Form MD-14

[See sub-rule (1) of rule 34]

Application for issue of import licence to import medical device

1. Name of Authorised agent:
2. Nature and constitution of Authorised agent:
   (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) Authorised Agent address including telephone number, mobile number, fax number and e-mail id as per wholesale licence or manufacturing licence:

   (iii) Address for correspondence:
   [corporate/ registered office/ authorised agent]
4. Particulars of overseas 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 medical device(s) to be imported [Annexed]:
6. Whether substantial equivalence to a predicate device is claimed: (Yes/ No)
7. Fee paid on_____Rs_____receipt/challan/transaction id_____.
8. I have enclosed the documents as specified in the Fourth Schedule for grant of licence to import medical device(s).
9. I hereby state and undertake that:
   (i) I shall comply with 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]

S.N.	Generic name	Model No.	Intended use	Class of medical device	Material of construction	Dimension (if any)	Shelf life	Sterile or Non sterile	Brand Name (if registered under Trade Marks Act 1999)