medical device certification mdc	**Structure of Technical Documentation (Medical Devices)**	001/12.2018 ID: 2379

The following structure is based on Regulation (EU) 2017/745 (MDR) but is also suitable for technical documentation according to Directive 93/42/EEC.

1. Device description and specification

1.1. General description of the device, its variants and its intended purpose

1.1.1. Name and address of the manufacturer

1.1.2. Overview of devices/ device groups/device types e.g. table with designation and reference to the REF number, including UDI-DI (if applicable)

1.1.3. All trade names under which the device is placed on the market

1.1.4. Specification of the device including its intended purpose, indication(s), contraindication(s) and warnings, the intended patient group and the medical conditions to be diagnosed/treated/monitored

1.1.5. UMDNS/GMDN classification (if applicable)

1.1.6. Technical specifications of the device, such as characteristics, dimensions and performance attributes of the device

1.1.7. Variants/components/configurations and accessories of the device

1.1.8. Exact software version (if applicable)

1.1.9. Explanations of new characteristics and new intended purposes/indications

1.2. UDI (as soon as implemented or obligatory)
Description of the Basic-UDI-DI or (until EUDAMED is fully implemented) description of the traceability by unique identification e.g. by product code, catalogue number or other unambiguous reference.

1.3. Designation / Classification
Justification for the designation as a medical device and description of the classification of the device including justification for on the applied classification rule(s), exact identification of the applied indent, statement for the classification

1.4. Declaration of Conformity (DoC)
DoC according to Annex IV MDR *or according to MDD (considering EK-MED-Beschluss 3.9 A4).* For initial certifications (e.g. MDR) the DoC has to be filed in draft status.

1.5. Description of the principles of operation of the device and its mode of action
Description of principles of operation of the device and its mode of action comprehensible to third parties, in combination with other components/accessories if applicable

1.6. Summary of safety and clinical performance
Summary report acc. to Art. 32 MDR on safety and clinical performance – only necessary for implantable devices and for class III devices except custom-made or investigational devices

1.7. Raw materials, components, packaging materials

1.7.1. Overview of all raw materials, components, packaging materials (e.g. bill of materials)

1.7.2. Specifications of raw materialscomponents/subassemblies

1.7.3. Specifications of packaging materials (primary and secondary packaging)

1.7.4. Certificates of analysis from the suppliers, material certificates, inspection certificates, if applicable

1.7.5. Identification of substances that come into direct or indirect contact with the human body

1.8. Declaration on particular substances:

1.8.1. Formal statement in a separate document if the device is manufactured utilizing tissues or cells of human origin, or their derivatives

1.8.2. Formal statement in a separate document if the device is manufactured utilizing tissues or cells of animal origin, or their derivatives

1.8.3. Formal statement in a separate document if the device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as referred to in the first subparagraph of Article 1(8)

1.9. Previous and similar generations

1.9.1. Overview of the previous generation(s) of the device produced by the manufacturer

1.9.2. Overview of the similar generation(s) of the device available on the market in the European Union or on international markets

1.10. *QM-System (only for MDD procedures)*
Description of the QM-System – typically by submission of the applicable certificates or alternatively by submission of the QM documentation (e.g. quality manual, etc.).- this aspect is only required for documentation according to MDD.

2. Labelling / instructions for use

2.1. Labelling (product, single unit packaging, sales packaging and transport packaging in case of specific management conditions) in all languages accepted in the Member States where the device is intended to be sold

2.2. Instructions for use in all languages accepted in the Member States in which the device is intended to be sold

3. Design and manufacturing information

3.1. Description of the design

3.1.1. Description of the applied design process, the phases (e.g. milestones) that were applied within in the design of the device and a summary of the results of these phases

3.1.2. Identification of all sites where design processes were performed (e.g. outsourced design units, research sites, etc.)

