Technical Documentation Requirements under MDR

(including requirements for legacy files)

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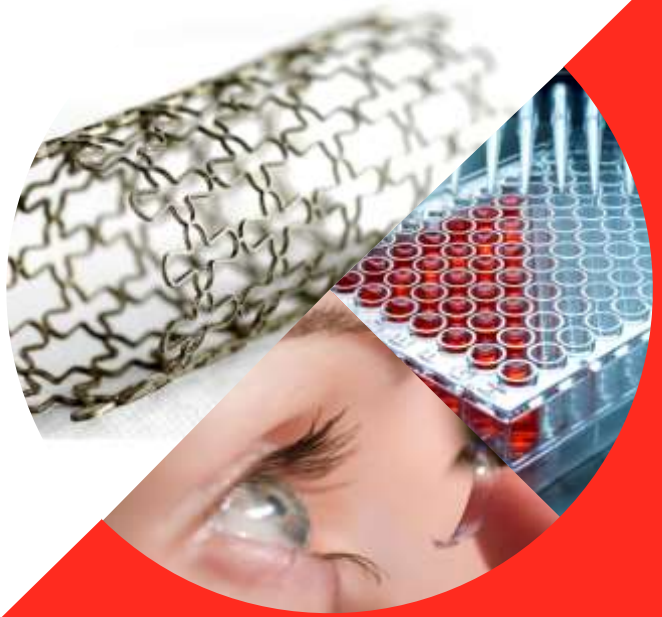
BSI Notified Body



Topics

- Overview of Technical Documentation Requirements
- New requirements?
- Clinical investigations and equivalence
- Reclassifications

Overview of Technical Documentation Requirements

MDR Requirements for technical documentation

Annex II: Technical Documentation

1: Device description

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

MDR Requirements for technical documentation

Annex II: Technical Documentation

- 1: Device description
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- Annex III: Technical Documentation on Post-Market Surveillance

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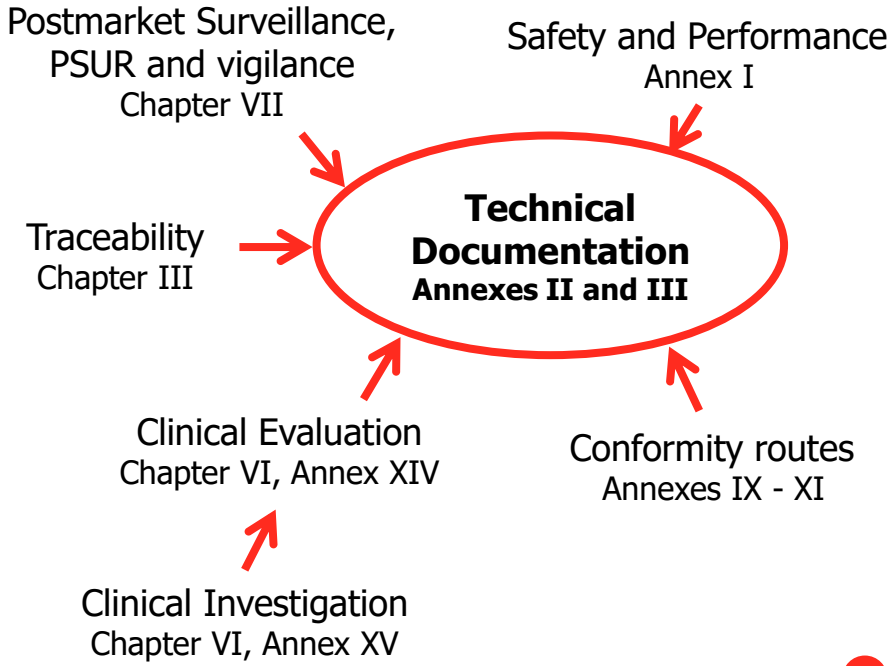
Annex III: Technical Documentation on Post-Market Surveillance



MDR Requirements for technical documentation

Annex II: Technical Documentation

1: Device description

- Product name, description, intended purpose
- Product identification including basic UDI-DI
- Principles of operation and mode of action
- Technical and material specification, description of key functional elements and any novel features
- Overview of previous generations of the device
- Overview of similar devices available in the EU or elsewhere

