# LISAvienna Business Treff: Die neuen Herausforderungen für Medizinprodukte und IVD
# The new MDR / IVDR – major changes

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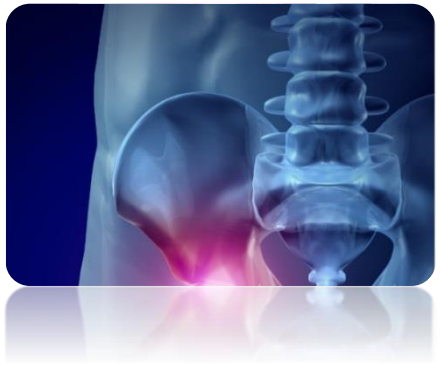
# HEALTH AND MEDICINE



## NOTIFIED BODY FOR THE MEDICAL DEVICES

SIQ is the only notified conformity assessment body in South East Europe for Medical Device Directive 93/42/EGS in conformity assessment procedures of medical devices according to Annexes II, III, IV, V and VI.

We are authorized to verify the type of non-active and active medical devices of all classes, which can be sterile or contain software.

CE 1304

The scope of notification is evident under the Agency of the Republic of Slovenia for Medicines and Medical Devices (ARSZMP) and NANDO database

## CE marking – Medical Device Directive (MDD)

# Content

- Regulatory framework and structure of MDR and IVDR
- Major changes
- Transitional provisions

# THE MAIN REASONS FOR CHANGE

Problems:

- Diverging interpretation of directives within different EU states (MDD, IVDR, AIMD)
- Incidents which show the weaknesses and damaged confidence in the system

Goals:

- Consolidate role of EU as global leader in the sector
- System providing **high level of health and safety protection of users of medical devices**
- Adaptation to significant technological and scientific progress

