Form MD-24

[See sub-rule (2) of rule 59]

Application for grant of permission to conduct clinical performance evaluation of new *in vitro* diagnostic medical device

1. Name of Applicant:
2. Nature and constitution of applicant:
   (i.e. proprietorship, partnership including Limited Liability Partnership, company, society, trust, other to be specified)
3. (i) Sponsor address including telephone number, mobile number, fax number and e-mail id:
   (ii) Laboratory(s) or institution(s) address including telephone number, mobile number, fax number and e-mail id:
   (iii) Address for correspondence:
4. Details of new *in vitro* diagnostic medical device and laboratory(s) or institution(s) [Annexed].
5. Clinical performance evaluation plan number with date:
6. Fee paid on_____Rs_____receipt/challan/transaction id_____.
7. I have enclosed the documents as specified in sub-rule (3) of rule 59 of Medical Devices Rules, 2017.
8. I hereby state and undertake that:
   (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2017.

Place:
Date:

Signature
(Name and designation)
[To be signed digitally

Annexure:

Details of new *in vitro* diagnostic medical device

S. N.	Generic name	Intended use	Class of medical device

Details of laboratory(s)/institution(s) involved

S. N.	Name and address of laboratory(s)/ institution(s)	Ethics Committee details	Name of Principle Investigator