

Form MD-22

[See sub-rule (1) of rule 51]

Application for Grant of permission to conduct clinical investigation of an investigational 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) Clinical investigation site address including telephone number, mobile number, fax number and e-mail id:
(iii) Address for correspondence:
4. Details of investigational medical device(s) and Clinical investigation site [Annexed].
5. Clinical investigation plan number with date:
6. Fee paid on _____ Rs _____ receipt/challan/transaction id _____.
7. I have enclosed the documents as specified in the Seventh Schedule 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:

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

S. N.	Name and address of site(s)	Ethics Committee details	Name of Principle Investigator