DRUG REGULATORY AUTHORITY OF PAKISTAN
FORM-2
[see rule 4(2), 5(1), 6(3) and 8(3)(a)]

APPLICATION FORM FOR GRANT OR RENEWAL OF AN ESTABLISHMENT LICENCE TO IMPORT MEDICAL DEVICES

I/We ……..of M/s……..hereby apply for grant or renewal of establishment licence to import medical devices or approval of proposed change regarding the particulars provided in relation to establishment licence to import medical devices at the premises situated at …….

Sr. No.	Description	Particular
1.	**Purpose of application, whether;**	**Please select appropriate column**
(i)	Fresh/New Application	
(ii)	For renewal of establishment licence to import medical devices	
	(i) Licence number and date:	
	(ii) Validity date:	
	(iii) Last renewal date and its validity:	
	(iv) Attach certificate of licence and last renewal:	
(iii)	Proposed change of any particular of a licensed establishment (in case of any proposed change, please mention details of change	
2.	**Establishment details**	**Please provide detail against each, where applicable**
(i)	Establishment name and address:	
(ii)	Type of ownership i.e. partnership, proprietorship, public limited, private limited etc:	
(iii)	Business registration as issued by the Registrar of Companies or any other authorized body:	
(iv)	Drug Sale Licence issued by Provincial Govt.	
(v)	Names of partners/proprietors/directors:	
(vi)	Addresses of partners/proprietors/directors:	
(vii)	Date of establishment:	
(viii)	Drug Sale Licence issued by Provincial Governments	
(ix)	Details of equipments and machinery for Storage and Handling of Medical Devices:	

Sr.No.	Name of Equipment	Make	Model	Capacity
(1)	(2)	(3)	(4)	(5)

3.	**Detail Of Qualified technical Person (Attached copies of CNIC, Photographs, Degrees , Experience Certificate and**

	Certificate of Concerned council)	
(a)	Names of Qualified Technical Person for supervising sale, distribution or wholesale of medical devices	
	Qualifications of Qualified technical person	
(b)	Other technical staff working in these departments:	
4.	**Proof of fee deposited:**	
5.	**Details of medical devices intended to be Imported:**	
6.	Any other relevant information that may be required by the MDB.	

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.

UNDERTAKING

affidavit binding of the partners/proprietors/directors and qualified persons, duly verified to the effect that they:—

i. shall comply with the provisions of DRAP Act, 2012 and the rules made there under,
ii. have not been convicted of any offence from any court of law.
iii. shall inform MDB and the inspector as soon as possible when either of the party ceases to have interest in the licence issued under these rules
iv. shall not sell or stock any expired, spurious, substandard, unregistered, misbranded, counterfeit or any medical device in violation of the DRAP Act, 2012 and the rules made there under.

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 import medical devices**.** For this purpose, provision of relative information is mandatory.
- Provide readable softcopy along with application in USB/CD.