Form MD-12

[See sub-rule (1) of rule 31]

Application for licence to manufacture medical device for purpose of clinical investigations, test, evaluation, examination, demonstration or training

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) Testing or evaluation site address including telephone number, mobile number, fax number and e-mail id:
   (iii) Address for correspondence:
   [corporate office/ testing site]
4. Details of medical device(s) to be manufactured [Annexed]:
5. Fee paid on_____Rs_____receipt/challan/transaction id_____.
6. I hereby state and undertake that, I shall comply with all applicable provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place:_____ Signature

Date:_____ (Name and designation)

[To be signed digitally]

Annexure:

S.N.	Generic name	Class of medical device	Quantity proposed to be manufactured