MDR Requirements for technical documentation

Annex II: Technical Documentation

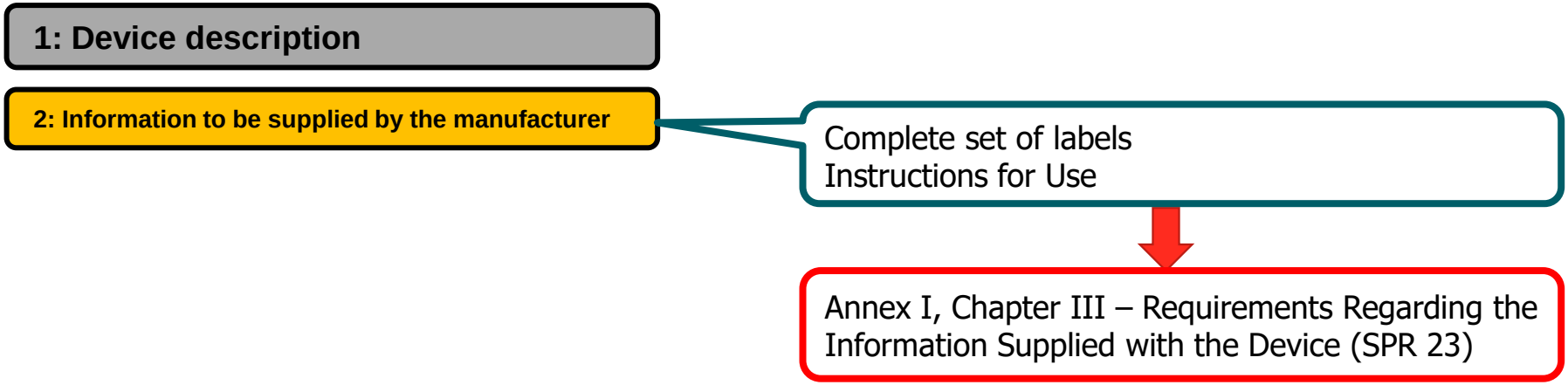
1: Device description

2: Information to be supplied by the manufacturer

Complete set of labels
Instructions for Use

MDR Requirements for technical documentation

Annex II: Technical Documentation



MDR Requirements for technical documentation

Annex II: Technical Documentation

1: Device description

2: Information to be supplied by the manufacturer

3: Design and manufacturing information

- Information to allow key design stages to be understood
- Description of manufacturing processes
- Manufacturing validations, monitoring and final product testing
- Identification of all suppliers and sub-contractors undertaking design or manufacturing processes for the manufacturer

MDR Requirements for technical documentation

Annex II: Technical Documentation

1: Device description

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Evidence of conformity with the Safety and Performance Requirements set out in Annex I, including:

- Identification of applicable SPRs
- Methods used to demonstrate conformity
- Applicable standards, Common Specifications or other requirements
- Links to documents demonstrating conformity with SPRs

MDR Requirements for technical documentation

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- Benefit-risk analysis as required by SPRs 1 and 8
- Solutions adopted and results of Risk Management as required by SPR 3

MDR Requirements for technical documentation

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5: Benefit-risk analysis and risk management

- Benefit-risk analysis as required by SPRs 1 and 8
- Solutions adopted and results of Risk Management as required by SPR 3

SPR 1 & 8: benefits > risks, risks reduced as far as possible and acceptable in light of the current state of the art

SPR 3: outlines the key clauses of EN ISO 14791

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- Pre-clinical and clinical testing
- Clinical evaluation report and plan
- PMCF plan and evaluation report
- Specific validations for devices incorporating medicinal substances, animal or human tissues, CMR or endocrine-disrupting substances, absorbable devices, sterile devices, devices with measuring function, devices used in combination

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Annex III: Technical Documentation on Post-Market Surveillance

- Includes PMS Plan, PMS Report and PSUR
- Minimum requirements for PMS Plan sources of information
- Specific guidance on how to evaluate PMS data
- Requirement (via Article 83) to update clinical evaluation, SSCP, design and manufacturing information and information for use on the basis of PMS output

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Topics

- ✓ Overview of Technical Documentation Requirements
- New requirements?
- Clinical investigations and equivalence
- Reclassifications

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- (explicitly stated) technical requirements (Annex I)

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- Post Market Clinical Follow Up (Chapter VI and Annex XIV, Part B)

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- (explicitly stated) technical requirements (Annex I)
- Potential for Common Specifications (Article 9)
- Clinical evaluation? (Chapter VI and Annex XIV, Part A)
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- Post Market Clinical Follow Up (Chapter VI and Annex XIV, Part B)
- Device reclassifications

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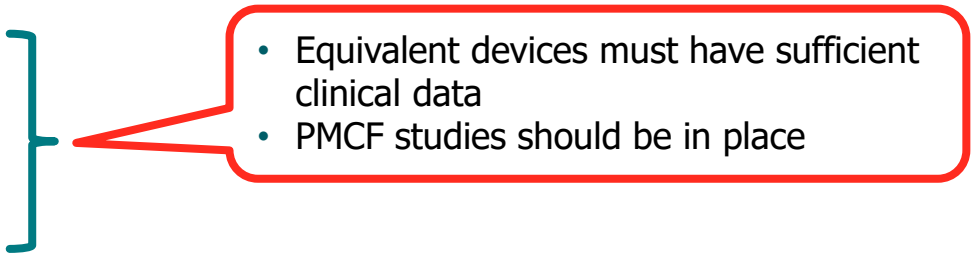

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- Compliant with CS if available

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- For other devices, the requirement is based on a risk assessment and totality of evidence of conformity to safety and performance requirements

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Conclusions of consultation must be documented in the clinical evaluation report

Rationales must be substantiated within the technical documentation

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Reclassifications

Device reclassifications (Annex VIII)

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Device reclassifications (Annex VIII)

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- Devices incorporating nanomaterials (if high or medium potential for internal exposure)
- Non-invasive devices used in direct contact with human cells for IVF
- Devices incorporating human derived substances
- Implantable contraceptives
- Absorbable non-implants (eg skin or GI)

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- Devices incorporating human derived substances
- Implantable contraceptives
- Absorbable non-implants (eg skin or GI)
- Software that could have an impact that may cause death or irreversible deterioration of a person's state of health

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