Technical Documentation for Medical Devices

Guidance for submission

The technical documentation must be kept in the premises of the manufacturer or the Authorized Representative in a clear, organized, readily searchable and unambiguous manner and shall include the elements presented in this document.

Technical Documentation has to be assessed by HTCert prior to CE-Marking of the product. The assessment of the documentation is usually conducted partly off-site as a desk review and partly at the manufacturer's premises during on-site audits. In the case of class IIa and class IIb devices, the assessment of technical documentation may be conducted for devices selected on a representative basis.

Technical documentation should preferably be submitted in electronic form, yet paper version is also acceptable. The preferred document format is PDF files with bookmarks for ease of locating specific content. If the documentation is submitted in more than one files, each file should be titled and numbered. All files submitted should not be file protected or locked. If hard copies are submitted, these will be converted to electronic format, and hard copies will be shred. Part of the documentation may be available at the manufacturer only. This will inevitably add time to the on-site audit.

All data should be in the English or Greek language. Test reports may be accepted in another language if an executive summary is submitted in either English or Greek, yet in some cases it may be necessary to translate all the documentation.

It is recommended to compile the Technical Documentation as follows.

1. Introduction

- Table of contents
- File status (file date and issue number) and revision history. Individual documents should also indicate date, revision history and status.
- Details of any related previous submissions
- Signatures are required for any signed document in the file. For documentation submitted in electronic form:
  - Documents may be digitally signed
  - Signature pages can be scanned and inserted into the electronic document

2. General Information

- Manufacturer's name and address
- European Representative (if applicable)
- Original Equipment Manufacturer (if applicable)

3. General description of the product

- Brief description of the product:
  - model names, product codes, configurations, variants and a description of the packaging where this is relevant to the preservation of the intended characteristics and performances of the product
  - a general pictorial representation of the product, e.g. a schematic diagram, photograph or drawing
  - intended use: medical condition(s) for which the device is intended, method of use and basic principles of operation, intended users, intended patient population and the indications and contraindications of the product.
  - accessories for the product

  - for device(s) incorporating a medicinal substance:
    - justification on the primary mode of action of the device
    - description of the purpose of including the substance
    - evidence that the above substance is ancillary
    - clear description of its mode of action in this application.
- Product History:
  - approvals (e.g. FDA 510(k) or PMA clearance)
  - status of any pending request for market clearance
  - countries in which product is marketed
  - vigilance data for the last 5 years, if applicable

4. Classification

- Classification, indicating the rule (bullet point) according to Annex IX of Directive 93/42/EEC together with a brief rationale for this classification, and reasons why particular rules do not apply, if this is not self-evident
- Where not self-evident, the manufacturer should document the rationale for classifying as a medical device
- Classification according to EN ISO 10993-1 Annex A.1
- UMDNS and GMDN code (if available)
- Statement as to whether the product incorporates, as an integral part, a substance as defined in Annex I Section 7.4 of Directive 93/42/EEC

5. Standards applied

- Applied standards (title, identification number, issue date)
- Rationale if the applicable harmonized standards have not been applied in full or in part

6. Declaration of conformity

- In the case of initial certifications in the form of a draft

7. Fulfilment of Essential Requirements

- Proof of compliance with the Essential Requirements. A checklist should be submitted, presenting the solutions adopted by the manufacturer and the corresponding documents and records. A checklist could have the structure below:

E.R.	Applicable Yes / No	Standards applied	Documentation demonstrating compliance (test reports, procedures, records of application of SOPs, etc.) or Rationale for non-applicability

8. Other applicable directives and regulations

- Description of all applicable Directive(s) and Regulations (e.g. 2005/50/EC, 89/686/EEC)
- Proof of compliance with any requirements apply from legislation other than 93/42/EEC Directive.

