Form MD-27

[See sub-rule (2) of rule 63]

Permission to import or manufacture for sale or for distribution of medical device which does not have predicate medical device

Permission No. _____

1. M/s._____ (Name and full address of manufacturer with telephone, and e-mail) having manufacturing site _____ (address of manufacturing site), is hereby permitted to import / manufacture for sale or for distribution of following medical devices.

2. Details of medical device(s) to be imported or manufactured [Annexed].

3. This permission is subject to conditions as specified in the Drugs and Cosmetics Act (23 of 1940) and the Medical Devices Rules, 2017.

Place:_____ Central Licensing Authority

Date:_____ [To be signed digitally]

Annexure:

S.N.	Generic Name	Brand name	Model No.	Dimension	Intended Use	Shelf life	Sterile/ Non Sterile	Class of medical device