
SWEDISH STANDARDS INSTITUTE
STANDARD DEVELOPER 2017
SWEDISH Medtech
EA AR
European Association of Authorised Representatives
SEK SVENSK ELSTANDARD
Breakfast seminar
Ready – Set – MDR!
QAdvis seminar Lund 2017-11-14, Uppsala 2017-11-15, Stockholm 2017-11-16
QAdvis
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QAdvis key competence areas

QMS in-the cloud

Turn key QMS
Digital signatures
Efficient and lean
Validated and compliant

System development

Project management
Product software validation
Regulated software validation
Requirement management
Risk management
Verification and validation
Process validation

QA&RA/Clinical Consulting

Interim management
Expert advise
Audits/Mock audits/Due diligence
Warning letters, compliance projects
PMA, 510k, CE-mark
Global regulatory support
Vigilance, recall, post market surveillance
Clinical evaluation and clinical studies

Training/courses

CE-marking
ISO 13485 & 21CFR820
IEC 62304 & IEC 82304-1
IEC 60601-1
IEC 62366-1
SW life cycle
SW risk management
Risk management
And more…

Lean and Six Sigma

Training and Consulting
In cooperation with USA based partner.

European Authorized Representation

Providing European representation for non-EU MedTech companies

Active board member of EAAR: European Association of Authorised Representatives

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Presentation of the speaker Maria Eklycke

Work experience:

- Medical Device testing
- Notified Body for Medical Devices
  - Product assessment
  - Review of Technical Files
  - Notified Body approval for a wide range of products (active and non-active devices)
- Quality and Regulatory Consultant
- Member of the board for European Association of Authorized Representatives (EAAR)

Presentation of the speaker Emma Axelsson

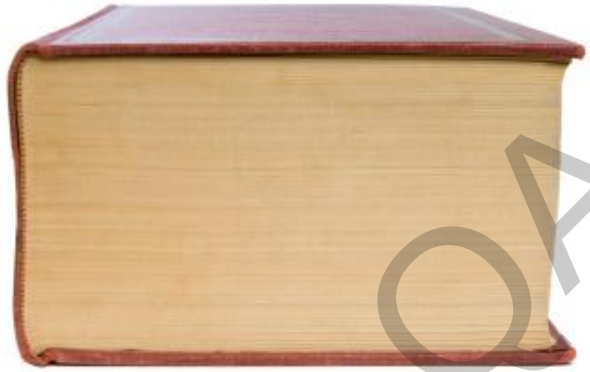
- Quality and regulatory consultant for medical devices and in vitro diagnostics
- Quality and Regulatory Manager medical device company
- Quality management system (ISO 13485:2016)
- Medical Device Directive (MDD) and Medical Device Regulations (MDR)

Agenda

- Introduction and background
- MDR news
- Conformity routes and classification
- Technical Documentation
- General Safety and Performance Requirements
- Quality Management System
- Timelines and implementation
- Additional information
- Questions and answers
- QAdvis services

Background

Background



- Directives

  AIMDD
  (90/385/EEG, LVFS 2001:5)

  MDD
  (93/42/EG, LVFS 2003:11)

  MDR 2017/745

- Directive

  IVDD
  (98/79/EG, LVFS 2001:7)

  IVDR 2017/746

Background - Timeline

- Oct 2012 Proposal
- April 5, 2017 Adopted
- May 5, 2017 Published
- May 26, 2017 Enter into force
- May 26, 2020 Date of application MDR

(Article 123)

MDR news

Delegated acts
Implementing acts

- **Delegated acts**

Acts used to modify or amend the regulation.

- **Implementing acts**

Acts used to clarify and explain how the regulations should be interpreted and used.

Common specifications (CS)

- When there are no harmonized standards or the harmonized standards are not sufficient, the Commission can adopt a common specification
- For example for devices with non-medical purpose and single use devices to be re-processed

(Article 2 (71))

Person responsible for regulatory compliance

- Manufacturer shall have available within their organization at least one person responsible for regulatory compliance.

