

**FORM-2**

[see SRO --- dated 15<sup>th</sup> March, 2017]

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

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

S.No	Requirements	To be filled by the applicant
1.	Details of importer:  (i) Name of establishment: (ii) Complete address and contact information as telephone numbers, fax numbers, email addresses, official websites, etc : (iii) Provisional Establishment Certificate number and date of issuance (attach copy of Provisional Establishment Certificate):	
2.	General Information:  (i) Medical device brand name, non-proprietary name (GMDN/UMDNS), type: (ii) Original and valid Free sale certificate from regulatory authorities of reference countries mentioned in rule 142 of the Medical Devices Rules, 2015 or valid CE authorized based on the certificates issued by CABs notified by European Union Directive:93/43/EEC: (iii) Copy of valid authorized agency agreement with manufacturer abroad: (iv) Original Bank deposit slip:	
3.	Information of manufacturer:  (i) 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.

**UNDERTAKING**

I/we also undertake that I/we;

- i. shall comply with the provisions of Drug Regulatory Authority of Pakistan Act, 2012 and the rules made there under,
- ii. 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.