Form MD-2

[See sub-rule (6) of rule 13]

Certificate of Registration for a Notified Body under the Medical Devices Rules, 2017

Registration No.: _____

1. M/s, _____(Name of the firm) situated at _____(full address with telephone and e-mail) has been registered as a Notified Body of following Class A and/or Class B medical devices.

2. Details of Medical device(s):

S.N.	Standards for which it is registered	Class of medical devices

3. This Registration is subject to the conditions as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: _____ Central Licensing Authority
Date: _____ [To be signed digitally]

Form MD-3

[See sub-rule (2) of rule 20]

Application for Grant of Licence to Manufacture for Sale and Distribution of Class A or Class B medical device

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.