DRUG REGULATORY AUTHORITY OF PAKISTAN

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

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

Sr.#	DESCRIPTION	SELECT (YES/NO/NA)
1.	**Application on Form-6A (Duly signed & stamped)**	
i	New Application.	
ii	For Renewal Purpose (copy of enlistment letter & last renewal.)	
iii	Provided the Change of any particular of an enlisted 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 (approved) in establishment licence:	
4.	**Manufacturer Detail:**	
i	Provided the details of the manufacturer, that include complete address, telephone number, fax number and its official website:	
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:	
5.	**Product Detail:**	
i.	Provided the Medical device brand & generic name.	
ii.	Provided the HS code/ GMDN code.	
iii.	Provided the shelf-life & storage conditions, i.e., justified with stability studies:	
iv.	Provided the Proposed MRP of medical device:	
v.	Provided the medical device only for export or to be placed in local market?	
vi.	Provided the MD contain any active ingredient/poison/drug;	
vii.	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:	
viii.	Provided the Free sale certificate in the country of origin duly attested by Embassy of Pakistan.	

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ix.	Provided the Original and valid free sale certificate of any RRA as per rule 67 duly attested by Embassy of Pakistan.	
x.	Provided the Grouping of medical devices:	
xi.	Provided list of MDs, constituents-components that are grouped together:	
xii.	Provided the description of the accessories, other medical devices and other products that are not medical devices which are intended to be used in combination with:	
xiii.	Provided the complete list of various configurations to be registered;	
xiv.	Provided the Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized by the country of origin:	
xv.	Provided the Full QA certificate or equivalent, duly notarized by the country of origin.	
xvi.	Provided the Essential principle of safety and performance.	
xvii.	Provided the Declaration of conformity (DoC) to be printed on manufacturer letterhead, filled and duly signed by responsible person.	
6.	**Technical Information**	
i.	Provided the Complete description, Key functional elements, formulation & composition with functionality:	
ii	Provided the Indications (Diagnose, treat, prevent, cure/ mitigate);	
iii	Provided the explanation of novel features:	
iv	Provided the Contraindications & Warnings to use medical device;	
v.	Provide the details of manufacturing and quality control processes.	
vi	Provided the sample of labels and its packaging;	
7.	Provided the DECLARATION (on stamp paper) as per Form-6A.	
8.	Provided the readable softcopy along with application in USB/CD.	

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