Technical documentation in the new MDR

Annex I/II

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Annex I of the MDR

- ER 1a / 2 Requirements for risk management (similar to ISO 14971)
  (hint: warnings are a risk mitigation measure also MDR wise)
- ER 6 How to deal with risk/benefit of Annex XV devices (e.g. cosmetic devices)
- ER 7.4 Substances in direct contact: less than 0.1% weight or justification: carcinogenic, mutagenic, toxic to reproduction, endocrine disrupting (link to other regulations)
- ER 7.1 Impact of processes on material properties
- ER 7.6 Size and properties of particles / nano materials
- ER 11.4 Adjustment, calibration and maintenance safe and effective
- ER 11.5 Show compatibility and interoperability
- ER 13.4aa Reference to 2013/59/EURATOM for ionizing radiation
1. Core changes, Essential Requirements

Annex I of the MDR

- ER 14.3a IT security (IT security measures, protect against unauthorized access)
- ER 14.3 Mobile computing platforms (size, contrast of screen, noise)
- ER 15.8 Minimize unauthorized access
- ER 18 Use by lay persons
- ER 19.1 Information supplied has to be available on the web site of the manufacturer

Remember:
- All your TDs have to show compliance with the new essential requirements!
- As shown: many new or changed requirements!
- You will have to generate additional evidence!
2. Role of Common Specifications

Harmonized Standards

Common specifications

Mandatory for devices without medical purpose (annex XV)

When harmonized standards seem insufficient
3. Technical Documentation

- Shall be kept 10 / 15 years after the last piece is placed on the market

- The term design dossier will not exist anymore and is substituted by “Technical Documentation”

- Specific content of the technical documentation can be found in dedicated annex (II, IIa)
3. Technical Documentation

Structure is now defined

- Device description and specification
- Information supplied by the manufacturer
- Design and manufacturing information
- General safety and performance requirements
- Risk management
- Product verification and validation
3. Technical Documentation

Device description and product specification

- Basic UDI DI
- Patient population
- Principle of operation (scientifically demonstrated)
- Novel features
- Key functional elements
- Raw materials and technical specifications
- Reference to previous and similar devices (own devices and other devices)
3. Technical Documentation

Design and manufacturing information

- Information about the design stages
- Manufacturing processes and their validation
- Details on continuous monitoring and final product testing
- Identification of all sites (suppliers, sub-contractors)
3. Technical Documentation

Product verification and validation

- Results and critical analysis of all verification and validation tests
- Pre-clinical and clinical data
- Additional information in specific cases (e.g. medicinal products and tissues/cells involved)

Remember:
- Structure of the TD changed
- New evidence documents required
- Again: you have to rework your TDs!!!
3. Technical Documentation

**Summary of safety and clinical performance**

- It shall be submitted to the Notified Body

- The minimum content is clearly defined in the regulation

- The commission may set out form and presentation of the data elements to be included in the summary

- It is only applicable for class III and implantable devices
3. Technical Documentation

Article 26

Summary of safety and clinical performance

- It shall be made available to the public via Eudamed

- It shall be written in a way that it is clear to the user (and the patient, where applicable)

- Its location in terms of availability shall be mentioned in the accompanying documents
Declaration of Conformity

- Reference to Common Specifications applied is mandatory (not standards!)

- It shall claim conformity also to other directives, when applicable

- It shall mention the basic UDI-DI and the Single Registration Number

- Is it in an official union language or languages required by the Member State in which the device is made available
4. Interfaces

**Interfaces to other parts of the MDR**

- Post market surveillance results (annex IIa) are part of the technical documentation
- Clinical investigations (annex XIV) are part of the Technical Documentation
- Annex I defines requirements for risk management

- Assessment of the TD:
  - Sampling approach for class IIa / IIb
  - IIb implantable (with exceptions) and III → every device

- During unannounced audits (min. once every five years): „verify that the manufactured device is in conformity with the TD“
- Unannounced audits may include sampling from the market: „verify that the manufactured device is in conformity with the TD“
Open Discussion