

GOVERNMENT OF PAKISTAN  
Ministry of National Health Services, Regulations and Coordination  
(Drug Regulatory Authority of Pakistan)

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Islamabad, the 18<sup>th</sup> March, 2022.

NOTIFICATION

**S.R.O. 430(I)/2022.**— In exercise of the powers conferred by sub-rule (3) of rule 63 of the Medical Devices Rules, 2017, the Drug Regulatory Authority of Pakistan, on the recommendation of the Medical Devices Board, is pleased to make the following amendments in Form 6A and Form 7A of the Medical Devices Rules, 2017, namely:—

In the aforesaid Rules,—

(I) for Form 6A, the following shall be substituted, namely;-



“DRUG REGULATORY AUTHORITY OF PAKISTAN  
FORM-6A

[See rule 14(2)(a), 16(1) and 17(2)]

**APPLICATION FORM FOR ENLISTMENT OR RENEWAL OF CLASS A  
MEDICAL DEVICE OR ACCESSORY OR COMPONENT FOR IMPORT**

I [name and designation] ..... of M/s ..... hereby apply for enlistment or renewal of enlistment or proposed change of any particular of enlisted Class A medical device or accessory or component for import, namely ....., manufactured by M/s ..... located at ..... details of which are mentioned below along with enclosures.

Sr. No.	Description	Particular to be filled by applicant
1.	<b>Purpose of application, whether;</b>	
(i)	Fresh/New Application	
(ii) *	For renewal of enlistment to import Class A medical device or accessory or component	
	(i) Enlistment number and date:	
	(ii) Validity date:	
	(iii) Last renewal date and its validity:	
	(iv) Attach certificate of enlistment and last renewal:	
(iii)	Proposed change of any particular of an enlisted medical device (in case of any proposed change, please mention details of change)	
2. *	<b>Details of importer:</b>	
(i)	Name of establishment:	
(ii)	Complete addresses:	

(iii)	Name of responsible persons:	
(iv)	Establishment licence No, date of issuance and renewal. Also attach copy of valid establishment licence:	
3.	<b>Manufacturer Detail:</b>	
(i) *	Provide the details of the manufacturer. The details also include complete address, telephone number, fax number and its official website:	
(ii)	If the manufacturing process of a medical device consists of a number of sub-assembly processes, the details of all manufacturing sites where each of these sub-assembly processes are carried out must be provided along with processes:	
(iii)	If multiple sites manufacture the same product, details of each of these sites must be provided including design and manufacturing activities:	
4.	<b>Product details</b>	<b>Please provide detail against each where applicable</b>
(i) *	Medical device brand name:	
(ii) *	Medical device generic name:	
(iii)	HS code for the medical device, if applicable:	
(iv)	GMDN code for the medical device, if applicable:	
(v)	Shelf life supported with stability studies, where applicable:	
(vi)	Proposed MRP of medical device:	
(vii)	Storage condition:	
(viii)	Is the medical device for export only?	
(ix) *	Proof of fee deposited:	
(x) *	Original Agency agreement/Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin.	
(xi) *	Free sale certificate in the country of origin duly attested by Embassy of Pakistan.	
(xii) *	Is the product available on Free Sale in reference countries provided in rule 67 of Medical Devices Rules, 2017? If so, then provide original Free Sale Certificate duly attested by Embassy of Pakistan OR if the product is WHO prequalified, then provide WHO prequalification report/evidence.	
5.	<b>Grouping of medical devices:</b>	
(i)	Specify medical device grouping applicable to the medical device:	
	<b>Single</b>   <b>Set</b>   <b>Family</b>   <b>System</b>   <b>Kit</b>   <b>Cluster</b>	
	Note: Grouping shall be accepted as per Schedule-B-II of the Medical Devices Rules, 2017.	
(ii)	List the constituent-components or medical devices that are grouped together:	
(iii)	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;	
(iv)	Description or complete list of the various configurations of the medical device to be registered using the format under	

	these rules	
(v)	Complete description of the key functional elements, its formulation, its composition and its functionality;	
(vi) *	Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized in the country of origin:	
(vii)	Full Quality assurance certificate or equivalent as applicable duly notarized in the country of origin:	
(viii)	Essential principle of safety and performance.	
(ix) *	Declaration of conformity (DoC):- Please attach the complete DoC. The DoC need to be printed on the manufacturer's letterhead, filled and signed by the responsible person.	
6.	<b>Technical Information</b>	
(i)	Complete description of the medical device with intended use, indications, contraindications; Provide instructions for use / manual.	
(ii)	Explanation of novel features, if any;	
(iii)	Provide manufacturing flow chart and quality control tests performed on the medical device	
(iv)	Sample of labels of the medical device, brochure and its packaging;	
7.	Any other relevant information that may be required by the MDB.	
<b>NOTE: For renewal application, only fields marked with (*) are required along with an affidavit that all the other technical details remains unchanged and in case of any change, these details will be provided for evaluation and approval.</b>		

### 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.”; and

(II) for Form 7A, the following shall be substituted, namely;-



**“DRUG REGULATORY AUTHORITY OF PAKISTAN  
FORM-7A**

*[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 IMPORT**

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 import, namely ..... manufactured by M/s ..... located at ..... details of which are mentioned below along with enclosures.

