

CDSCO REGISTRATION

Medical Device Registration

Document Checklist for CDSCO Registration

For registering medical devices with CDSCO prior to import, manufacture or sale in India.

Documents Required

- Business registration/incorporation proof of the manufacturer/importer
- Device Master File (DMF)/Plant Master File (PMF) of the manufacturer
- Free Sale Certificate from the country of origin (for imported devices)
- ISO 13485 certification of the manufacturing site
- CE certificate/US FDA approval, if available
- Test reports and product performance evaluation data
- Labelling and Instructions for Use (IFU) of the device
- Risk classification details of the device (Class A/B/C/D)
- Wholesale/import licence of the applicant, as applicable

Note: The above list indicates commonly required documents. Additional documents may be requested by the Central Drugs Standard Control Organisation (CDSCO) or State Drug Licensing Authority depending on the specific case. Expert Registration confirms the exact requirement after a brief consultation.