Form MD-11

[See clause (vii) of rule 26]

Form in which the Audit or Inspection Book shall be maintained.

(A) The cover of the audit or inspection book shall contain the following particulars, namely:-

1. The name and address of the licencee _____
2. Licence Number _____

(B) (i) The pages of the audit or inspection book shall be serially numbered and duly stamped by the Central Licensing Authority*/State Licensing Authority*. The pages, other than the first and the last pages, shall have the following particulars:-

Name and designation of the auditor or medical device officer who audited or inspected the premises:
Date of audit or inspection _____
Observations of the auditor or medical device officer _____

Signature of the auditor or medical device officer

(ii) The first and last pages of the audit or inspection book shall be endorsed by the Central Licensing Authority*/State Licensing Authority* with the following words, namely:-
Audit or inspection book maintained by M/s _____situated at _____ for licence number _____ in Form _____ under the Medical Devices Rules, 2017.

*Central Licensing Authority/
*State Licensing Authority
[To be signed digitally]

*Delete whichever is not applicable.

Notes:

(i) Printed copy of the Inspection Book may be obtained by the licencee from the Licensing Authority on payment of fee as may be specified by the concerned Licensing Authority from time to time.
(ii) The audit or inspection book shall be maintained at the premises of the licencee.
(iii) The original copy of observations made by the auditor or medical device officer shall be maintained in the premises of the licencee and duplicate copy shall be sent to the Central Licensing Authority/ State Licensing Authority. The triplicate copy shall be taken as record by the auditor or medical device officer.

Form MD-12

[See sub-rule (1) of rule 31]

Application for licence to manufacture medical device for purpose of clinical investigations, test, evaluation, examination, demonstration or training

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) Testing or evaluation site address including telephone number, mobile number, fax number and e-mail id:
   (iii) Address for correspondence:
   [corporate office/ testing site]
4. Details of medical device(s) to be manufactured [Annexed]:
5. Fee paid on _____ Rs_____ receipt/challan/transaction id_____.

6. I hereby state and undertake that, I shall comply with all applicable provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.

Place: _____ Signature
Date: _____ (Name and designation)
[To be signed digitally]

Annexure:

S.N.	Generic name	Class of medical device	Quantity proposed to be manufactured

Form MD-13
[See sub-rule (3) of rule 31]
Licence to Manufacture Medical Devices for the Purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training

1. M/s ....., of....., is hereby licenced to manufacture the medical device(s) specified below for the purposes of clinical investigations or test or evaluation or demonstration or training at …… (address of the premise).

S.N.	Generic name	Class of medical device	Quantity permitted to be manufactured

2. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

3. This licence shall be in force for a period of three year from the date specified below.

Place: _____ Central Licensing Authority
Date: _____ [To be signed digitally]

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: