing name and complete address of manufacturer, product or category of medical device(s) for which sole authorization is given, validity of agreement, duly notarized by the country of origin:	
(x)	Provided the Free sale certificate in the country of origin duly attested by Embassy of Pakistan.	
(xi)	Provided the Original and valid free sale certificate of any RRA as per rule 67 duly attested by embassy of Pakistan.	
(xii)	Provided the Grouping of medical devices:	
(xiii)	Provided list of MD, constituents-components that are grouped together:	
(xiv)	Provided the description of accessories, other medical devices or products that are not MD, are intended to be used in combination with:	
(xv)	Provided the complete list of various configurations to be registered;	
(xvi)	Provided the Complete description with intended use, Key functional elements, formulation & composition with functionality:	
(xvii)	Provided the Production Quality Management System Certificate (ISO 13485)/ GMP	

	Certificate duly notarized by the country of origin:	
(xviii)	Provided the Full QA certificate or equivalent, duly notarized by the country of origin:	
(xix)	Provided the Design examination certificate (if applicable), duly notarized by the country of origin	
(xx)	Provided the Essential principle of safety and performance.	
(xxi)	Provided the Declaration of conformity (DoC) to be printed on manufacturer letterhead, filled and duly signed by responsible person.	
(xxii)	Provided label (as approved in the country of origin) and its packaging, promotion material and brochure:	
From this onward, information is only applicable for those medical devices not approved or allowed for free sale in RRA as mentioned in rule-67.		
6.	**Technical Information**	
(i)	Provided the Explanation of novel features, if any;	
(ii)	Provided the Contraindications & Warnings to inform on specific risk or hazard to use medical device;	
(iii)	Provided the instruction for use (IFU).	
(iv)	Provided the Information on validation for medical devices with sterile or with measuring function,	
7.	Attached the 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. **(For active medical devices.)**	
(i)	Provided the Instructions for installation and maintenance;	
8.	**As applicable, following information to be provided on medical devices containing biological material:**	
(i)	Provided the 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)	Provided the Detailed information of the selection of sources or donors;	
(iii)	Provided the Detailed information on harvesting, processing, preservation, testing and handling of tissues, cells and substances;	
(iv)	Provided the Process full description of system for record keeping allowing traceability from sources to the finished medical device.	
(v)	Provided the Report or certificate containing information on objectives, methodology, results, discussion and conclusions of biocompatibility tests conducted on materials used.	
(vi)	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.	
(vii)	Provided the Information on validation for medical devices with sterile or with measuring function, where applicable:	
9.	Provided the DECLARATION (on stamp paper) as per Form-7A.	
10.	Provide readable softcopy of application in USB/CD.	