9. Risk Management

- Risk Management process. A copy of Risk Management Procedure(s) that include the definition of the rating systems used for risk analysis and risk acceptability should be provided.
- Risk Management File including risk management plan, risk analysis, risk evaluation, implementation and verification of the risk control measures and assessment of the acceptability of any residual risk(s)
- Risk Management report

Risk Management assessment should be conducted for the entire life-cycle of the device (from initial design concept up to and including device disposal). This should be updated (as appropriate) with data from the post-production phases.

10. Specifications, drawings and diagrams for components and complete product

- Comprehensive description of the product
- Identification of the functional characteristics and technical performance specifications (e.g. mechanical, physical, electrical, biological, chemical)
- Final product release criteria
- Specifications of raw materials/components: chemical, biological and physical characterization
- Specifications of packaging (primary and secondary packaging)
- Certificates of materials
- Product compatibility with the sterilization process where applicable

11. Outsourced processes, subcontractors, suppliers

- Names and locations of critical subcontractors and crucial suppliers
- suppliers of raw materials/components and finished products
- Certificates of subcontractors/suppliers
- Agreements with critical component suppliers / subcontractors for outsourced critical processes

12. Manufacturing process

- Description of the manufacturing process (e.g. flowcharts including in-process controls). This should clearly identify any subcontracted processes
- Procedures, work instructions etc. including those for cleaning and packaging
- Environmental conditions during production / cleaning and packaging
- Cleaning instructions
- Cleaning process validation report if applicable
- Revalidation report if applicable
- Packaging process validation report if applicable
- Revalidation report if applicable

13. Sterilization

- Summary description of the process
- Description of manufacturing conditions
- Bioburden controls and monitoring

- Procedures, work instructions etc.
- Proof for compliance of the packaging material with the sterilization method
- Validation documents – Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ)
- Revalidation report if applicable
- Criteria and plan for revalidation

14. Preclinical evaluation

- Description of the testing conducted (visual, chemical, biological, physical/mechanical testing, efficacy/performance testing, simulated use)
- Acceptance criteria
- Justification if applicable standards or parts thereof are not considered
- Test reports
- Proof of stability including accelerated and real-time ageing data where applicable
- Drug compatibility if applicable
- Pre-clinical animal studies if applicable
- Biological Evaluation
    - Categorization of the medical device based on EN ISO 10993-1
    - List of tests performed
    - Justification for tests not performed
    - Test reports
    - Biocompatibility evaluation and summary report

15. Devices incorporating a medicinal substance

- for the ancillary medicinal substance
    - Relevant parts of CTD-Module 3 in accordance with the format of the “Notice to Applicants”.
    - Reference to the European Pharmacopoeia (PhEur) monograph or, in the absence of one, to a national pharmacopoeia of one of the Member States, or in the absence of one, to other national monographs or to the manufacturer's specification and methods of analysis.
    - Quality Overall Summary (CTD-Module 2.3)
- for the ancillary medicinal substance as incorporated in the medical device
    - Qualitative and quantitative particulars of the constituents
    - Description of method of manufacture
    - Controls of starting materials
    - Control tests carried out at intermediate stages of the manufacturing process of the medical device
    - Final Control tests of the ancillary medicinal substance in the medical device
    - Stability
- Non-clinical pharmacology
    - Pharmacodynamics
    - Pharmacokinetics
    - Toxicity (including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable).
    - Local tolerance

16. Clinical evaluation

- Clinical evaluation report compliant with current version of MEDDEV 2.7.1.
- PMCF plan if applicable
- All protocols and reports quoted in the clinical report
- Copies of the publications quoted in the clinical report
- In case a clinical study was performed, Clinical Investigation Report and all relevant documentation, including the communication with the Ethics Committee (initial submission and continuing communication)

17. Labelling and instructions for use

- Sample of labels (primary and secondary packaging)
- Instructions for use

18. Plan for "post-marketing surveillance"

- The plan for market surveillance must also include a clinical surveillance or a documented justification that this is not required