

CDSCO REGISTRATION

In Vitro Diagnostic Device Manufacturing License

Document Checklist for CDSCO Registration

For manufacturing In Vitro Diagnostic (IVD) devices, licensed under the Medical Device Rules.

Documents Required

- PAN card of the business/company
- Business registration/incorporation proof
- Site plan and building layout of the manufacturing unit
- Ownership/lease proof of the manufacturing premises
- List of machinery and equipment installed
- Qualified technical staff details (degree/experience certificate)
- Device Master File and product technical specifications
- ISO 13485 certification of the manufacturing site
- Risk classification details of the IVD device
- List of products proposed to be manufactured

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.