

Form MD-39

[See sub-rule (1) of rule 81]

Application for grant of registration to Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf of manufacturer

1. Name of Applicant:
2. Nature and constitution of applicant:
(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 laboratory address including telephone number, mobile number, fax number and e-mail id:
(iii) Address for correspondence:
[corporate office/ testing laboratory]
4. Details of medical device(s) to be tested or evaluated [Annexed].
5. Fee paid on _____Rs _____receipt/challan/transaction id _____.
6. I have enclosed the documents as specified in the sub-rule (2) of rule 82 of Medical Devices Rules, 2017.
7. I hereby state and undertake that:
(i) the testing laboratory is ready for inspection or shall be ready for inspection on in accordance with the requirements of Medical Devices Rules, 2017.

(ii) I shall comply with the applicable 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	Class of medical devices