Form MD-8

[See sub-rule (1) of rule 21 and sub-rule (2) of rule 21]

Application for Grant of Loan Licence to Manufacture for Sale or for Distribution of Class C or Class D 1. Name of Applicant:
2. Nature and constitution of manufacturer:
(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) Manufacturing site address including telephone
number, mobile number, fax number and e-mail id:
(iii) Address for correspondence:
[corporate office/ manufacturing site]
4. Details of medical device(s) to be manufactured [Annexed]:
5. Whether substantial equivalence to a predicate device is claimed: (Yes/ No)
6. Fee paid onRsreceipt/challan/transaction id
7. I have enclosed the documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.
8. I hereby state and undertake that:
(i) the manufacturing site is ready for audit or shall be ready for audit onin accordance with
the requirements of the Medical Devices Rules, 2017.

(ii) I shall comply with all the 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]

Annexure:

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