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ISO 13485 Certification Readiness Checklist

Planning

- Define device classification and markets
- Select notified body or registrar
- Allocate QMS resources and appoint management rep

Documentation

- Quality Manual aligned to ISO 13485:2016
- SOPs for design, production, and post-market activities
- Risk management file per ISO 14971
- Device Master Record & Technical Documentation

Implementation

- Internal audit program in place
- Training records for relevant personnel
- Supplier evaluation & control procedures
- CAPA and NCR procedures

Certification

- Pre-certification audit
- Certification body engagement
- Surveillance audit calendar