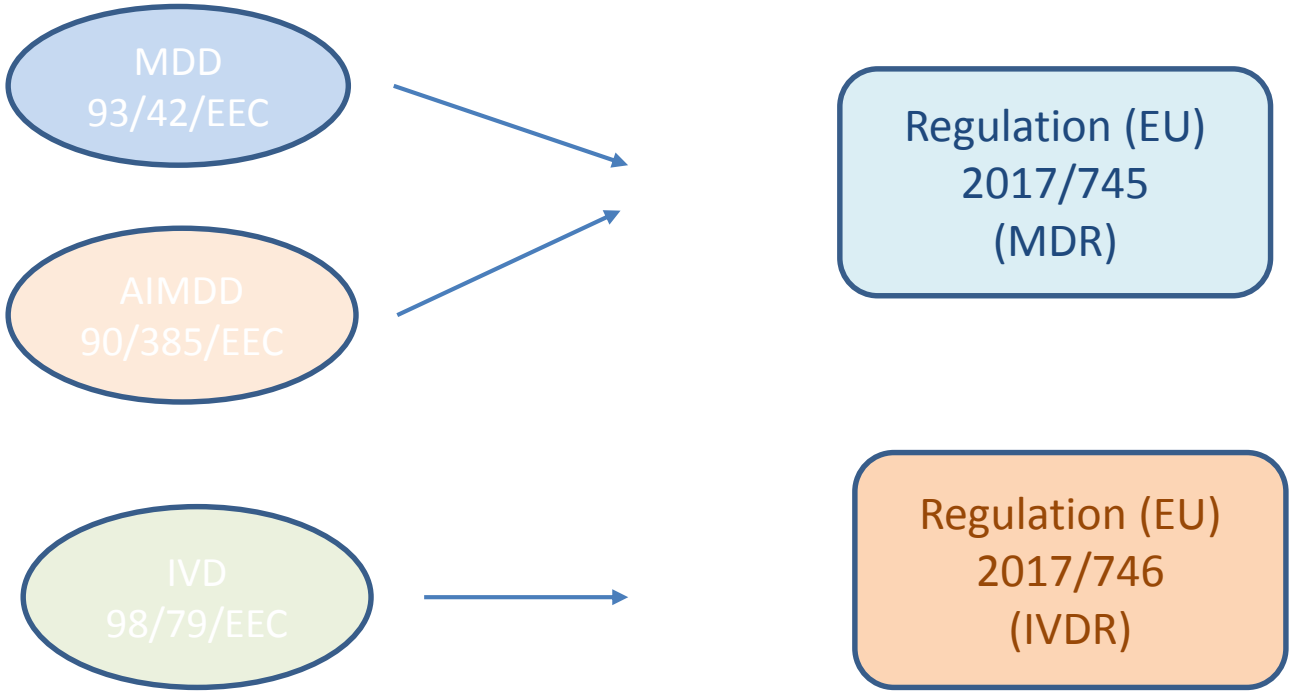
# LEGAL DOCUMENTS

**Transposition to national legislation,** can be adjusted

- Directives

**Directly applicable,** form part of each member state Law

- Regulation



# Legal documents and references

- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on **medical devices**, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on ***in vitro* diagnostic medical devices and** repealing Directive 98/79/EC and Commmission Decision 2010/227/EU
- Book MANUFACTURER A-Series, Version 1 / March 2017, Manfred Kohler https://www.mdlaw.eu/global-packs

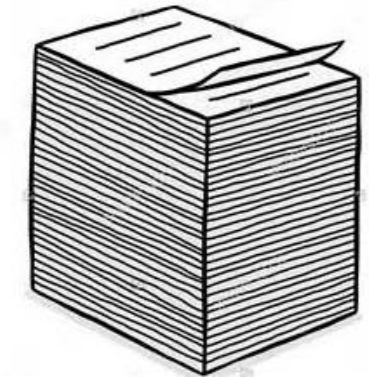
# COMPARISON OF MDD AND MDR

**MDD 93/42/EEC** (60 pages)

- 23 Introduction paragraphs
- 23 Articles
- **XII Annexes**

**Regulation (EU) 2017/745** (175 pages)

- 101 introduction paragraphs
- 10 Chapters / 123 Articles
- **XVII Annexes**



# MDR STRUCTURE

- Chapter I – **Scope and definition** (Articles 1-4)
- Chapter II – **Making available on the market and putting into service of devices**, obligations of economic operators, reprocessing, CE marking, free movement (art. 5-24)
- Chapter III – **Identification and traceability of devices**, registration of devices and of economic operators, summary of safety and clinical performance, european database on medical devices (art. 25-34)
- Chapter IV – **Notified bodies** (art. 35-49)
- Chapter V – **Classification and conformity assessment** (art. 50-60)

# MDR STRUCTURE

- Chapter VI – **Clinical evaluation and clinical investigations** (Articles 61-82)
- Chapter VII – **Post-market surveillance, vigilance and market surveillance** (art. 83-100)
- Chapter VIII – **Cooperation between member states**, medical device coordination group, expert laboratories, expert panels and device registers (art. 101-108)
- Chapter IX – **Confidentiality, data protection**, funding and penalties (art. 109-113)
- Chapter X – **Final provisions** (art. 114-123)

# MDR Annexes

**I General safety and performance requirements**

**II Technical documentation**

**III Technical documentation on post-market surveillance**

**IV EU declaration of conformity**

**V CE marking of conformity**

**VI Information to be submitted upon the registration of devices and economic operators** in accordance with Articles 29(4) and 31; core data elements to be provided to the UDI database together with the UDI-DI in accordance with Articles 28 and 29;and the UDI system

**VII Requirements to be met by notified bodies**

**VIII Classification rules**

**IX Conformity assessment** based on **a quality management system and assessment of the technical documentation**

**X Conformity assessment based on type examination**

**XI Conformity assessment based on product conformity verification - PART A – Production quality assurance , PART B – Product verification**

