Duly filled specimen pro forma for submission of application in Form MD-8 for obtaining Manufacturing loan license for marketing of Medical Devices

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

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

3. (ii) The address of the site where manufacturing activity of the applied devices is to be carried out

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

4.(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)

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

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

4.(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.

4.(10The storage condition of device should be mentioned as specified in the DMF & IFU/ UM/ PI and device labels (in metric units).

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

FORM MD-8

[See sub-rule (1) of rule 21 and sub-rule (2) of rule 21]

Application for Grant of Loan License to Manufacture for Sale or for Distribution of Class C or Class D medical device

1. Name of Applicant:
2. Nature and constitution of manufacturer:
3. (i) Corporate/ registered office address:
   (ii) Manufacturing site address:
   (iii) Address for correspondence:
4. Details of medical device(s) to be manufactured

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:

5. Whether substantial equivalence to a predicate device is claimed:
6. Fee paid on _____, INR _____ receipt/challan/transaction id _____.
7. I have enclosed the documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.
8. I hereby state and undertake that:
   (i) The manufacturing site is ready for audit or shall be ready for audit on _____ in accordance with the requirements of Medical Devices Rules, 2017.
   (ii) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules,2017.

Place:

Date:

Signature

(Name & Designation)

Shall be in DD/MM/YYYY

Place where the applicant address is located

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

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

3. (iii) The address shall be mentioned either of Corporate office or registered office and shall not be manufacturing site address

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

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

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

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

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

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

4. (14))If the substantially equivalent device is already approved by CLA then the applicant shall mention as "YES" otherwise "NO".

8.(i) Should mention the proposed date by which the manufacturing site is ready for inspection.

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