NIST Conformity Assessment Workshop

EU MDR MDI CA - OVERVIEW & CHALLENGES

Michael Bothe / 27.09.2022, 8:30 Uhr ET
Agenda

01 European Stakeholder Interaction

02 Conformity Assessment Procedures under MDR

03 Proposal for MDI

04 Summary
EUROPEAN STAKEHOLDER INTERACTION
European Stakeholder Interaction

European Commission

- Issuing European regulations
- Orchestrating Operational Work of Notified Bodies by Oversight group (NBO)
- Coordinating Designation of Notified Bodies via Joint Assessment Teams (JAT)
- Issuing Mandates for the Standardization Bodies (CEN (ISO)/ CLC (IEC))
- Involving Harmonized Standards Consultants (HAS) before Harmonization

Represented by

Member States

Transposing requirements into national legislation

Competent Authorities

- Instating

Notified Bodies

Performing Conformity Assessments organized in TEAM-NB

Supervising Notified Bodies within their Member State organized in CAMD Competent Authority Group for Medical Devices
CONFORMITY ASSESSMENT PROCEDURES UNDER MDR
Interoperability – A Simple Task?

Citations in MDR

(26) ‘interoperability’ is the ability of two or more devices, including software, from the same or different manufacturers, to:
(a) exchange and use that information for the correct execution of a specified function without changing the content of the data, and/or
(b) communicate with each other, and/or
(c) work together as intended.

14.5. Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.

6.5.2. A new UDI-DI shall be required whenever there is a modification that changes:
(a) the original performance;
(b) the safety or the intended use of the software;
(c) interpretation of data. Such modifications include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability.

Assuming at least a temporarily static ecosystem of interoperable devices!
## Conformity Assessment Routes under MDR

### Overall Framework

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### Class I

Class I

- **Class I (m,s,r)**
  - Annex IX Chapter I + III or Annex XI Part A

### Class IIa

Class IIa

- Annex IX Chapter I + III + TD IX Section 4 of a representative Sample per Product category or TD Annex II + III + Annex XI Section 10 or 18 a representative Product per each Product category

### Class IIb

Class IIb

- Annex IX Chapter I + III + representative Product per generic Product group (TD Assessment acc. Annex IX Section 4) or Annex X + Annex XI

### Class IIb Implantable

Class IIb Implantable

- Assessment of the TD for any Product acc. to Annex IX Section 4 or Annex X + Annex XI

### Class III

Class III

- Annex IX or Annex X + XI

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Note: Exemption Products stated
Conformity Assessment Routes under MDR

Most Common Risk Classes for MPI

Class IIa

Annex IX
Chapter I + III
+ TD IX Section 4
of a representative Sample per Product category

Class IIb

Annex IX
Chapter I + III
+ TD IX Section 4
of a representative Sample per Generic Product Group
Conformity Assessment Routes under MDR
What and when @ Initial Certification

ASSESSMENT OF TECHNICAL DOCUMENTATION

ASSESSMENT OF QUALITY MANAGEMENT SYSTEM (Stage 1 Audit)

ASSESSMENT OF QUALITY MANAGEMENT SYSTEM (Stage 2 Audit)

QMS-Certificate
Synchronized

Product Certificate
# Technical Documentation

## Annex I: General Safety and Performance Requirements

### Chapter I: General requirements

1. Safety & Performance
2. Risk reduction
3. Risk management system
4. Risk control & handling of risks
5. Elimination or reduction of User errors
6. Verification of service life
7. Transport & storage
8. Benefits - Risks
9. Products Annex XVI

### Chapter II: Requirements regarding Design and Manufacture

10. Chemical, physical & biological characteristics
11. Infection and microbial contamination
12. Substances considered as medicinal products and products consisting of substances or combinations of substances
13. Products whose components include materials of biological origin
14. Manufacture of products and interactions with their environment
15. Products with diagnostic or measuring function
16. Protection against radiation
17. Programmable electronic systems: products whose components include programmable electronic systems and products in the form of software
18. Active products and products connected to them
19. Special requirements for active implantable products
20. Protection against mechanical and thermal risks
21. Protection against risks to the patient or user from devices that emit energy or substances
22. Protection against the risks posed by medical devices for which the manufacturer envisages use by lay persons

### Chapter III: Requirements reg. Information supplied with the Device

23. Labeling & instructions for use
Technical Documentation
Annex I : Software Specific Requirements

17. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves

17.1 R & R, Performance

Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.

