WEBINAR on the new Medical Device Regulation

2017-07-12

One-stop testing, inspection, certification and training solutions
TÜV SÜD at a glance

- **150+** YEARS OF QUALITY, SAFETY & SUSTAINABILITY
- **1,000** LOCATIONS WORLDWIDE
- **€2.3 BILLION** IN ANNUAL REVENUE
- **24,000** EMPLOYEES
- **574,000** CERTIFICATES
- **100%** INDEPENDENT & IMPARTIAL
- **43%** OF REVENUE OUTSIDE GERMANY
- **150+ YEARS OF QUALITY, SAFETY & SUSTAINABILITY**

Note: Figures have been rounded off.
Disclaimer

This presentation is based on information available as of today and prepared to my best knowledge. This presentation presents my personal understanding of the medical device requirements in Europe. The presentation includes figures that were copied from public websites. A citation to the original source is included in the Footnote of this presentation.
EU’s Medical Device Regulation (MDR)

<table>
<thead>
<tr>
<th>Year</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>2008</td>
<td>Commission: consultation on medical device framework</td>
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<tr>
<td>2012</td>
<td>Commission: proposal for new MDR</td>
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<td>2014 Q2</td>
<td>Parliament: position on MDR</td>
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<td>2015 Q3</td>
<td>Council position on proposed Regulation</td>
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<td>2015 Q4</td>
<td>Trilogue: Commission, Parliament, Council</td>
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<td>2017</td>
<td>MDR published on May 5, 2017</td>
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<tr>
<td>2020</td>
<td>End of three-year transition on May 26, 2020</td>
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How long is the grace period?

Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its issuance. They shall however become void at the latest four years after the date of application of the Regulation.
Structure of the MDR - New Chapters

Chapter I
- Scope and definitions

Chapter II
- Making available and putting into service of devices, obligations of economic operators, reprocessing, CE marking, free movement

Chapter III
- Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European databank on medical devices

Chapter IV
- Notified bodies

Chapter V
- Classification and conformity assessment

Chapter VI
- Clinical evaluation and clinical investigations

Chapter VII
- Post-market surveillance, vigilance and market surveillance

Chapter VIII
- Cooperation between Member States, Medical Device Coordination Group, Expert laboratories, Expert panels and device

Chapter IX
- Confidentiality, data protection, funding, penalties

Chapter X
- Final provisions
Manufacturers shall

- establish, execute, maintain and document a system for **risk management** as described in Section 1a in Annex I.
- conduct a **clinical evaluation** in accordance with the requirements set out in Article 61 and Annex XIV, including **post-market clinical follow-up**.
- draw up and keep up to date the **technical documentation** ... include the elements set out in Annex II, etc.
Article 2 – Definitions „Economic Operators“

- Manufacturer outside EU
- Manufacturer inside EU
- Authorised Representative
- Distributor
- Importer
Changes between MDD/AIMDD and MDR

Classification Rules

- There were 18 rules within the current MDD (Annex IX)
- Active implantable medical devices were covered in a separate Directive
- Within the new MDR there will be 22 Rules (Annex VIII)
- Some definitions were changed
New MDR Proposal
Classification Dispute

Art. 51

Manufacturer (registered place of business) and notified body in the same Member State

Manufacturer

Classification

NB

Dispute

Accepted

Competent authority of the Member State of the manufacturer (address of business)

Manufacturer (registered place of business) and notified body in different Member States

Notification to MDCG

Consultation with competent authority of the Member State which designated the notified body

Competent authority of the Member State of the manufacturer (address of business)
MDR Article 10 – Number 4

General obligations of manufacturers

Manufacturers of devices other than custom-made devices **shall draw up and keep up to date technical documentation for those devices.**

The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. **The technical documentation shall include the elements set out in Annexes II and III.**

The Commission is empowered to adopt **delegated acts** in accordance with Article 115 amending, in the light of technical progress, the Annexes II and III.
The technical documentation shall be presented in a:

- clear
- organized
- readily searchable
- unambiguous manner
General Overview – Technical Documentation

- Process Data
- Validation Data
- Pre-clinical Data
- Information on Design Stages

Major elements
General Overview - Chapters of Annex II

Device description and specification, including variants and accessories
- Device description and specification
- Reference to previous and similar generation of the device

Information to be supplied by the manufacturer

Design and manufacturing

General safety and performance requirements

Benefit-risk analysis and risk management

Product verification and validation
- Pre-clinical and clinical data
- Additional information required in specific cases
General Overview – Annex III

Annex III – Post-Market Surveillance

Introduction
The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 83 to 86 shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements described in this Annex.

