DRUGS CONTROL DEPARTMENT
GOVERNMENT OF KERALA

Standard Operating Procedure and Checklist – Medical Devices Manufacturing Licence

Application for	Manufacture of Medical Devices
Mandatory supporting documents required	1. Application in Form MD-3/MD-4 (For class A & B Medical device & In-vitro diagnostic devices) 2. Licence fee via online payment receipt of Rs. 5000/- for each manufacturing site & Rs.500/- for each product. 3. Constitutional details of the firm (Proprietorship/Partnership including Limited Liability Partnership/ Private or Public company/ Society/Trust) 4. Document from local authority to prove ownership of premises 5. Plan of the premises 6. Declaration of technical staffs for manufacturing & testing 7. Documents to prove the qualification and experience of technical staffs 8. Device master file 9. Details of labels 10. Standard operating procedures for medical devices
Process description	1. Submission of application via online portal (www.cdscomdonline.gov.in) 2.Verification of the documents by concerned staff in the Office of the Drugs Controller 3.Pre-licensing auditing within 90 days from the date of application by notified body for Class B medical devices/ In-vitro Diagnostic devices. 4.Issue of Manufacturing licence by State Licensing Authority In Form MD-5/MD-6 within 20 days from the date of receipt of audit report. 5.For Class A medical devices/ In-vitro Diagnostic devices, pre-licensing auditing is not required. If the application is in order as per the requirements stipulated in Rules, Manufacturing Licence for Class A Medical devices/ In-vitro Diagnostic devices,will be granted by the Drugs Controller within 45 days from the date of application. The required audit of such site by the notified body shall be carried out within 120 days from the date of grant of licence.
Procedure for Fees payment	Payment can be done through e-treasury
List of Reference Documents	Drugs & Cosmetics Act,1940, Medical Devices Rules, 2017
Time line for completing the process	140 days
Checking of Application Status	Online provision is available
Key Contact Person from department	Drugs Controller