**XII Certificates issued by a notified body**

**XIII Procedure for custom-made devices**

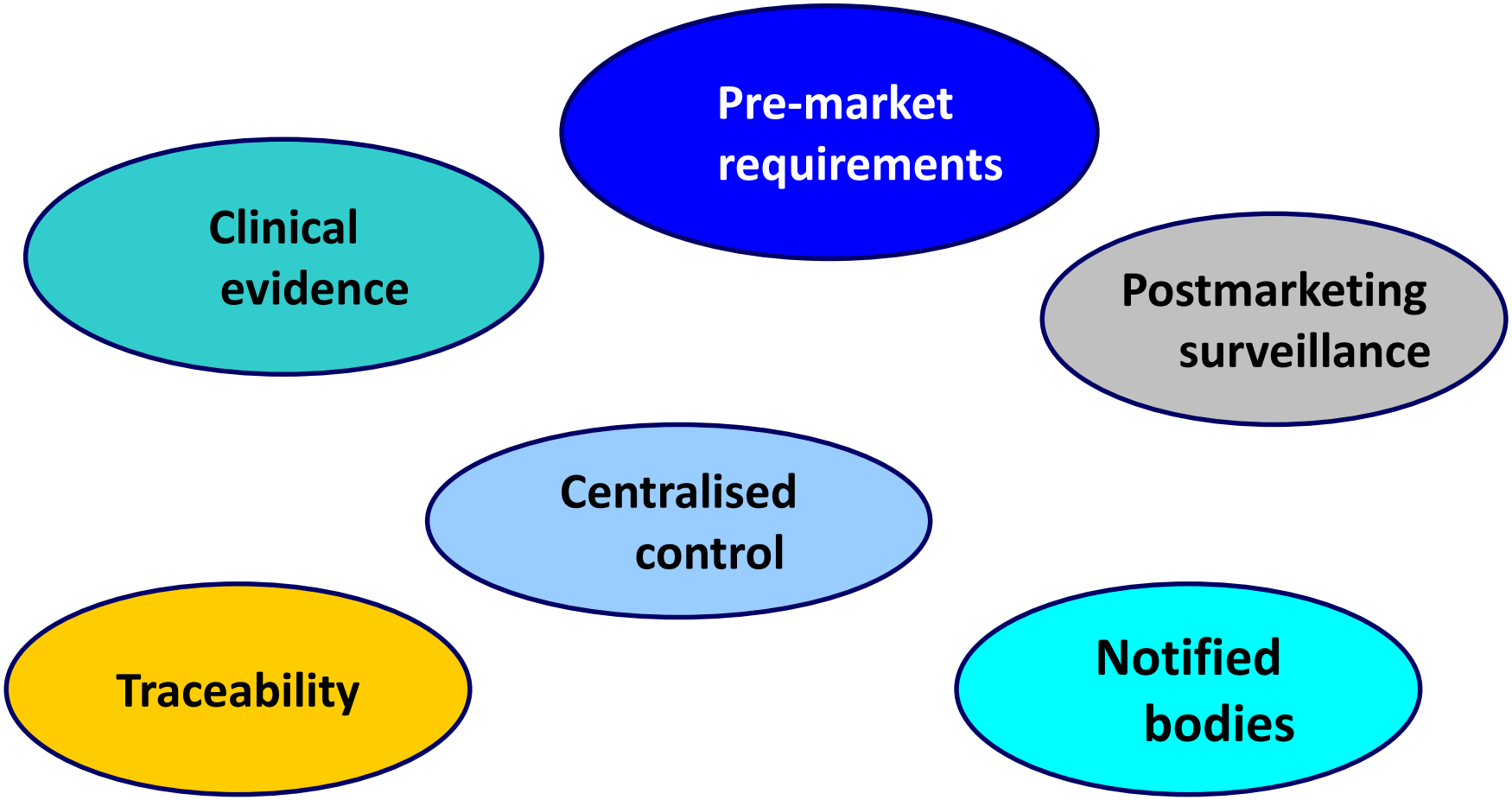
**XIV Clinical evaluation and post-market clinical follow-up**

**XV Clinical investigations**

**XVI List of groups of products without an intended medical purpose referred to in Article 1(2)**

**XVII Correlation table**

# MDR - MAJOR CHANGES



# MAJOR CHANGES


PRE-MARKET REQUIREMENTS

- Clinical evaluation consultation for class III MD and active IIb MD administering drugs (obligatory for NB / voluntary for manufacturer) *'Scrutiny procedure'* art. 54
- Common specifications (presumption of conformity with general safety and performance requirements, substituting clinical data) art. 9
- **Person responsible for regulatory compliance** at manufacturer and authorised representative art. 15

# MAJOR CHANGES


POST-MARKET SURVEILLANCE AND VIGILANCE

- Post market surveillance plan, art. 84
- Central data base (electronic sistem), art. 92
- Periodic safety update report – content and update period defined, submited to central data base for class III and implantable MD (Post-market report for class I) art. 86
- Trend reports on incidents / side-effects art. 88