Changes compared to MDD & AIMDD
Completely new Annex with new content and requirement to keep Post-Market Surveillance data as part of the Technical Documentation.

Major Elements
• Post Market Surveillance Plan
  – Post Market Clinical Follow Up plan / justification why not applicable
• Periodic Safety Update Report (PSUR)
Annex IX

Chapter I: A QUALITY MANAGEMENT SYSTEM

Chapter II: ASSESSMENT OF TECHNICAL DOCUMENTATION

Annex X

TYPE EXAMINATION

Annex XI

PART A: PRODUCTION QUALITY ASSURANCE

PART B: PRODUCT VERIFICATION

Annex XIII

PROCEDURE FOR CUSTOM-MADE DEVICES
To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements laid down in this Regulation should be based on clinical data that, for class III devices and implantable devices should, as a general rule, be sourced from clinical investigations that have been carried out under the responsibility of a sponsor.
The manufacturer demonstrates the equivalence based on the comparison testing following the applicable SOP.

It shall be clearly demonstrated that manufacturers have sufficient levels of access to the data relating to devices with which they are claiming equivalence in order to justify their claims of equivalence.
In the case of implantable devices and devices falling within class III, clinical investigations shall be performed, except if:

- the device has been designed by modifications of a device already marketed by the same manufacturer
- the modified device has been demonstrated by the manufacturer to be equivalent to the marketed device
- the clinical evaluation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements.
- In this case the notified body shall check that the PMCF plan is appropriate and includes **post market studies** to demonstrate the safety and performance of the device.

*Clear contract between different device manufacturer*
A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by him, may also rely on the previous wording in order not to perform a clinical investigation provided that the following conditions are fulfilled in addition to what is required in that paragraph:

- the two manufacturers have a contract in place that explicitly allows the manufacturer of the second device full access to the technical documentation on an ongoing basis
- the original clinical evaluation has been performed in compliance with the requirements of this Regulation,
- the manufacturer of the second device provides clear evidence thereof to the notified body.
The requirement to perform clinical investigations pursuant to previously presented requirements shall not apply to implantable devices and devices falling into class III:

- which have been lawfully placed on the market or put into service in accordance with Directive 90/385/EEC or Directive 93/42/EEC and for which the clinical evaluation
- is based on *sufficient clinical data*
- is in compliance with the relevant product-specific common specification for the clinical evaluation of that kind of device, where such a common specification is available
The requirement to perform clinical investigations pursuant to previously presented requirements shall not apply to implantable devices and devices falling into class III:

- that are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which the clinical evaluation is based on sufficient clinical data and is in compliance with the relevant product-specific common specification, where such a common specification is available.
The manufacturers should:

- establish a comprehensive post-market surveillance (PMS) system
- set up under the quality management system
- and based on a PMS plan.

The post-market surveillance system shall be suited to actively and systematically gathering, recording and analyzing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.
What is a active PMS?

Examples of PROACTIVE PMS Methods

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<th>Method</th>
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<tr>
<td>Planned Customer Surveys</td>
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<td>Prospective and retrospective Post-market clinical studies or trials</td>
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<td>Company-supported Investigator-Sponsored Studies (ISS)</td>
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<td>Extended clinical investigations</td>
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<td>Company registry based on the output of the risk management file and the CER</td>
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<tr>
<td>Planned Analysis of Regional or National Device Registries - Hospital Databases, Registries</td>
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Per device and where relevant per category or group of devices, the manufacturer shall prepare a periodic safety update report summarizing the results and conclusions of the analyses of the gathered post-market surveillance data according to Annex Ila together with a rationale and description of any preventive and corrective actions taken.

Throughout the lifetime of the device concerned this report shall set out:

- the conclusion on the benefit risk determination
- the main findings of the Post Market Clinical Follow-up Report
- the volume of sales of devices and an estimate of the population that use the device involved and, where practicable, the usage frequency of the device.
In the case of devices classified as class III and implantable devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance.