(Article 15)

Economic operator

"economic operator means a manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3)"

- Responsibilities and authorities
- Control of each other
- Eudamed
- Importers – name and address on device, packaging or accompanying documentation

(Article 2 (35), 10, 11, 13, 14)

Unique Device Identification (UDI) system

“Unique Device Identifier (UDI) means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.”

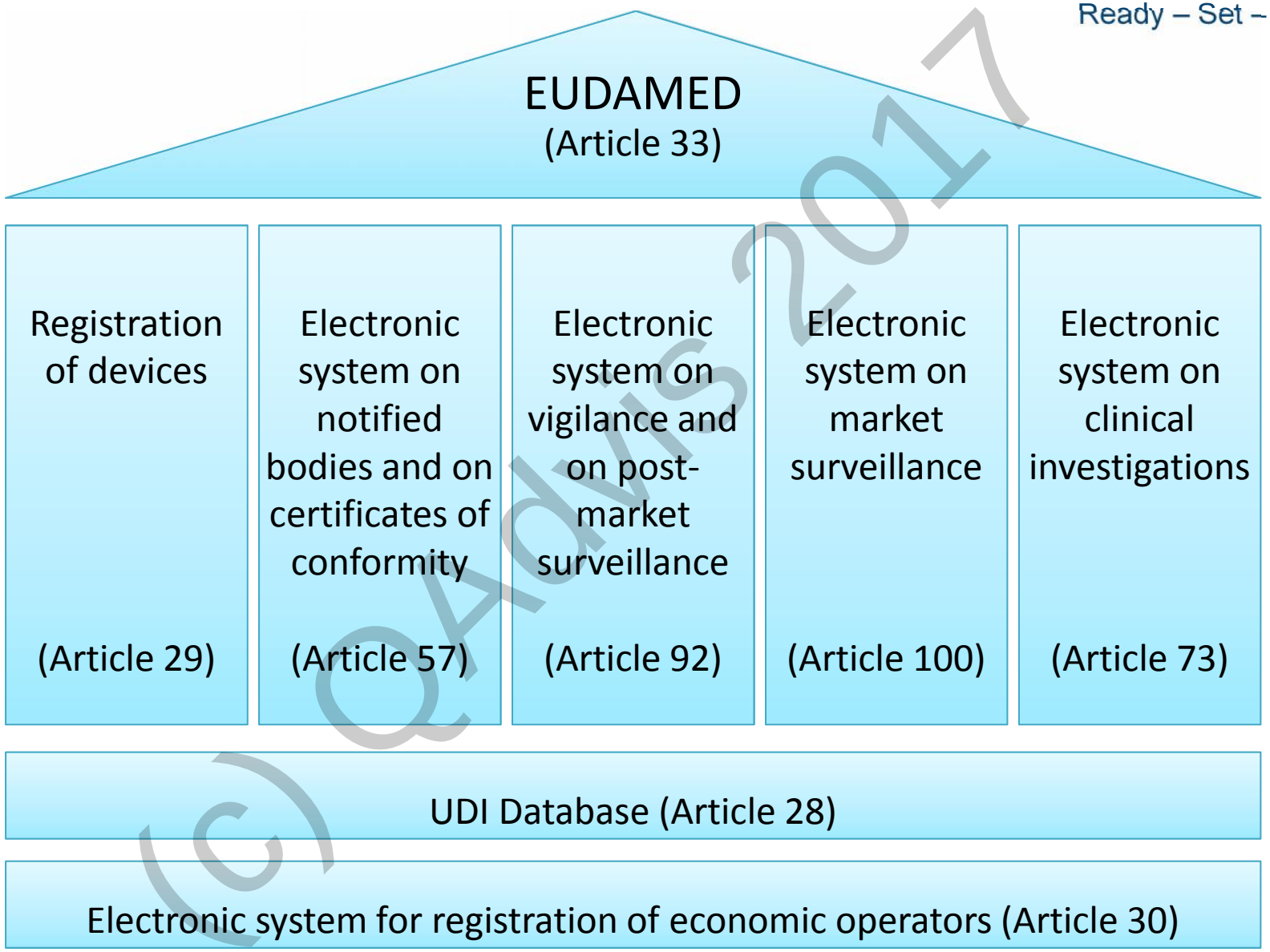
(Article 27)

