

CDSCO REGISTRATION

In Vitro Diagnostic Device Import License

Document Checklist for CDSCO Registration

For importing In Vitro Diagnostic (IVD) devices into India under the Medical Device Rules.

Documents Required

- Business registration/incorporation proof of the Indian Authorised Agent/importer
- CDSCO device registration certificate (prior registration of the device)
- Free Sale Certificate from the country of origin
- ISO 13485 certificate of the manufacturing site
- Power of Attorney from the foreign manufacturer to the Indian Authorised Agent
- Wholesale licence of the importer, if applicable
- Device Master File and test reports
- Labelling and Instructions for Use (IFU) of the device
- List of devices/models to be imported

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.