CDSCO CHECKLISTS: WHICH FORM FITS YOUR MEDICAL DEVICE APPLICATION?

When it comes to Medical Devices, we use various types of MD forms for submitting applications to the Indian regulatory authorities. However, it often becomes a challenge to determine which form is appropriate for a specific type of application. Questions frequently arise, such as which portal to use for submission and the process for applying.

This article aims to simplify your dilemma by providing a clear understanding of MD forms, the required checklists, and the relevant portals under CDSCO (Central Drugs Standard Control Organization) for obtaining the necessary licenses for your medical devices

The table outlines the various MD forms commonly used by manufacturers to submit applications and obtain licenses for medical devices in India.

Requirements

FORM No.	MD-3	MD-4	MD-7	MD-8	MD-12	MD-14	MD-16	MD-22
Title of the Checklists	Application for manufacture for sale or for distribution of Class A (other than non-sterile and non-measuring) or Class B medical device	Application for loan license for manufacture for sale or for distribution of Class A (other than non-sterile and non-measuring) or Class B medical device	Application for manufacturing Class C or Class D devices	Application for loan license for manufacturing Class C or Class D devices	Checklist for the grant of a Test license to manufacture medical devices for the purposes of Clinical investigations or test or evaluation or demonstration or training	Application for grant of import licence to import Medical Devices	Checklist for the grant of Test license to import medical devices for the purposes of clinical investigations or test or evaluation, demonstration, or training	Application for the grant of permission to conduct clinical investigation of an investigational medical device

A portal for submitting application	Sugam Portal	Sugam Portal	Sugam Portal	Sugam Portal	Sugam Portal	Sugam Portal	Sugam Portal	Sugam Portal
Cover Letter	Mandate	Mandate	Mandate	Mandate	Mandate	Mandate	Mandate	Mandate
Constitution of the firm (Incorporation Certificate)	Mandate	Mandate	Mandate	Mandate	Mandate	N/A	Mandate	N/A
The Establishment /Site ownership /Tenacy Agreement	Mandate	Mandate	Mandate	Mandate	Mandate	N/A	N/A	N/A
QMS Certificate (ISO 13485)	Optional	Optional	Optional	N/A	Optional	Optional	Optional	N/A
Plant Master File	Mandate	Mandate	Mandate	N/A	N/A	Mandate	N/A	N/A
Device Master File	Mandate	Mandate	Mandate	N/A	N/A	Mandate	N/A	N/A
QMS Requirement	Mandate	Optional	Mandate	Optional	N/A	N/A	N/A	N/A
Test License obtained for testing and generation of quality control data	Optional	Optional	Optional	N/A	N/A (Instead ask for Manufacturing license which is optional	N/A	N/A Instead ask for Manufacturing license which is optional	N/A
Undertaking signed stating that the manufacturing site is in compliance with provision of Fifth schedule	Mandate	Mandate	Mandate	N/A	N/A	N/A	Mandate	N/A
Undertaking signed stating that the required facilities, including equipment, instruments, and personnel, have been provided to manufacture such medical devices.	N/A	N/A	N/A	N/A	Mandate	N/A	Mandate	N/A

Copy of Permission in Form MD-27 (incase of Medical device which does not have Predicate medical device)	N/A	N/A	Mandate	N/A	N/A	N/A	N/A	N/A
Agreement between the applicant and the manufacturer whose manufacturing site is to be utilized for the manufacturing of applied device(s)	N/A	Mandate	N/A	N/A	N/A	N/A	N/A	N/A
Regulatory status of the device if approved by any National regulatory authority (if any) along with the copy of approval letter	Mandate	Mandate	Mandate	Mandate	Mandate	Mandate	Mandate	Mandate
Stability Study data	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Optional
Risk Management Report on the Investigational medical device	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Mandate
Biocompatibility and Animal performance study data for Investigational medical device (as applicable)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Mandate if Applicable
Proposed Labelling information	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Mandate
The agreement between the Sponsor and Principal investigator	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Mandate
Appropriate Insurance certificate	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Optional
Forms for reporting any adverse event and serious adverse event	Mandate	N/A	Mandate	N/A	N/A	N/A	N/A	Mandate

Investigators Brochure as per Seventh Schedule of MDR-2017	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Mandate
Clinical Investigational Plan as per Seventh Schedule of MDR-2017	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Mandate
Case Report Form as per Seventh Schedule of MDR-2017	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Mandate
Informed Consent Form as per Seventh Schedule of MDR-2017	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Mandate
Undertaking by the Investigator as per Seventh Schedule of MDR-2017	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Mandate
Published technical documents/literature	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Optional
Ethics Committee Approval letter	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Mandate