The manufacturer shall mention on the label or instructions for use where the summary is available.
The SSCP shall be:

- written in a way that is clear to the intended user and, if relevant, to the patient
- made available to the public via Eudamed.
- part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 52
- validated by that body
The summary of safety and clinical performance shall include at least the following aspects:

- the identification of the device and the manufacturer, including the basic UDI-DI and the single registration number SRN;
- the intended purpose of the device, including indications, contra-indications and target populations;
- a description of the device, including a reference to previous generation(s) or variants if such exist, and the description of the differences, as well as a description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the medical device;
- possible diagnostic or therapeutic alternatives;
- reference to harmonized standards and common specifications;
- the summary of the clinical evaluation as referred to in annex XIII, and relevant information on the post-market clinical follow up;
- suggested profile and training for users;
- information on any residual risks and any undesirable effects, warnings and precautions.
EU MDR Regulation
Applicable for Class III and Implantable Medical Devices

PSUR: Periodic Safety Update Report
CER: Clinical Evaluation Report
SSCP: Summary of Safety and Clinical Performance
PMCFR: Post-Market Clinical Follow-Up Evaluation Report

Art. 61(11) • Annual for Class III and Implants
PMCFR
Partial TD • Annual for Class III and Implants
SSCP

PSUR: Start after approval
CER: Prepare by considering the post-market experience
SSCP: Summarise the technical documentation

t= 0Y
The conclusion on the risk benefit determination

t= 1Y
The summary of the clinical evaluation
For implantable devices and devices classified as class III devices, the PSUR shall be:
- Updated annually
- Submitted via EUDAMED for assessment by Notified Body annually
- Submitted in combination with an updated Clinical Evaluation Report
- Submitted in the language accepted by the Notified Body

For devices classified as IIa devices, the PSUR shall be:
- Updated biennially and when necessary
- Included in the technical documentation
- Submitted in combination with an updated Clinical Evaluation Report for assessment by Notified Body or other interested parties when requested
- Submitted in the language accepted by the Notified Body

For devices classified as IIb devices, the PSUR shall be:
- Updated annually
- Included in the technical documentation
- Submitted in combination with an updated Clinical Evaluation Report for assessment by Notified Body or other interested parties when requested
- Submitted in the language accepted by the Notified Body
Mechanism for scrutiny of conformity assessments of certain class III and class IIb devices

For class III implantable devices and class IIb active devices intended to administer and/or remove a medicinal product, notified bodies should, except in certain cases, be obliged to request expert panels to scrutinise their clinical evaluation assessment report.
Clinical evaluation consultation procedure for certain class III and class IIb devices – Article 54

Applicable for implantable devices classified as class III, and for Class IIb active devices intended to administer and/or remove a medicinal product, as referred to in section 6.4 of Annex VIII (Rule 12)

Immediate transfer to Expert Panel
Opinion within 60 days
Submission to EU Commission
Clinical Evaluation Report
Post-Market Clinical Follow-up Plan
Promotional Materials
Promotional Materials
Post-Market Clinical Follow-up Plan
Submission to EU Commission
Immediate transfer to Expert Panel
Eudamed: Modules

- Traceability (UDI)
- Devices
- Market surveillance
- Vigilance
- Eudamed
- Actors
- Certificates
- Studies / CI
- NBs
MDR Services – No Consulting Services

**Mock TD Assessment**
- Check readiness of TD creation and updating procedures in QMS
- Check availability of data
- Provides observations and potential deficiencies to your TD

**Mock MDR Audits**
- Check readiness of Quality Management System
- Check readiness of specific procedures
- Provides observations and potential deficiencies to your QMS

**Product Portfolio Workshop**
- General MDR Training
- Check available evidence on
  - Clinical data
  - Market surveillance data
  - Compliance data for the fulfillment of the MDR
- Identify and discuss non-MDR compliant devices now
Save the Date! 2017 Fall MDR Roadshows

Join us for

*Latest News on the European Medical Device Regulation!*

Boston, MA – Tuesday, October 17th
Location TBD

Raleigh, NC – Thursday, October 19th
Location TBD

Visit [www.tuv-sud-america.com/MHSRoadshows](http://www.tuv-sud-america.com/MHSRoadshows) for more information
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