3.2. Description of the manufacturing

3.2.1. Comprehensible description of manufacturing (e.g. procedures, flow charts, sample batch protocols ...)

3.2.2. Addresses of all manufacturing sites with information on the manufacturing steps
3.2.3. Information on specific processes and their validation (e.g. coating processes, injection moulding, soldering, bonding, welding, lyophilization, cleaning, etc.)
3.2.4. Information on controlled conditions under which certain manufacturing steps take place

3.3. Description of quality control
Description (e.g. procedures, flow charts, test specifications, sample test protocols, ...) of the quality controls (incoming controls, in-process controls and final tests) including acceptance criteria.

3.4. Outsourced processes, subcontractors
3.4.1. Overview in tabular format of outsourced processes and name/address of the executing companies
3.4.2. Evidence of qualification of subcontractors (e.g. certificates, evidence of accreditation)
3.4.3. Quality assurance agreements with subcontractors for outsourced production steps and in the case of sterile devices for outsourcing of packaging and/or sterilisation

4. General Safety and Performance Requirements
4.1. Systematic evidence of compliance with the General Safety and Performance Requirements (preferably in the form of a checklist) including the following items:
- Justification for applicability / inapplicability of the requirement
- Reference to applied common specifications, standards or parts thereof (specific reference to the applied date of issue)
- Reference to controlled documents and records as evidence of compliance
- Evaluation if the requirements are fulfilled
- Approval by a responsible person (date, signature).

4.2. *List of applied standards and common specifications*
A current list of applied standards including the applied issue and, if applicable, indication of which parts of the standards have not been applied. (This item is part of 4.1 according to MDR, but explicitly required for Directive 93/42/EEC)

5. Benefit-risk analysis and risk management
The following items must be submitted from the current risk management file covering the whole life cycle:
5.1. Risk management plan
5.2. Risk analysis including risk control measures
5.3. Risk management report including the evaluation of residual risks and the evaluation of benefit-risk ratio

6. Product verification and validation
For each of the following items, a summary evaluation of the tests or a statement for non-applicability shall be provided. The test reports shall be submitted for the referenced tests.
The performance of testing in an accredited or recognized testing laboratory is not obligatory, but typically facilitates evidence of suitability.

6.1. Biocompatibility
All components and materials which (can) have direct or indirect contact with the patient or user must be considered
6.1.1. Chemical characterisation of materials
6.1.2. Literature research
6.1.3. Test reports of performed biological tests
6.1.4. Summary evaluation of all data and test results for the finished product.

6.2. Physical, chemical and microbiological testing
Evidence of characterisation and preclinical suitability of the devices with regard to applicable test parameters (e.g. physical composition, chemical characterisation and purity of raw materials and finished product, microbiological condition of the finished device, etc.)
6.2.1. Planning and overview of performed tests
6.2.2. Test reports of performed tests
6.2.3. Evaluation of data and test results

6.3. Electrical safety and electromagnetic compatibility EMC (if applicable)
6.3.1. Planning and overview of performed tests
6.3.2. Test reports of performed tests
6.3.3. Evaluation of data and test results

6.4. Software verification and validation (if applicable)
6.4.1. Description of the software development process (e.g. according to EN 62304)
6.4.2. Description of the software design (e.g. according to EN 62304, EN 62366)
6.4.3. Validation of the software as used in the finished device: e.g. a. summary results of verifications, validations and tests performed (in-house or in a simulated or in a real user environment)

6.5. Stability, including shelf life
6.5.1. Planning and overview of performed tests
6.5.2. Evidence that the devices meet the defined specifications during the defined shelf life. Results of the individual stability studies and evaluations on the following aspects:
6.5.3. Storage stability (accelerated ageing (e.g. Arrhenius equation) and real-time data)
6.5.4. Transport stability
6.5.5. In-use stability
6.5.6. Concept for maintenance and servicing over the entire lifecycle
6.5.7. Evaluation of data and test results

6.6. Other pre-clinical tests
Other preclinical tests not addressed under 6.1 to 6.5:
6.6.1. Planning and overview of performed tests
6.6.2. Test reports of performed tests
6.6.3. Evaluation of data and test results