Additional products covered by MDR

- Annex XVI defines products without an intended medical purpose.
- Common specifications is to be developed for these product groups.

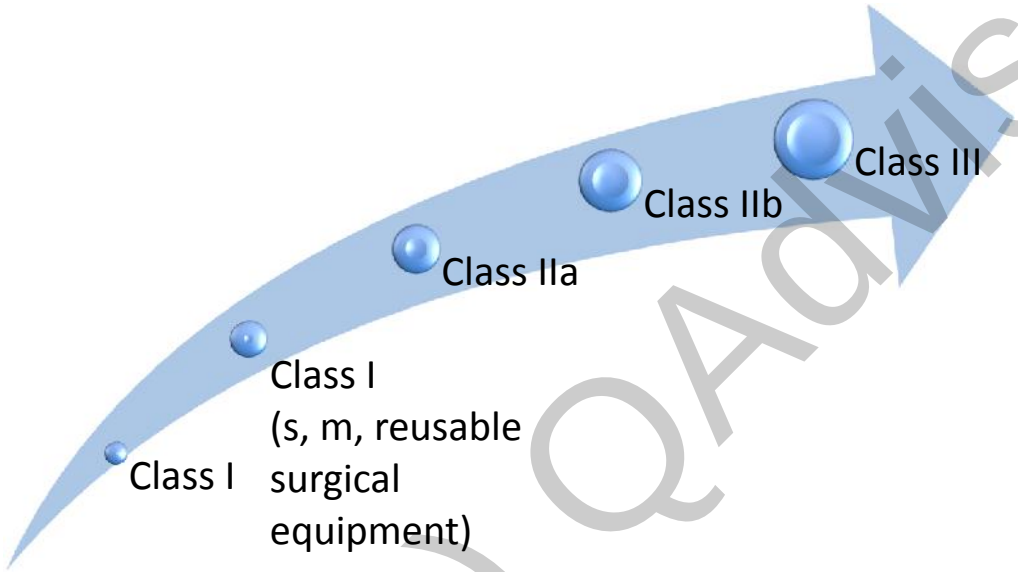
(Article 1 (2) / Annex XVI)

