Duly filled specimen pro forma for submission of application in Form MD-26 for obtaining permission for import/manufacture for marketing of medical device which does not have a predicate device

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 wherever applicable.

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

6. The fee in Rupees shall be as per the Second Schedule of the Medical Devices Rules, 2017

Place where the address of the applicant is located

Shall be in DD/MM/YYYY

Form MD-26

[See sub-rule(1) of rule 63]

Application for grant of permission to import/manufacture for sale or for distribution medical devices which does not have predicate medical device

1. Name of applicant:

2. Nature and constitution of applicant:

3.(i)Corporate/registered office address:

(ii)Manufacturing site/Authorized Agent address:

(iii)Address for correspondence:

4. Particulars of Manufacturer, Manufacturing site(s):

Sr.No	Name and address of manufacturer	Name and address of manufacturing site

5. Details of medical devices(s)to be imported or manufactured[Annexed].

Sr.No	Medical Device Details
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.Model/Catalogue No./Name:

6. Fee paid on _____, **NULL** receipt/challan/transaction id_____.

7.I have enclosed the documents as specified in the part IV of the Fourth Schedule to the Medical Devices Rules,2017.

Place: _____

Date: _____

Signature
(Name and designation)
[To be signed digitally]

3. (i) The applicant shall mention address of the firm as registered under applicable law like company act, proprietorship etc.

3.(iii) The applicant shall mention address either of their Corporate office or registered office or authorized agent or manufacturing site.

4. The name and address of the manufacturer of applied device(s) shall be mentioned.

4. The name and address of the actual manufacturing site of the applied device(s) shall be mentioned.

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

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*