



# Technical Documentation

## Annex II

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### Technical Documentation

“The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner... ..”

Key Change: The MDR is very prescriptive regarding the Technical Documentation content and formatting.

## Annex II Technical Documentation

Technical Documentation requirements are subdivided into the following 6 sections:

1. Device description and specification, including variants and accessories
2. Information to be supplied by the manufacturer
3. Design and manufacturing information
4. General safety and performance requirements
5. Benefit-risk analysis and risk management
6. Product verification and validation

## Annex II 1. Device description and specification, including variants and accessories

- Product name, description, intended purpose, intended users
- Basic UDI-DI or other unambiguous reference (product code, catalogue number etc.)
- Intended population, indications, contraindications, warnings
- Principle of operation of the device and mode of action; scientifically demonstrated...
- Rationale for considering the product a medical device
- Device classification, applicable rules & rationale
- Explanation of any novel features
- Description of accessories provided with or without the device
- Description of all the relevant variants of the device... sizes, shapes, material thicknesses, etc.
- Device pictures, relevant drawings
- Description of all the relevant raw materials along with a risk assessment from biological safety perspective
- Technical specifications, dimensions & performance attributes
- Reference & overview of previous and similar generations of the subject device and device market history
- Discussion of medicinal therapies used in conjunction with procedure

## Annex II 2. Information to be supplied by the manufacturer (SPR 23)

A complete set of:

- the label or labels on the device and on its packaging and the instructions for use in the languages accepted in the Member States where the device is to be sold
- Promotional materials (Article 20)
- Implant Card (Article 18, SPR 23.4 aa)
- Summary of safety and clinical performance (SSCP, Article 32)

## Annex II 3. Design and manufacturing information

- Information to allow the design stages applied to the device to be understood
- Complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation

Note: ISO 13485:2016 requires design validation to be conducted on representative product (e.g., sterile finished devices).

- Identification of all sites including suppliers and subcontractors; where design and manufacturing activities are performed

## Annex II 4. General safety and performance requirements

- Documentation shall contain information to demonstrate conformity to general safety and performance requirements (GSPR or SPRs) that are applicable (Annex I) taking into account its intended purpose and shall include methods used to demonstrate conformity (justification, validation and verification).

SPR	Applicability	Standard or CS	Demonstration/ testing (justification, validation and verification)	Location  (Precise identity)
X				
Y				
Z				

Have to clearly show/demonstrate how each SPR is met/satisfied.

## Annex II 5. Benefit-risk analysis and risk management

The documentation shall contain information on:

- The benefit-risk analysis (Annex I, Section 1 and 8)
- The solutions adopted and the results of the risk management referred to in Section 3 of Annex I (SPR 3)

SPR 3 is essentially a summary of the requirements of EN ISO 14971:2012

## Annex II 6. Product verification and validation

The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity with the requirements of the MDR and in particular the applicable SPRs

### **Pre-Clinical and Clinical data**

- In Vitro & In Vivo test outcomes, simulated use testing, evaluation of the published literature and overall discussion of preclinical safety in combination with conformance with specifications
- Detailed discussion of test design, test protocols and reports with data analysis and conclusions in particular for the following:
  - biocompatibility (Annex I, SPR 10)
  - physical, chemical and microbiological characterization (Annex I, SPR 10 and 11)
  - electrical safety and electromagnetic compatibility (Annex I, SPR 18, AIMD: SPR 19)
  - software verification and validation (Annex I, SPR 17)
  - stability, including shelf life (Annex I, SPR 7)
  - performance and safety (Annex I, SPR 1 and 6)

Where applicable conformity to Directive 2004/10/EC (GLP Directive) must be demonstrated (for devices containing medicinal substances)

Where no new testing has been conducted the documentation shall incorporate a rationale for that decision

- Very prescriptive requirements with links to SPRs and CER; evaluation of the published literature with respect to pre-clinical testing
  - Clinical evaluation plan and report (along with updates) per Article 61(12) [CER] and Part A of Annex XIV (detailed description of CER)



## Annex II 6. Product verification and validation

### Additional information for specific cases:

- Medicinal substances requirements per Directive 2001/83/EC (Annex I, SPR 12)
- Requirements for devices utilizing tissues or cells of human or animal origin or their derivatives (Annex I, SPR 13)
- Devices composed of substances or combinations thereof intended to be introduced into the human body that are absorbed by or locally dispersed (Annex I, SPR 12)
- Carcinogenic, mutagenic or toxic to reproduction (CMR) and endocrine-disrupting substances (Annex I, SPR 10.4)
- Sterility and microbiological condition (Annex I, SPR 11)
- Measuring Function (Annex I, SPR 15)
- Devices connected to other devices, description and compliance with SPR (Annex I, SPR 14)