Eudamed



Conformity routes

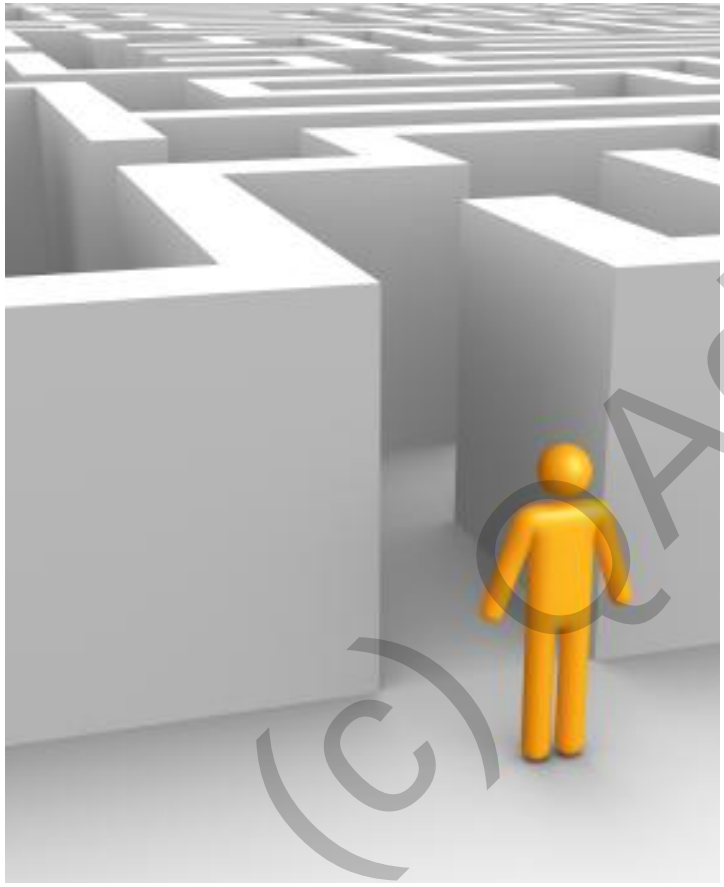
Conformity route



- Conformity route to be selected for each device category – different routs to chose between depending on classification of device
- Involvement of Notified Body differs depending on assessment route and device classification

(Article 52)

Conformity route



- **Annex IX** – Conformity assessment based on a quality management system and on assessment of technical documentation
- **Annex X** – Conformity assessment based on type-examination
- **Annex XI** – Conformity based on product conformity verification
  - Part A – Production quality assurance
  - Part B – Product verification
- **Annex XIII** – Procedures for custom-made devices

(Article 52)

Classification

Classification rules overview

- Non-invasive devices: Rule 1-4
- Invasive devices: Rule 5-8
- Active devices: Rule 9-13
- Special rules: Rule 14-22

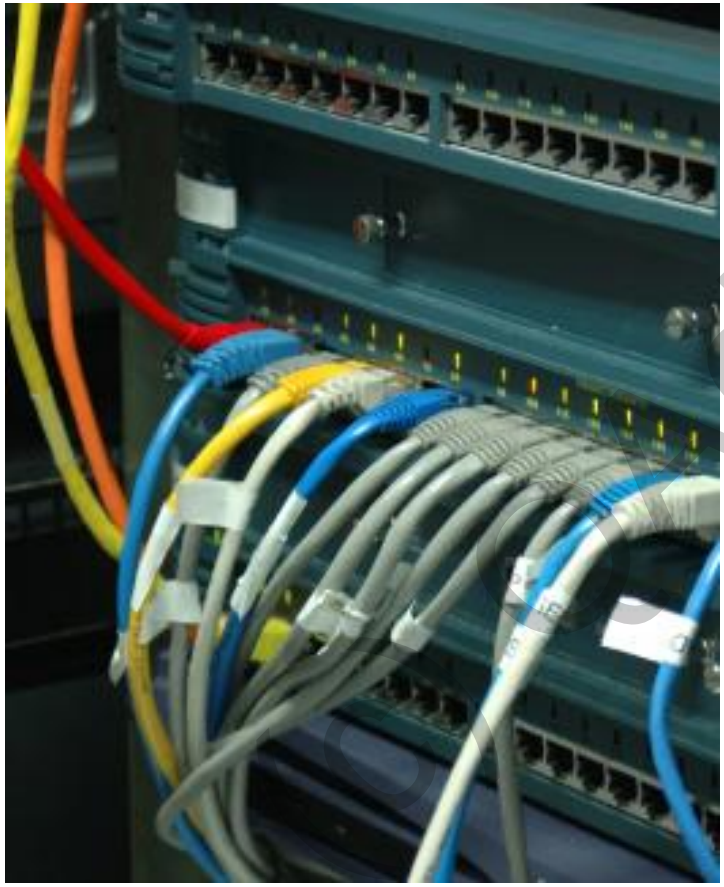
(Annex VIII)