6.7. Clinical evaluation
6.7.1. Clinical evaluation *(in case of Directive 93/42/EEC preferably according to MEDDEV. 2.7.1)*
Including information on the qualification of the author
6.7.2. Reviewed literature
6.7.3. Evidence of performed clinical investigations including
- Clinical investigation plan
- Clinical investigation report
- Vote(s) of the ethics committee(s)
- Regulatory approval of the clinical investigation
- Justification for the non-performance of a clinical investigation (class III and implantable devices)

6.7.4. Evidence of performed post-marketing clinical follow-up (PMCF)

6.8. Medicinal products within the meaning of Directive 2001/83/EC (if applicable– pursuant to the provisions of the consultation authority – following documents pursuant to the provisions of BfArM)
6.8.1. General information
6.8.2. Description of the composition of the active substance(s);
6.8.3. Statement regarding the reasonableness of the pharmaceutical content
6.8.4. GMP-certificate for the manufacturing of the medicinal product(s)
6.8.5. Description of the manufacturing steps relating to the medicinal product(s)
6.8.6. Control of the active substances (e.g. a declaration for the pharmaceutical quality)
6.8.7. Description of the in-process-controls of the medical device relating to the medicinal product
6.8.8. Description of the final quality controls of the medical device (e.g. identity, purity, content, release, compatibility)
6.8.9. Stability tests (or reference to the information given in chapter 6.5)
6.8.10. Toxicity - pharmacological/toxicological profile
6.8.11. Pharmacokinetics
6.8.12. Local compatibility
6.8.13. Clinical documentation (or reference to chapter 6.7)
6.8.14. Labelling / instruction for use (or reference to chapter 2)

6.9. Tissues or cells of animal origin (if applicable)
6.9.1. Explanation/justification for the use of material of animal origin in comparison to alternative products of non-animal origin
6.9.2. Evidence of the origin, rearing, feeding and age of the animals
6.9.3. Evidence of slaughter of animals and preparation/handling of tissues
6.9.4. Evidence of reduction/removal of transmissible pathogens
6.9.5. Description of the traceability for the products
6.9.6. Evidence of conformity with EN 22442-1, -2 und -3 and Regulation (EU) 722/2012

6.10. Substances that are intended to be introduced into the human body (if applicable)
6.10.1. Planning and overview of performed tests
6.10.2. Evidence of absorption, distribution, metabolism and excretion
6.10.3. Testing the interactions of those substances or of their metabolites in the human body with other devices, medicinal products or other substances, considering the target population and its associated medical conditions
6.10.4. Biocompatibility tests – particularly evidence of local compatibility, single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive toxicity and developmental toxicity

6.11. CMR or endocrine-disrupting activity (if applicable)
6.11.1. Planning and overview of performed tests
6.11.2. Test reports of performed tests
6.11.3. Evaluation of data and test results

6.12. Sterile devices and devices to be sterilised (if applicable)
6.12.1. Description of environmental conditions during manufacturing or cleaning and packaging
6.12.2. Description of cleaning
6.12.3. Description of packaging
6.12.4. Bioburden (initial microbial count) before sterilisation (EN ISO 11737-1)
6.12.5. Pyrogens/endotoxins
6.12.6. Description of the sterilization method and validation of sterilization (if applicable)

6.13. Measuring function (if applicable)
6.13.1. Planning and overview of performed tests
6.13.2. Test reports of performed tests
6.13.3. Evaluation of data and test results

6.14. Combination with other devices (if applicable)
6.14.1. Planning and overview of performed tests
6.14.2. Test reports of performed tests
6.14.3. Evaluation of data and test results

6.15. Hygienic (re-)processing of devices (if applicable)
- **6.15.1.** Validation of cleaning/disinfection processes specified in the instruction for use
- **6.15.2.** Validation of sterilisation processes specified in the instruction for use
- **6.15.3.** Evidence of numbers of specified reprocessing cycles
- **6.15.4.** Evidence of maintenance and functioning control specified in the instruction for use

7. Technical documentation on post-market surveillance
- **7.1.** Post-market surveillance plan (PMS-Plan)
- **7.2.** Post-market clinical follow-up plan (PMCF-Plan)
- **7.3.** Periodic safety update report according to Article 86 (MDR only)
- **7.4.** Post-market surveillance report according to Article 85 (MDR only)