# Procedure to obtain Manufacturing License for Medical Devices

**License for manufacturing of Medical Devices including in-vitro diagnostic devices are issued online at the CDSCO portal cdscomdonline.gov.in** as per the provisions of Drugs & Cosmetics Act and Medical Device Rules 2017. The Licensing Authority for such licenses for Class A and B products is the Drugs Controllerof the state.
[License for Class C and D products is granted by the Central Licensing Authority, New Delhi]

**Step 1**

Application for grant of Manufacturing Licence
The applicant has to make application online at the CDSCO portal cdscomdonline.gov.in inrequisite form such as MD-3 (or MD-4 for loan license) for license to be issued on form MD-5, or as applicable as per the Medical Device Rules, along with necessary fees challan as given in fee chart under 'Forms & Fees'.
Fee can be paid through Government Treasury challan, under Head of Account-
0210- 04-800-02-00 Other receipts
Department Name: Commissionerate, Food Safety and Drug Control Jaipur
Office Name: Commissioner Food Safety & Drug Control

**Documents to be uploaded along with the application form:**

1. Covering Letter
2. Application Form.
3. Receipt of fees challan
4. Constitution of firm including
    a. Partnership deed / Memorandum & Article of Association
    b. Declaration of Proprietor/ Partners/ Director(s)/ Managing Director
    c. List of all the Partners/ Directors with age & complete postal & residential address.

5. Documents of Site ownership / Tenancy agreement
6. Plant Master File (as per appendix I of Part III of fourth schedule)
   Apart from the mandatory information as per appendix I of Part III of fourth schedule, following documents should also be submitted:
    a. Declaration of Manufacturing Chemist.
    b. Declaration of Analytical Chemist.
    c. Documents of educational qualification, experience and approval certificates of proposed Manufacturing Chemist & Analytical Chemist; Appointment Letters; Id proof.
    d. Registration from District Industries Centre.

e. Consent to establish & consent to operate from Rajasthan State Pollution Control Board.

7. Device Master File for each product (as per appendix II / appendix III of fourth schedule)
8. Performance Evaluation Report (if applicable)
9. Copy of Test License (if applicable).
10. Undertaking that the manufacturing site is in compliance with the provisions of Fifth Schedule.

Following additional documents are required if applied for loan license on Form MD-4:

1. Consent letter from principal manufacturing unit in case of loan license.
2. Wholesale licenses of the applicant loan licensee.
3. Valid manufacturing licenses and copies of product permission of the product in question of the principal manufacturer.

**Step 2**

Scrutiny of application. In case any shortcoming / discrepancy is noted, query shall be raised. Further action shall be taken upon receipt of reply of query from the applicant. In case the application is found in order, it will be processed for audit of factory premises by a notified body as per Medical Device Rules.

**Step 3**

Audit of applicant premises by notified body. The non-compliances, if any, shall be rectified by the applicant. The audit report and the NC closure will be uploaded by the notified body.

**Step 4**

Upon receipt of the audit report, it will be examined and if found satisfactory, it will be forwarded for the next step.

**Step 5**

Products Scrutiny. The details of the products applied for shall be scrutinized and if they are found to comply with the norms, the application will be considered for grant of license.

**Step 6**

Grant of Licence

If all the prescribed conditions are complied with, licence is granted.