Classification rules news and updates

- Rule 8 – addition
  Active implantable devices, breast implants or surgical meshes, joint replacement, spinal disc replacement implants – class III
- Rule 19 – new rule
  Incorporating nanomaterial
  – Class IIa, IIb or III
- Rule 20 – new rule
  Inhalation of medicinal products
  - Class IIa or IIb
- Rule 21 – new rule
  Substances intended to be introduced into the human body via a body orifice or applied to the skin – Class IIa, IIb or III

(For complete wording, see Annex VIII)

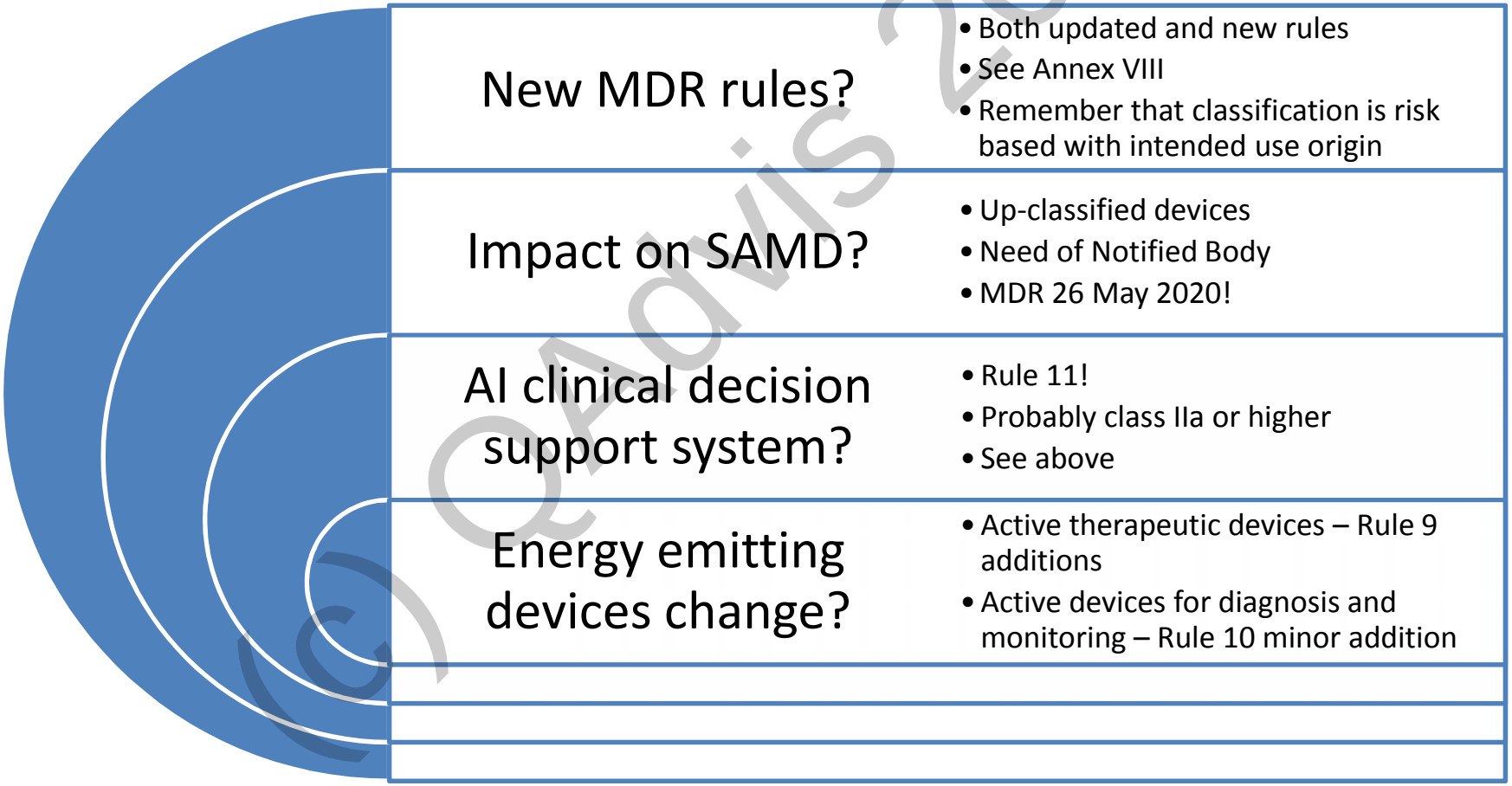
Classification rules news and updates



(For complete wording, see Annex VIII)

