Implications of the new MDR from a Product Testing and Certification Perspective

Helping You to Access Global Markets – FAST and PREDICTABLY
MDR - Implications from Certification Perspective
Certification under the new MDR

1. Check Definition of Medical Device
   - Article 2

2. Determine “Device Class”
   - Article 41, Annex VII

3. Select “Conformity Assessment Procedure”
   - Article 42

4. Identify Applicable “Safety and Performance Requirements”
   - Article 4, Annex I

5. Assemble “Technical Documentation”
   - Annex II

6. Apply Conformity Assessment Procedure
   - Annexes VIII, IX, X, XI

7. Complete “Declaration of Conformity”
   - Article 17, Annex III

8. Affix “CE Mark”
   - Article 18, Annex IV
Rules and Classifications – Annex VII

- 21 rules, 1-4 non-invasive, 5-8 invasive, 9-12 active, 13-23 special (18&20 deleted)
- Known classes: custom made, Is, Im, Ila, IIb, III
- **New categories / new requirements:**
  - Class III custom-made implantable devices, class Ir (reusable), class IIb (implants), class IIb (active), class III (implants)
- With increased device classification increased involvement of different parties is required:
  - Self-certification
  - Notified Body Conformity Assessment
  - Competent Authority Assessment
  - Commission Assessment - New
Conformity Assessment Routes – Article 42

- **Custom made devices – No principle change**
  
  Annex XI (Procedure) in combination with Annex XIII (PMS / PMCF / Incidents)

- **Custom made devices which are Class III implants – New**
  
  Annex XI in combination with either Annex VIII (QMS) or Annex X – Part A (Production QA)

- **Class I devices (none s / m / r) – No principle change**
  
  Annex II (Technical Documentation)

- **Class I(s), I(m), I(r) devices - New I(r) for reusable devices**
  
  Annex II (Technical Documentation) in combination with either Annex VIII (QMS) or Annex X – Part A (Production QA)
Conformity Assessment Routes – **Article 42**

- **Class IIa devices – No principle change**
  Annex II (TD for each category) in combination with Annex VIII (QMS) or
  Annex II in combination either with Annex X – part A (Production QA) or Annex X – part B (Product Verification)

- **Class IIb devices – No principle change**
  Annex II (TD for each category) in combination with Annex VIII (QMS) or
  Annex IX (Type Examination) in combination either with Annex X – part A (Production QA) or
  Annex X – part B (Product Verification)

- **Class IIb implantable devices – new with the exception of:**
  - sutures, staples, dental fillings & braces, tooth crowns, wedges, plates, pins, clips & connectors
  Annex VIII (Technical Documentation) in combination with Annex VIII (QMS) or
  Annex IX (Type Examination) in combination either with Annex X – part A (Production QA) or Annex X – part B (Product Verification)
Conformity Assessment Routes – Article 42

- **Class III devices – No principle change**
  Including those with medicinal substances, human tissues or animal tissues
  Annex VIII (Technical Documentation) in combination with Annex VIII (QMS) or
  Annex IX (Type Examination) in combination either with Annex X – part A (Production QA) or Annex X – part B (Product Verification)

- **Class III implantable & Class IIb Active Devices intended to administer medicinal products**
  Annex VIII (Technical Documentation) in combination with Annex VIII (QMS) or
  Annex IX (Type Examination) in combination either with Annex X – part A (Production QA) or Annex X – part B (Product Verification)
  Consultation Procedure – Annex VIII or Annex IX Section 6 - New
Requirements to be met by Notified Bodies – Annex VI

- **Certificate Requirements**
  to be shown on QMS and Technical Documentation Certificates – Annex XII
  - From Ila devices upwards the definition of the “Indented Use”
  - Device, Classification, Intended Use, new UDI-DI (Annex V)

- **Re-designation Process for NB**
  - Early part of second half of 2017
  - Schedule to be seen at the end of this presentation
Clinical Evaluation – Annex XIII

- **Article 2 defines Scope and Definitions**
  - Clinical Data, Clinical Evaluation and Clinical Evidence

- **Annex XIII - Part A: Clinical Evaluation**
  - Definition of similar devices / not clinically significant different
  - Equivalence based on proper scientific justification
  - Sufficient level of access to the data from devices to which equivalence is claimed.
Clinical Investigations – Annex XIV

- **Clinical Evaluation and Investigation – Article 49**
  
  Potentially no clinical investigation for implantable devices & class III when:

  - Devices which have been placed onto the market under current directives and for which clinical evaluation is based on sufficient clinical data and in compliance with common specifications, where available.

