



DRUG REGULATORY AUTHORITY OF PAKISTAN

[Form-6 rule 14(2)(a), 16(1), and 17(2)]

CHECKLIST FOR ENLISTMENT OR RENEWAL OF CLASS-A MEDICAL DEVICE OR ACCESSORY OR COMPONENT FOR LOCAL MANUFACTURE.

Sr.#	DESCRIPTION	SELECT (YES/NO/NA)
1.	Application on Form-6 (Duly signed & stamped)	
i.	New Application	
ii.	For Renewal purpose (copy of enlistment certificate & last renewal)	
iii.	Provide the details of change of any particular of enlisted MD (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 that the MD contain any active ingredient, poison or drug;	
iii.	Provided the HS code/ GMDN code.	
iv.	Provided the Shelf life & Storage condition:	
v.	Provided the Proposed MRP of medical device:	
i.	Provide the details of manufacturing & QC processes.	
ii.	Provided the medical device only for export or to be placed in local market?	
iii.	Provided the complete description, Key functional elements, formulation & composition with functionality:	
iv.	Provided the Description of accessories, other MD and other products that are not MD intended to be used in combination;	
v.	Provided the List of various configurations to be registered;	
vi.	Provided the Explanation of novel features, if any;	
vii.	Provided the Indications (Diagnose, treat, prevent, cure/ mitigate);	
viii.	Provided the Contraindications & Warnings to inform on specific risk or hazard to use medical device;	
ix.	If Active MD , attach 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.	
x.	Provided the Instructions for installation and maintenance.	
xi.	Provided the Sample of labels and its packaging;	
xii.	Provided the Promotional material and product brochures.	
5.	Provided the Grouping of medical devices:	
i.	Provided List of constituent/components/ MD are grouped together.	
6.	Provided the DECLARATION (on stamp paper) as per Form-6.	
7.	Provided the readable softcopy along with application in USB/CD.	