- Rule 11 – new rule
  Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes – Class IIa
  - May cause death or irreversible detoriation of state of health – Class III
  - May cause serious detoriation of state of health or surgical intervention – Class IIb
  - Monitoring of physiological processes – Class IIa
  - Monitoring of vital physiological parameters, variations of those parameters could result in immediate danger – Class IIb
  - All other software – Class I

Classification rules – Questions



(Annex VIII)

Technical Documentation - Overwiew

- Technical Documentation (Annex II)
- Technical Documentation on PMS (Annex III)
- DoC (Annex IV)
- GSPR (Annex I)
- Clinical Evaluation (Annex XIV)

(Annex I, II, III, IV, XIV)

Technical Documentation – Contents

– MDR!

No.	Description
1	Device description and specification
2	Information to be supplied by the manufacturer
3	Design and manufacturing information
4	General safety and performance requirements
5	Benefit-risk analysis and risk management
6	Product verification and validation

UDI, rationale for MD, classification

UDI, indication for MD, substances? importer?

Identification of all sites, suppliers and subcontractors

Update entire checklist!

Make sure Annex I (1, 3, 8) is fulfilled

Clinical evaluation, additional requirements on substances

More: Update structure, DoC

(Annex II)

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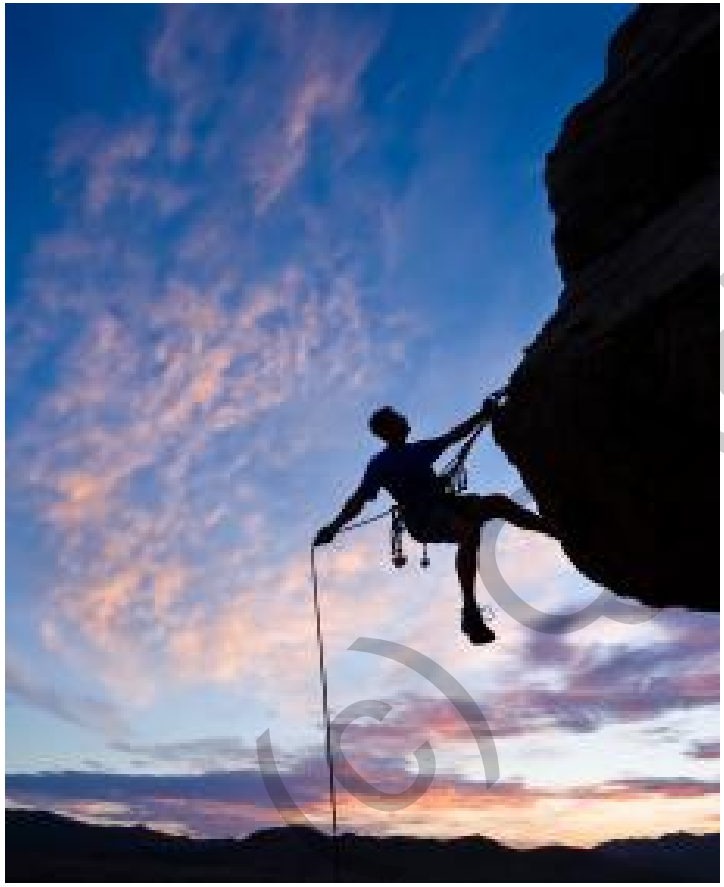
General Safety and Performance Requirements

