Duly filled specimen pro forma for submission of application in Form MD-16 for obtaining Import Test license

1. The name of the applicant (firm) shall be mentioned as registered under applicable law like company act, proprietorship etc.

3. Name and address of the manufacturer from where the device is to be imported shall be mentioned

5.1.1 Only the common name or generic name of device shall be mentioned.

5.1.3 Should mention the model number/name or catalogue number as mentioned in DMF & IFU/ UM/ PI and labels of the device(s), if available.

5.1.5 The materials/ composition used for the manufacturing of main devices as mentioned in the DMF/ IFU/ UM/ PI of the device.
In case of medical equipments, groups or kits as per grouping criteria, it should be mentioned as 'Not applicable'

5.1.6 Proposed risk class of the devices shall be as per classification list published on the CDSCO website or as per the claim of the manufacturer (Click here)

5.1.8 Only applicable for sterile product otherwise the applicant shall mention 'Not Applicable'.

7. The applicant shall select the appropriate option as provided in the portal

Shall be in DD/MM/YYYY

FORM MD-16

[See sub-rule (2) of rule 40]

Application for licence to import medical devices for the purpose of Clinical Investigations or Test or Evaluation or Demonstration or Training

1. Name of Applicant:
2. Address of Applicant:
3. Name and address of device Manufacturer:
4. Name and Address of site(s) where test or evaluation is proposed to be conducted:
5. Details of medical device(s) to be manufactured

S. No.	Details of Device(s)
1	1. Generic Name: 2. Brand Name (if any): 3. Model No (if any): 4. Intended Use: 5. Material of Construction (if applicable): 6. Proposed Class of Medical Device: 7. Shelf life (If applicable): 8. Whether Sterile or Non-sterile: 9. Quantity to be imported:

6. Brief description of medical device (Kindly refer above device detail table):
7. Purpose of Import: Demonstration
8. Justification for quantity to be imported (Kindly refer above device detail table):
9. An undertaking stating that required facilities including equipment, instrument and personnel have been provided to test or evaluate medical device.
10. An undertaking stating that the medical device proposed to be imported to be used exclusively for purpose specified above and shall not be used for commercial purpose.
11. Please refer Payment details in receipt attached.
12. I hereby state and undertake that, I shall comply with applicable provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place:
Date:

Signature
(Name & Designation)

Place where the address of the applicant (firm) is located

It should be digitally signed using digital signature certificate as per IT Act.

2. The address shall be mentioned as registered under applicable law like company act, proprietorship etc.

4.
- In case of testing/ evaluation/ examination, the applicant shall mention the name and address of the testing centre(s) where the proposed test is to be carried out.
- In case of demonstration/ training, the applicant shall mention the name and address of the site(s) where the demonstration/ training is to be performed.
- In case of Clinical investigation, the applicant shall mention the name and address of each site(s) where the clinical study is to be carried out.

5.1.2 The specific brand name of the device shall be mentioned (If any).

5.1.4 Should be the same as mentioned in manufacturer's DMF & IFU/ UM/ PI.

5.1.7 It should be as per the claim made by the manufacturer

5.1.9 The proposed quantity (in metric units) shall be properly justified in the line of test/ demonstration/ training/ evaluation protocol submitted

9. The applicant shall select the option of "Yes or Not applicable"

10. The applicant shall select "Yes"

11. Payment shall be made as per the Second schedule of Medical Devices Rules, 2017

Abbreviations: *DMF: Device Master File* *IFU/ UM/ PI: Instructions for use/ User Manual/ Package Insert* *CLA: Central Licensing Authority*