Sr. No.	Description	Particular to be filled by applicant
1.	<b>Purpose of application, whether;</b>	
(i)	Fresh/New Application	
(ii) *	For renewal of registration to import medical devices or accessories or components	
	(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 a registered medical device or accessory or component (in case of any proposed change, please mention details of change)	
2. *	<b>Details of importer:</b>	
(i)	Name of establishment:	
(ii)	Complete addresses:	
(iii)	Name of responsible persons:	
(iv)	Establishment licence No, date of issuance and renewal. Also attach copy of valid establishment licence:	
3.	<b>Manufacturer Detail:</b>	
(i) *	Provide the details of the manufacturer. The details also include complete address, telephone number, fax number and its official website:	
(ii)	If the manufacturing process of a medical device consists of a number of sub-assembly processes, the details of all manufacturing sites where each of these sub-assembly processes are carried out must be provided along with processes:	
(iii)	If multiple sites manufacture the same product, details of each of these sites must be provided including design and manufacturing activities:	
(iv)	Credentials of the manufacturer abroad duly notarized in the country of origin:	

4.	<b>Product details</b>	<b>Please Provide Detail against each where applicable</b>						
(i) *	Medical device brand name:							
(ii) *	Medical device generic name:							
(iii)	HS code for the medical device, if applicable:							
(iv)	GMDN code for the medical device, if applicable:							
(v)	Does the medical device contain any active ingredient, poison or drug?							
(vi)	Provide manufacturing flow chart and quality control tests performed on the medical device							
(vii)	Class of medical device or accessory or component whether Class B, Class C or Class D							
(viii)	Shelf life supported with stability studies where applicable:							
(ix)	Proposed MRP of medical device:							
(x)	Storage condition:							
(xi)	Is the medical device for export only?							
(xii)	Proof of fee deposited:							
(xiii) *	Original Agency agreement/Letter of Authorization from Manufacturer/Market Authorization Holder duly notarized from the country of origin.							
(xiv) *	Free sale certificate in the country of origin duly attested by Embassy of Pakistan.							
(xv) *	Whether the product is available on free sale in reference countries provided in rule 67 of Medical Devices Rules, 2017. Please attach original and valid free sale certificate duly attested by Embassy of Pakistan OR provide WHO prequalification report/evidence.							
5.	<b>Grouping of medical devices :</b>							
(i)	Specify medical device grouping applicable to the medical device :							
	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="text-align: center;"><b>Single</b></td> <td style="text-align: center;"><b>Set</b></td> <td style="text-align: center;"><b>Family</b></td> <td style="text-align: center;"><b>System</b></td> <td style="text-align: center;"><b>Kit</b></td> <td style="text-align: center;"><b>Cluster</b></td> </tr> </table>	<b>Single</b>	<b>Set</b>	<b>Family</b>	<b>System</b>	<b>Kit</b>	<b>Cluster</b>	
<b>Single</b>	<b>Set</b>	<b>Family</b>	<b>System</b>	<b>Kit</b>	<b>Cluster</b>			
	<b>Note: Grouping shall be accepted as per Schedule-B-II of the Medical Devices Rules, 2017.</b>							
(ii)	List the constituent-components or medical devices that are grouped together:							
(iii)	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;							
(iv)	Description or complete list of the various configurations of the medical device to be registered using the format under these rules							
(v)	Complete description of the key functional elements, its formulation, its composition and its functionality;							
(vi)*	Production Quality Management System Certificate (ISO 13485)/ GMP Certificate duly notarized in the country of origin:							
(vii) *	Full Quality Assurance Certificate or equivalent as applicable							

	duly notarized in the country of origin:	
(viii) *	Design Examination certificate, as applicable duly notarized in the country of origin;	
(ix)	Brief Description of the Medical Device	
(x)	Sample of labels of the medical device, brochure and its packaging;	
(xi)	Essential principle of safety and performance.	
(xii) *	Declaration of conformity (DoC):— Please attach the complete DoC. The DoC need to be printed on the manufacturer's letterhead, filled and signed by the responsible person.	
(xiii)	Description of the medical device with intended use, indications, contraindications; novel features, if any. Provide instructions for use / manual;	
From this section onward, information is only applicable for those medical devices not approved or allowed for free sale in reference countries mentioned in rule 67 of the Medical Devices Rules, 2017 or not CE marked or not WHO Prequalified.		
6.	<b>Technical Information</b>	
(i)	Instructions for installation and maintenance, if applicable;	
(ii)	Any information and instructions given to the patient, including instructions for any procedure the patient is expected to perform, if applicable.	
(iii)	Promotional material.	
(iv)	Information on validation for medical devices with sterile or with measuring function, where applicable:	
(v)	Provide complete documentation related to the manufacturing and quality control processes.	
7.	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)
8.	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.	
(v)	Report or certificate containing information on the objectives, methodology, results, discussion and conclusions of the biocompatibility tests conducted on materials used in the medical device	
(vi)	Attach the report or certification containing information on the objectives, methodology, results, discussion and conclusions of the pre-clinical tests, clinical studies conducted on the medical device,	
9.	Any other relevant information that may be required by the MDB.	
<p><b>NOTE: For renewal application, only fields marked with (*) are required along with an affidavit that all the other technical details remains unchanged and in case of any change, these details will be provided for evaluation and approval.</b></p>		

### DECLARATION

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Name(s).....  
Designations.....  
Signature(s).....  
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**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.
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[No. F.10-1/2020-MD]

**AAMAR LATIF,**  
*Deputy Director (Legal Affairs).*