Form MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B Medical Device.

Licence Number: .....

1. M/s _____(Name and full address of manufacturer with telephone, fax and e-mail) has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at _____ (address of manufacturing facility where the manufacturing will be carried out).
2. Details of medical device(s) [Annexed].
3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

Place: _____
Date: _____

State Licensing Authority
[To be signed digitally]

Annexure:

S.N.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non sterile	Brand Name (if registered under the Trade Marks Act, 1999)

Form MD-7

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

Application for Grant of Licence to Manufacture for Sale or for Distribution of Class C or Class D

1. Name of Applicant:
2. Nature and constitution of manufacturer:
   (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)
3. (i) Corporate/ registered office address including telephone number, mobile number, fax number and e-mail id:
   (ii) Manufacturing site address including telephone number, mobile number, fax number and e-mail id:
   (iii) Address for correspondence:
   [corporate/ registered office/ manufacturing site]
4. Details of medical device(s) to be manufactured [Annexed]:
5. Whether substantial equivalence to a predicate device is claimed: (Yes/ No)
6. Fee paid on _____ Rs_____ 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 and designation)
[To be signed digitally]

Annexure:

S.N.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non sterile	Brand Name (if registered under the Trade Marks Act, 1999)