# MAJOR CHANGES


TRACEABILITY

- Electronic system for registration of manufacturers, authorised representatives and importers
- Unique Device Identification system (UDI) art. 27
- Implant card art. 18

# Chapter III Identification and traceability

UDI - Unique Device Identification

**UNIQUE MEDICAL DEVICE IDENTIFICATION SYSTEM**

TARGET: enable identification and facilitate traceability of MD

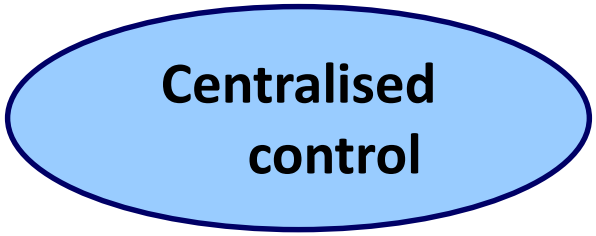
- Manufacturer has to define UDI before placing to the market



UDI – DI: Basic or Unit of use
(unique at each level of device packaging)

UDI – PI: Unit of device production
(lot, serial no., SW ident., expiry /manufacturing date...)

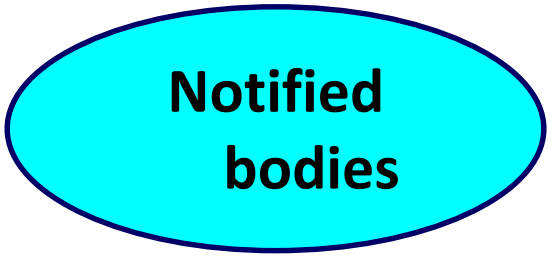
# MAJOR CHANGES




CONTROL

- Centralised decisions art. 51
  - decisions on MD classification in case of dispute (decision in member state of manufacturer, consultation with MS of NB, notifying commission)
  - Decisions on MD classification and reclassification to avoid divergation – obligatory for all member states (implementing act)
- Expert Panel, Expert Laboratories art. 106

# MAJOR CHANGES




NOTIFIED BODIES

- Changes in conformity assessment procedures: *Scrutiny procedures, review of* Periodic safety update report for class III and implantable MD class IIb
- Un-announced audits (once in 5 years, except for high risk MD)
- http://ec.europa.eu/growth/tools-databases/nando/

# MAJOR CHANGES - OTHER

- Inclusion of some aestethic devices (with same charasteristics and risk profile as similar medical devices) Regulation applies, after common specifications are adopted for those devices.
- Manufacturer shall provide sufficient financial coverage for potential liability
- Sampling of technical files, but no sampling for class IIb implantable devices (exceptions see ar. 52)

# ECONOMIC OPERATORS

- Manufacturer
- Authorised representative (one for generic device group, contract with manufacturer, keeps technical file, registration in electronic system, liability)
- Importer (verify that device is registered in electronic system, manufacturer is identified and authorised representative designated, keep register of complaints)
- Distributer (verify that device is CE marked and has all requested documentation, forward complaints to manufacturer)
- Person from art 22(1) that combines MD with other devices – systems or procedure packs (MD, IVD or other)
- Person from art 22(3) who sterilises systems or procedure packs

# ANNEX II – TECHNICAL DOCUMENTATION

## new or changed requirements:

- Presented in clear, organised, readily searchable manner
- **Device description** has to include basic UDI, intended patient population and medical conditions, principles of operation of MD, rational for qualification as device, reference to previous generation of device, owerview of similar devices at market
- Design process: Information to allow design stages applied to the device to be understood
- **Labels and instructions for use** in languages accepted in Member State where device is sold
- Special requirements not only for sterile devices but also devices placed in a defined microbiological condition
- Technical documentation on post market surveillance (annex III)

