Technical Documentation Requirements under MDR
(including requirements for legacy files)

Dr Amie Smirthwaite
Clinical Oversight and Training Lead
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

Annexes II and III

Postmarket Surveillance, PSUR and vigilance
Chapter VII

Safety and Performance
Annex I

Traceability
Chapter III

Clinical Evaluation
Chapter VI, Annex XIV

Conformity routes
Annexes IX - XI

Clinical Investigation
Chapter VI, Annex XV
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

1: Device description

2: Information to be supplied by the manufacturer

Complete set of labels
Instructions for Use

Annex I, Chapter III – Requirements Regarding the Information Supplied with the Device (SPR 23)
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
2: Information to be supplied by the manufacturer
3: Design and manufacturing information
4: General safety and performance requirements

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

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

- 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

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

- 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
MDR Requirements for technical documentation

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1: Device description
2: Information to be supplied by the manufacturer
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6: Product verification and validation

- 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
Topics

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  - New requirements?
  - Clinical investigations and equivalence
  - Reclassifications
New requirements
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- (explicitly stated) technical requirements (Annex I)
New requirements?

• (explicitly stated) technical requirements (Annex I)
• Potential for Common Specifications (Article 9)
New requirements?

- (explicitly stated) technical requirements (Annex I)
- Potential for Common Specifications (Article 9)
- Clinical evaluation? (Chapter VI and Annex XIV, Part A)
New requirements?

- (explicitly stated) technical requirements (Annex I)
- Potential for Common Specifications (Article 9)
- Clinical evaluation? (Chapter VI and Annex XIV, Part A)
- Clinical investigations and equivalence
New requirements?

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

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

✓ Overview of Technical Documentation Requirements
✓ New requirements?
  • Clinical investigations and equivalence
  • Reclassifications
Clinical investigations and equivalence
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For Class III and implantable devices, clinical investigations shall be performed, except for:

- certain design modifications of the manufacturer’s own device
Clinical investigations and equivalence

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- equivalent devices marketed by other manufacturers, where contract allows ongoing access to data
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- Equivalent devices must have sufficient clinical data
- PMCF studies should be in place
Clinical investigations and equivalence

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- equivalent devices marketed by other manufacturers, where contract allows ongoing access to data
- existing CE-marked devices

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Clinical investigations and equivalence

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- equivalent devices marketed by other manufacturers, where contract allows ongoing access to data
- existing CE-marked devices
- sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors

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- Equivalent devices must have sufficient clinical data
- PMCF studies should be in place
- devices must have sufficient clinical data
- Compliant with CS if available
What is “sufficient clinical data?”
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- In general, based on scientific validity and robustness of clinical evaluation data
What is “sufficient clinical data?”

• In general, based on scientific validity and robustness of clinical evaluation data

• For Class III and implantable devices, the manufacturer may get advice from an Expert Panel appointed by the Commission
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Conclusions of consultation must be documented in the clinical evaluation report
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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

Conclusions of consultation must be documented in the clinical evaluation report
What is “sufficient clinical data?”

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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

Conclusions of consultation must be documented in the clinical evaluation report

Rationales must be substantiated within the technical documentation
Topics

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  • Reclassifications
Reclassifications
Device reclassifications (Annex VIII)

New Class III devices:
Device reclassifications (Annex VIII)

New Class III devices:

- Total and partial joint replacement implants
- Implants in contact with spinal column
Device reclassifications (Annex VIII)

New Class III devices:

- Total and partial joint replacement implants
- Implants in contact with spinal column
- 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)
 Device reclassifications (Annex VIII)

New Class III devices:

• Total and partial joint replacement implants
• Implants in contact with spinal column
• 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)
• Software that could have an impact that may cause death or irreversible deterioration of a person’s state of health
Topics

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✓ Clinical investigations and equivalence
✓ Reclassifications