

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 materials/components/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 ...)

- 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)