  - Devices modified by the same manufacturer who placed the device legally on the market

  - Devices for which demonstration of equivalence is endorsed by NB (Annex XIII) and clinical evaluation is sufficient demonstrated

  - Devices falling under sutures, staples, dental fillings, etc. where compliance with the relevant product specific common specification is confirmed

  - Devices for which two manufacturers have a contract in place allowing full access to their technical documentation
Post Market Surveillance – PMS / PMCF – Annex XIII

- **Article 60 C - Periodic Safety Update Report (IIa, IIb and III devices)**
  - Manufacturer to prepare the PSUP (annual or biannual updates)
  - Manufacturer to submit reports to NB’s
  - Depending on device classification NB will evaluate the report and submit to Competent Authorities through the EUDAMED electronic system (next slide)

- **Article 26 – Summary of Safety and Clinical Performance (III implantable devices)**
  - Manufacturer to prepare the SSCP (annual update)
  - To be made public via EUDAMED
  - Drafted version to be submitted to NB
EUDAMED – Article 27

- Electronic System for Manufacturer Registration - SRN
- Electronic System for UDI
- Electronic System on Vigilance + Periodic Safety Update Report - PSUR
- Applications + Summary of Safety and Clinical Performance – SSCP
Technical Documentation – Annex II

- Device description, Specifications + UDI, Variants & Accessories
- Reference to previous / similar generations of the device
- Information supplied by the manufacturer
- Design and manufacturing information
- General Safety and Performance Requirements (todays ER’s)
- Risk/Benefit Analysis and Risk Management
- Product Verification / Validation
- Pre-clinical and Clinical Data
- Additional information in specific cases
  - Medicinal substances, tissues of human or animal origin, substances that are absorbed, sterile, measuring function, configuration of devices
UDI – Unique Device Identification – Article 24

- To be placed on individual and higher package systems (not on shipping containers)
- The UDI shall be used for reporting incidents and FSCA – Article 61
- The UDI shall appear on the D of C – Article 17
- The manufacturer shall have a up-to-date list for applied UDI’s in his TF
- SPR# 19.2 Information on the label
  - (h) the UDI carrier according to article 24 and Annex V, part C
Transition Timelines (Article 94 of draft dated June 2016)

Q4 2016*
Adoption of MDR

Entry into Force (EUOJ) (Q1 2017*)

Date of Application (Q1 2020*)

Transition period 3 years

MDD/AIMD certificates (max 5-year expiry from issue/renewal date)

MDR certificates

Last MDD/AIMD certificates expire (Q1 2024*)

NBs designation under MDR, e.g. BSI

* Dates are « best guess » based on our current understanding on the process/steps to be completed.
HOW TO GET EVIDENCE FOR THE TECHNICAL DOCUMENTATION
Overview

• Harmonized Standards and Common Specification
• Technical documentation & general safety
• Standard IEC 60601-1 (for medical electrical devices)
MDR

- Article 6 Use of Harmonised standards
  *Reference to the standards listed in the Official Journal*

- Article 7 Common specifications
  *when adopted by the Commission*
ANNEX I
General Safety and Performance Requirements

(I.2) …devices shall conform to safety principles, taking account of the generally acknowledged state of the art.
ANNEX II Technical Documentation

• (4c) the harmonised standards or CS applied or other solutions employed

• (4d) … offering evidence of conformity with each harmonised standard, CS or other method employed to demonstrate conformity with the general safety and performance requirements. …. 
IEC 60601 Series

60601-1

60601-1-xx

60601-2-xx
60601-1

• Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

• Valid for all Medical Electrical Equipment (Basic Standard)
Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems ...

Collaterals add new horizontal aspects
- IEC 60601-1-2 Electromagnetic compatibility
- IEC 60601-1-3 Radiation protection in diagnostic X-ray equipment
- IEC 60601-1-6 Usability
- IEC 60601-1-8 Alarm systems
- IEC 60601-1-9 Environmentally conscious design
- IEC 60601-1-10 Physiologic closed-loop controllers
- IEC 60601-1-11 Home healthcare environment
- IEC 60601-1-12 Emergency medical services environment

Already incorporated in the basic standard (3rd Ed.) Part -1-1 and -1-4
Medical electrical equipment — Part 2-x: Particular requirements for the basic safety and essential performance of …

Product specific requirements e.g.:
- IEC 60601-2-2 high frequency surgical equipment
- IEC 60601-2-18 Endoscopic equipment
- IEC 60601-2-22 Laser
- IEC 80601-2-60 Dental equipment
- ISO 80601-2-61 Pulse oximeter equipment
Roadmap 60601 Family

IEC 60601-1
Medical Electrical Equipment – Part 1: General Requirements for Safety

IEC 60601-1
Medical electrical equipment, Part 1: General requirements for basic safety and essential performance

IEC 60601-1
Medical Electrical Equipment ...
Thank you

Questions?
Contact

www.test-medical-devices.com

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