DRUG REGULATORY AUTHORITY OF PAKISTAN

FORM-21

[*see rule 52****]***

APPLICATION FORM FOR PROVISIONAL REGISTRATION OF A MEDICAL DEVICE FOR IMPORT PROVIDED IN SCHEDULE D

I/We (name(s) and designation)……..of M/s……..hereby apply for Provisional Registration of medical device for import provided in schedule D, namely ……, details of which are mentioned below along with enclosures.

S.No	Requirements	To be filled by the applicant
(1)	(2)	(3)
1.	Details of importer: (a) Name of establishment: (b) Complete address and contact information as telephone numbers, fax numbers, email addresses, official websites, etc : (c) Provisional Establishment Certificate number and date of issuance (attach copy of Provisional Establishment Certificate):	
2.	General Information: (a) Medical device brand name, (b) non-proprietary generic name (GMDN/UMDNS: (c) Classification of Medical Device: (d) Brief description of medical device: (e) Original and valid Free sale certificate from regulatory authorities of reference countries mentioned in rule 67 of the Medical Devices Rules, 2017 (f) valid CE mark from the conformity assessment body (CAB) notified by European Union under the directives concerning medical devices. (g) Copy of valid authorized agency agreement with manufacturer abroad: (h) Original Bank deposit slip:	
3.	Name and Address of Manufacturer aboard as per free sale certificate:	

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

I/we also undertake that I/we;

(a) shall comply with the provisions of Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under,

(b) shall not sell or stock any expired, spurious, substandard, unregistered, misbranded, counterfeit or any medical device in violation of the Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under.

Name(s) of partners/proprietors/directors/ authorized person……

Designation…….

Signature……..

Stamp…….

Date…….

Note: Incomplete application shall not be entertained and shall not be considered as submitted.