

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 licensee _____
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 licensee 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 licensee.

(iii) The original copy of observations made by the auditor or medical device officer shall be maintained in the premises of the licensee 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.