

ISO CERTIFICATION

ISO 13485 Certification

Document Checklist for ISO Certification

For Quality Management System certification specific to medical device manufacturers, under ISO 13485.

Documents Required

- Business registration/incorporation proof
- Manufacturing licence/CDSCO registration, if applicable
- Site plan and process flow of the manufacturing unit
- Quality policy specific to medical device manufacturing
- Device Master File/technical documentation of products
- Design and development control records, if applicable
- Risk management file for the medical device(s)
- List of products/device classes covered under certification scope

Note: The above list indicates commonly required documents. Additional documents may be requested by the certification body during the audit process depending on the specific case. Expert Registration confirms the exact requirement after a brief consultation.