

Form MD-18
[See sub-rule (1) of rule 42]

Application for licence to import investigational medical devices for the purposes by a government hospital or statutory medical institution for the treatment of patients

1. I (Name and designation)..... of (Name of the Government Hospital or Statutory Medical Institution) hereby apply for a licence to import small quantities of investigational medical device specified below manufactured by M/s. (Name and full address of overseas manufacturer) for the purpose of treatment of patients for the disease..... (Name of the disease)..... at(name and address of the hospital).

2. Details of medical device to be imported:

Name of the investigational Medical device	Name and address of the manufacturer	Quantities which may be imported

3. I shall comply with the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

4. A fee of Rs. _____ has been credited to the Government under the Head through Challan/receipt No. _____ dated _____ (copy attached).

Place: _____
Date: _____

Signature.....
Name.....
Seal or Stamp.....

Certificate

Certified that the investigational medical device specified above for import are urgently required for the treatment of patients suffering fromand that the said medical device is not available in India.

Place: _____
Date: _____

Signature.....
Medical Superintendent of the Government Hospital / Head of
Statutory Medical Institution Seal or Stamp