GSPR- Overview

- Change from MDD Essential Requirements (ER) to General Safety and Performance Requirements (GSPR)
- Checklist recommended
- Method of compliance
- Reference to evidence of compliance

(Annex I)

GSPR – News and updates



- Risk based approach – Stronger connection to Risk Management
- Annex XVI products included
- Clinical evaluation requirement deleted from Annex I (ER 6a). Included in Article 61, Annex XIV and Annex II.
- Requirements for active implantable devices added
- Substances specified with limitations
- Risk of particles released
- Risks with software and IT environment

(Annex I)

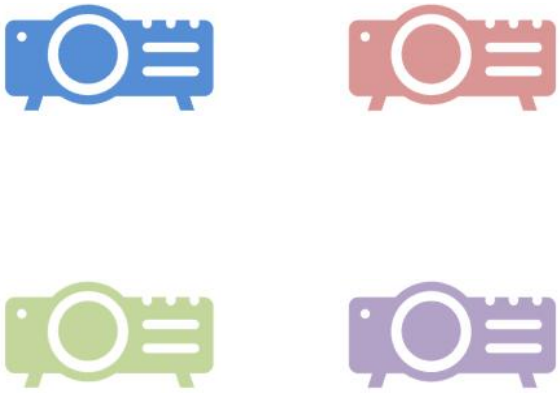
Clinical Evaluation

Clinical Evaluation – Extent based on

- Nature
- Classification
- Intended purpose
- Risks
- Manufacturer’s claims

(Annex XIV)

Clinical Evaluation – Equivalence



May be based on equivalent devices

- Technical equivalence, and
- Biological equivalence, and
- Clinical equivalence

Sufficient levels of access to the data in order to justify their claims of equivalence

(Annex XIV, Article 61)

Clinical Evaluation – Product Assessment

- Based on equivalence?
- Clinical evidence sufficient?
- Need of new clinical trials?
- Need of PMCF?
- MEDDEV 2.7/1 Rev 4?
  - Guidance, not legally binding
  - State of the art?
  - Inspiration
  - Recommendation; Follow MEDDEV 2.7/1 Rev 4 and make sure that Clinical Evaluation according to MDR is fulfilled.

(Annex XIV, Article 61)

