

Checklist for Structuring your Technical Documentation

This is an extra resource to go along with the original article: How to Structure your Medical Device Technical File

Here's a checklist of items you'll want to remember to include when structuring your medical device technical file:

Manufacturer name and address
Device description and UDI number
Facilities name and address
Notified Body name and address
Conformity assessment procedure
Declaration of conformity
Labeling and instructions for use
Common specifications and standards applied
Evidence of compliance
Design and manufacturing information
General safety and performance requirements
Risk analysis
Verifications and validation test reports
Post-market surveillance information

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Greenlight Guru is the only quality management software designed specifically for medical device companies to bring safe, true quality products to market faster. The cloud-based solution serves as a single source of truth by connecting all quality processes to streamline team and work efficiency throughout the life cycle of a medical device.