TECHNICAL DOCUMENTATION HAS TO BE KEPT **10 YEARS!**

# MDR CLASSIFICATION OF MD ANNEX VIII

New Class I reusable surgical instruments

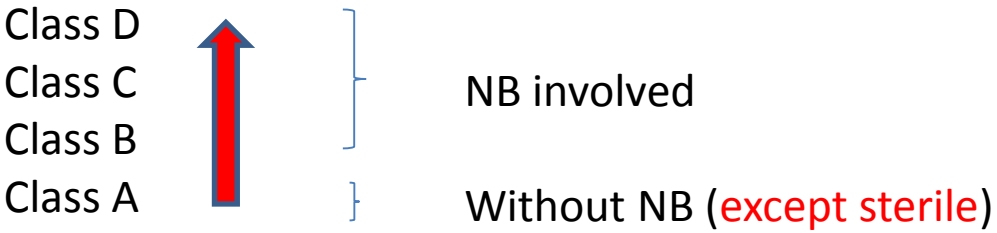
22 classification rules:

- 1-4 Non-invasive devices
- 5-8 Invasive devices
- 9-13 Active devices (11 – SW)
- 14-22 Special rules (19 – nanomaterials, 20 inhalation devices, 21 absorbable devices, 22 active therapeutic devices with diagnostic function)

Smaler changes in some rules can change product classification. CHECK!

# IVDR – new risk classification system

- Classification rules taking into account the intended purpose of the devices and their inherent risks.




- 7 classification rules
- Class D: e.g. detection of transmissible agent in blood, markers ABO system
- Class C: e.g. detection of sexually transmitted agent, human genetic testing, self testing
- Class B e.g. self testing for cholesterol level, not covered elsewhere
- Class A e.g. general laboratory equipment

# CONFORMITY ASSESSMENT PROCEDURE– ANNEXES IX - XI

Types of conformity assessment procedures, used individually or in combination

| MDR | MDD |
| --- | --- |
| **Annex IX**<br>**Quality management system** and<br>Assessment of **technical documentation**<br>(Chapter II for class III and some IIb) | Annex II<br>Full quality assurance system (including cl. 4 for Design dossier assessment) |
| **Annex X**<br>**Type examination** | Annex III<br>Type examination |
| **Annex XI**<br>**Product conformity assurance,**<br>**- Production quality assurance, part A** | Annex V<br>Production quality assurance |
| **- Product verification, part B (only MDR)** | Annex IV<br>Product verification |

# WHAT SHALL MANUFACTURER DO?

- Perform ‚gap analysis' – between MDD 93/42/EEC and MDR
- Adjust QMS to new regulation (requirements of ISO 13485:2016, responsible person for regulatory compliance, liability insurance proportionate to risk class of MD)
- Adjust Technical documentation to new regulation:

  - Checking if ***general safety and performance requirements*** are fulfilled *(instead of essential requirements),*

  *- Risk management*

  *- PMS proportionate to risk*

  *- Vigilance reporting*

  *- New **EU declaration of conformity** – New form*

  - Introduction of UDI system, traceability of MD

# Transitional provisions

MDR and IVDR

- Published in EU Official Journal 5.5.2017
- Entry into force 26.5.2017

- MDR Applies from 26.5.2020
- IVDR applies from 26.5.2022

# Transitional provisions 1

- IVD, AIMD and MDD Certificates issued prior or from 25 May 2017 shall remain valid until the validity date on the certificate, not more than **five years from its issuance** and at the **latest on 27 May 2024**.
- Exception: AIMD and MDD Certificates issued prior to 25 May 2017 according to **Annex 4 (IV)** become void at latest on 27 May 2022.

- MDD and AIMD certificates can not be issued sfter 26 May 2020.
- IVD certificates can not be issued after 26 May 2022 and

# Transitional provisions 2

IVD, MDD and AIMD certificates from previous slide are valid and devices can be placed on the market

- If from 25 May 2020 (2022 for IVD) device
  - continues to comply with AIMD and MDD and
  - there are no significant changes in the design and intended purpose.
  - BUT: requirements relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices of MDR shall apply instead AIMD and MDD requirements.

- Devices placed on the market under certificates mentioned on previous slide may continue to be made available on the market or put into service until **27 May 2025.**

# Transitional provisions 3

- Designated NB according to MDR may carry out the conformity assessment procedures accordance with MDR prior to 26 May 2020 (2022 for IVDR)
- devices which comply with MDR may be placed on the market prior to 26 May 2020 (2022 for IVDR)
- devices subject to the consultation procedure shall / can? apply provided that the necessary appointments to the MDCG and expert panels have been made

# Hvala! Thank you!

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