Quality Management System

General obligations of manufacturers

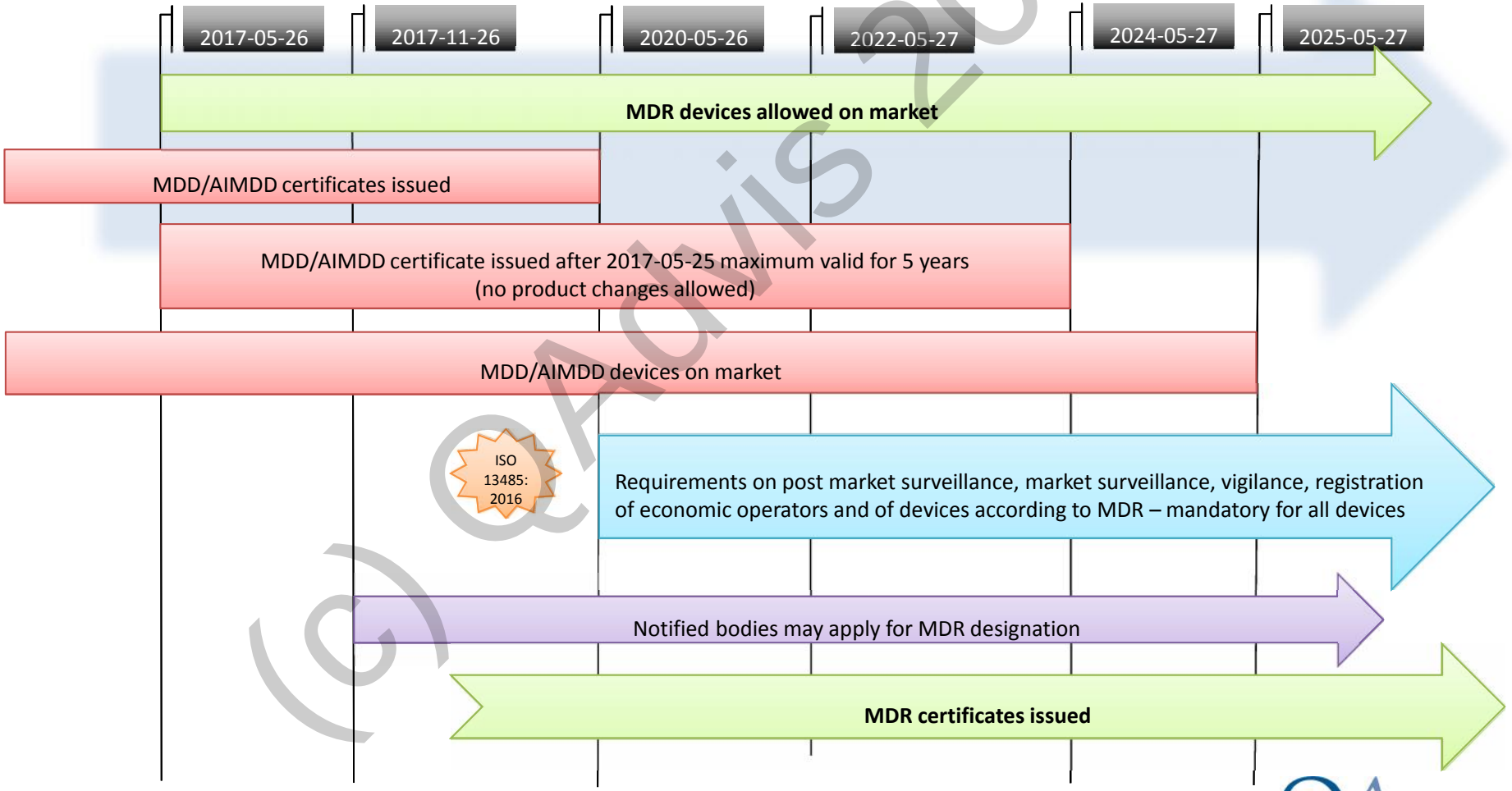
Requirements on

- Quality Management System
- Manufacturing and design
- Clinical evaluations
- UDI system
- Risk management
- Technical documentation and DoC
- Vigilance
- Post market surveillance system

(Article 10)

Timelines

Implementation timeline



(Article 120/123)

Implementation

Implementation

GAP Assessment

1	2	3	4	5	6	7
MDR awareness	Portfolio assessment	- Assessment Route - TD - QMS	- Notified Body - Economic operators - Global market	Implementation plan	Training	Audits

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Additional information

Additional information for the manufacturer

- Information from the Commission
- Information from Competent Authorities
- Information from Notified Bodies
- Notified Body Operations Group (www.nbog.eu)

Additional information – What is going on?

- Notified Bodies
  (designation process, applications)
- Setting up Medical Device
  Coordination Group
- Setting up expert panels
- EU work groups

  - Clinical investigation and evaluation

  - Vigilance

  - Borderline and classification
- Draft implementing regulation:
  List of device codes

Conclusion

MDR Conclusions

- MDR is published
- A lot of work – start now!
- No grandfathering:
  Not ready in time = products can not be placed on the market
- Stricter requirements on all players (Authorities, Notified Bodies and Manufacturers)
- Sufficient clinical evidence necessary
- Many products will be up-classified

(Annex VIII)

Thank you for your attention!
Questions & Answers

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QAdvis services

- GAP analysis and implementation plan
- Quality Management System
- Auditing
- Technical Documentation
- Clinical Evaluation
- Risk management
- Courses
  - MDR
  - ISO 13485:2016
  - Risk management & SW risk management
- Internal trainings
- Product specific workshop

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