Form MD-28

[See sub-rule (1) of rule 64]

Application for grant of permission to Import or Manufacture for sale or for distribution 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) Corporate/ registered office address including telephone number, mobile number, fax number and e-mail id:
   (ii) Manufacturing site/ authorised agent address including telephone number, mobile number, fax number and e-mail id as per wholesale licence or manufacturing licence or registration certificate:
   (iii) Address for correspondence:
   [Corporate/ registered office/ Manufacturing site / authorised agent]
4. Particulars of Manufacturer, Manufacturing site(s):

Sr. No.	Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer)	Name and address of manufacturing site (full address with telephone, fax and e-mail address of the manufacturing site)

5. Details of new *in vitro* diagnostic medical device to be imported or manufactured [Annexed].
6. Fee paid on_____Rs_____receipt/challan/transaction id_____.
7. I have enclosed the documents as specified in the part IV of the Fourth Schedule Medical Devices Rules, 2017.

Place:_____ Date:__

Signature (Name and designation) [To be signed digitally]

Annexure:

S.N.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non sterile