Form MD-4

[See sub-rule (2) of rule 20]

Application for Grant of Loan Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

| 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) Name and address of Manufacturing site including | |
| telephone number, mobile number, fax number and e- | |
| mail id: | |
| (iii) Address for correspondence: | |
| [corporate/registered office/ manufacturing site] | |
| 4. Details of medical device(s) to be manufactured [Annexed]: | |
| 5. Whether substantial equivalence to a predicate device is claimed: (Y | Yes/No) |
| 6. Fee paid on Rs receipt/ | |
| 7. I have enclosed the documents as specified in the Fourth Schedule of | |
| 8. I hereby state and undertake that: | |
| (i) I shall comply with all the provisions of the Drugs and Cosmo | etics Act, 1940 (23 of 1940) and the Medical |
| Devices Rules, 2017. | , , |
| , | |
| | |
| | |
| Place: | Signature |
| Date: | (Name and designation) |
| | [To be signed digitally] |
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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 registered |
| | | | | medical | | | | sterile | under the Trade |
| | | | | device | | | | | Marks Act, 1999) |
| | | | | | | | | | |
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