Medical Devices Division
Central Drugs Standard Control Organization
DGHS, MoHFW, Govt. of India

Regulatory pathway to be followed for the Medical Device from its development to commercialisation under Medical Devices Rules, 2017

Requirements for the test batches

Product Development/ Prototype

May be performed at R&D facility

Test License
Application in Form MD-12 → License in Form MD-13 (Manufacturing)
Application in Form MD-16 → License in Form MD-17 (Import)

- Demonstration of compliance with EPSP* to manufacture atleast three batches to generate QC data including Stability, Validation data, Pre-clinical studies, etc.

- If the device developed is to be used on human subject for the purpose of Clinical investigation, then the facility should be Quality Management System compliant

CI for Investigational MD

Applicable for Investigational Medical Device

Permission to conduct Clinical Investigation (CI)
Application in Form MD-22 → Permission in Form MD-23

Submit CI plan for approval as per Seventh Schedule of MDR-2017 for Pilot/Pivotal Study to generate Clinical data on Indian population (human subjects)

Permission to import/manufacture Investigational Medical Device
Application in Form MD-26 → Permission in Form MD-27

Submit the data related to Clinical evidence, Validation, DMF, etc. as per Part IV of Fourth Schedule of MDR-2017

Commercialisation

Manufacturing License for commercialization
Application in Form MD-3 → License in Form MD-5
Application in Form MD-4 → License in Form MD-6
(License issued by SLA for Class A & B)

Manufacturing License for commercialization
Application in Form MD-7 → License in Form MD-9
Application in Form MD-8 → License in Form MD-10
(License issued by CLA for Class C & D)

Import License
Application in Form MD-14 → License in Form MD-15
(License issued by CLA for Class A, B, C & D)

Regulatory documents, Legal documents, Technical documents (Plant/Site master file & Device Master File) as specified in Fourth Schedule of MDR-2017

₹ *Fees as per Second Schedule of MDR-2017*

SLA - State Licensing Authority
CLA - Central Licensing Authority

** EPSP – Essential Principles of Safety & Performance*

NOTE: # Class A (Non-sterile & non-measuring) Medical Devices exempted ## CI for Class A Medical not mandatory
All applications shall be submitted through Medical Devices online portal (www.cdscomdonline.gov.in, www.nsws.gov.in)