Duly filled specimen pro forma for submission of application in Form MD-14 for obtaining Import license for marketing of Medical Devices

1. The name shall be the same as mentioned Form 20B or Form 21B or manufacturing license obtained from licensing authority or Form MD-42.

2. The applicant may select the option as provided in the portal e. g., proprietorship, LLP, Pvt. Ltd. etc.

3.(ii) Address shall be the same as mentioned in Form 20B or Form 21B or manufacturing license obtained from licensing authority or Form MD-42.

5. (1) Only the common name or generic name of the device shall be mentioned.

5.(3) The risk class of the devices shall be as per classification list published on the CDSCO website or clarification letter as obtained from Central Licensing Authority.
(Click here)

5. (5) Only applicable for sterile product otherwise the applicant shall mention Not applicable

5.(8) The materials/composition used for the manufacturing of main devices as mentioned in DMF & IFU/ UM/ PI of the device.
In case of medical equipments, group or kits as per grouping criteria, It should be mentioned as Not applicable.

5.(9) Dimensions of the devices should be in the line of DMF & IFU/ UM/ PI , labels

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

5.(14) If the substantially equivalent device is already approved by CLA then the applicant shall mention as "YES" otherwise it should be mentioned "NO".

Place where the authorized agent address is located

Shall be in DD/MM/YYYY

FORM MD-14
[See sub-rule (1) of rule 34]
Application for issue of import license to import medical device

1. Name of Authorized agent:
2. Nature and constitution of Authorized agent:
3. (i) Corporate/ registered office address:
(ii) Authorized Agent address:
(iii) Address for correspondence:
4. Particulars of overseas Manufacturer, Manufacturing site(s):

Sr.No.	Name and Address of Manufacturer	Name and Address of Manufacturing Site

5. Details of medical device(s) to be imported

S. No	Details of Device(s)
1.	1. Generic Name: 2. Brand Name (if registered under the Trade Marks Act, 1999): 3. Class of Medical Device: 4. Shelf life: 5. Sterile/Non-sterile: 6. Medical Device Grouping Category: 7. Intended Use: 8. Material of Construction: 9. Dimension (if any): 10. Storage Condition: 11. Accessory: 12. Components: 13. Model/Catalogue No./Name: 14. Equivalence to predicate device:

6. Fee paid on¬¬_____, USD _____receipt/challan/transaction id _____.
7. I have enclosed the documents as specified in the Fourth Schedule for grant of license to import medical device(s).
8. I hereby state and undertake that:
(i) I shall comply with applicable provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and Medical Devices Rules, 2017.

Place:
Date:

Signature
(Name and Designation)

3. (i) The address of the firm should be mentioned as registered under applicable law like company act, proprietorship etc.

3.(iii) The address shall be mentioned either of their Corporate office or registered office or authorized agent.

4. The name and address of "LEGAL" manufacturer shall be same as mentioned in the Power of Attorney.

4. The name and address of "ACTUAL" legal manufacturer shall be same as mentioned in the Power of Attorney.

5.(2) The specific brand name of the device shall be mentioned.

5.(4)It should be as per the claim made by the manufacturer.

5.(6) The grouping category (Single, System, Group, Family, etc) shall be as per guidelines published on the CDSCO website.
(Click here: Link1 ; Link2)

5.(7) Should be the same as mentioned in manufacturer in DMF & IFU/ UM/ PI .

5.(10) The storage condition of device should be mentioned as specified in the DMF & IFU/ UM/ PI and device labels (in metric units).

5.(11) Only those accessories which are mentioned in the DMF & IFU/ UM/ PI .

5.(12) Only those components which are mentioned in the DMF & IFU/ UM/ PI/ Technical/Service manual

6. The fee in Rupees shall be calculated to USD as on the date of application submitted

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

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