17.2 LCM, RM, Cyber, V&V

For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.
### 17.3 External factors

Software referred to in this Section that is intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).

### 17.4 Minimum Requirements

Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorized access, necessary to run the software as intended.
General Safety and Performance Requirements
Context of Cybersecurity in MDCG 2019-16

Basic Cybersecurity Concepts

General safety and performance requirements with focus on cybersecurity

IT Security (sec. 17.4, 23.4ab)
Operation Security (sec. 14.1, 14.2, 17.1)
Information Security (sec. 17.2)

Safety/security and effectiveness (sec. 1)
Reduce risk to ensure intended device performance and high level of protection of health (sec. 2, 5, 6, 9)
- In all operation mode
- Intended/reasonable foreseeable risk

Secure Design and Manufacture (sec. 4a)
- Risk management across the life cycle (sec. 3, 14.4, 14.5, 19.3)
- Protection against risk during intended use and reasonable foreseeable misuse (sec. 3c. 8)
- Protection against unauthorised access (sec. 173, 188)
- Identify threats, vulnerabilities, hazards, risks (sec. 3b)
- Establish risk control measures (sec. 4)
- Minimum IT security requirements (sec. 17.4, 14.5)

MDR Annex I
Information for users, instructions and labelling (sec. 4, 23.1, 22.1, 23.4)
State of the art (sec. 1, 4, 17.2)

Verification/validation (sec. 17.2)
Acceptable residual risk (sec. 4)
Documentation* (sec. 3)

Regular updates

* See also Annex II of MDR

Technical Documentation

Annex III: Technical Documentation on Post-Market Surveillance

Post-market surveillance, vigilance and market surveillance
- Post-marketing surveillance (Art. 83-86 MDR)
- Vigilance (Art. 87 - 92 MDR)
- Market surveillance (Art. 93 -100 MDR)

Continuation of the TD Documentation of the PMS activities

MDR

Annex XIV Clinical evaluation and post-market clinical follow-up
- PMCF plan required
- Justification is required if such a plan does not apply

Annex XIV part A Clinical evaluation
- Collection of clinical data
- Updating/improving clinical evaluation
- Collected data is included in various reports
PROPOSAL FOR MDI
Proposal for MDI Products

Laboratory Testing
- Safety
- EMI
- Interface Interoperability
- Penetration Testing

Clinical Evaluation
- Validation
- Usability
- Clinical Performance

Assessment of Technical Documentation
General Safety and Performance Requirements
Cybersecurity

Assessment of Quality Management System
Regulatory Compliance
Design and Production
Cybersecurity

HCSP:
Integration Testing @ Installation

IEC/TR 80001-2-6
Guidance for Responsibility Agreements

MDM
Post Market Surveillance
Range Extension
Intended Purpose Extension
Complaints
Reports: PMS, PSUR, PMCFR
Vigilance
SUMMARY
Summary

• The European Regulation for Medical Devices is an evolutionary Approach
• Virtually all aspects as Life Cycle Approach, Risk Management, Validation, Clinical have been in place since long at least with lower levels
• There is an established Conformity Assessment Scheme, which fits well for Devices with embedded Software
• The only Gap is the dynamic interoperability with devices, not being defined, designed, assessed and certified at the initial certification of early products
• To fill that gap the following approach is proposed:
  • generic Interface tests before certification under the regime of MDM’s and
  • Integration tests during installation under the regime of HCSP’s