MDR Breakfast seminar
2019-09-24 Lund
2019-09-26 Kista

QAdvis

QAdvis – Key competence areas

QMS In-the-cloud

Turn Key QMS
Digital Signatures
Efficient and Lean

System Development

Product Software Validation
Computer Systems Validation
Risk Management
Verification and Validation
Process Validation

European Authorised Representation

Providing European representation for non-EU MedTech companies
Active member of EAAR (European Association of Authorized Reps)

Training/Courses

CE-Marking, MDR, IVDR
ISO 13485 & QSR & MDSAP
IEC 62304 & IEC 82304-1
IEC 60601-1
IEC 62366-1
Risk Management
And more…

Agile, Lean and Six Sigma

Training and consulting in cooperation with US partner

QA&RA/Clinical Consulting

Interim Management, Expert Advise
Audits/Mock audit/Due Diligence
Warning Letters, Compliance Projects
PMA, 510k, CE-Marking, Tech Files
Global Regulatory Support
Vigilance, Recalls, PMS
Clinical Evaluation and Clinical Studies

QAdvis

Presentation of the speaker – Anneli Wiedenkeller

- Worked within the medical device industry since 1988 (manufacturing, QA, R&D, RA).
- Background mainly from electrotechnical devices.
- Working the recent years as a senior product assessor (active and non-active devises) at a Swedish MDD NB.

Presentation of the speaker - Emma Axelsson

- Senior 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)

QAdvis

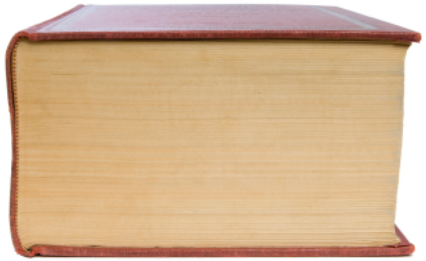
MEDICAL DEVICE REGULATION BACKGROUND

QAdvis

Background

- MDD, AIMDD and IVDD old
- Technological and scientific development
- Different interpretations in Member States
- Scandals
- Product traceability

Background



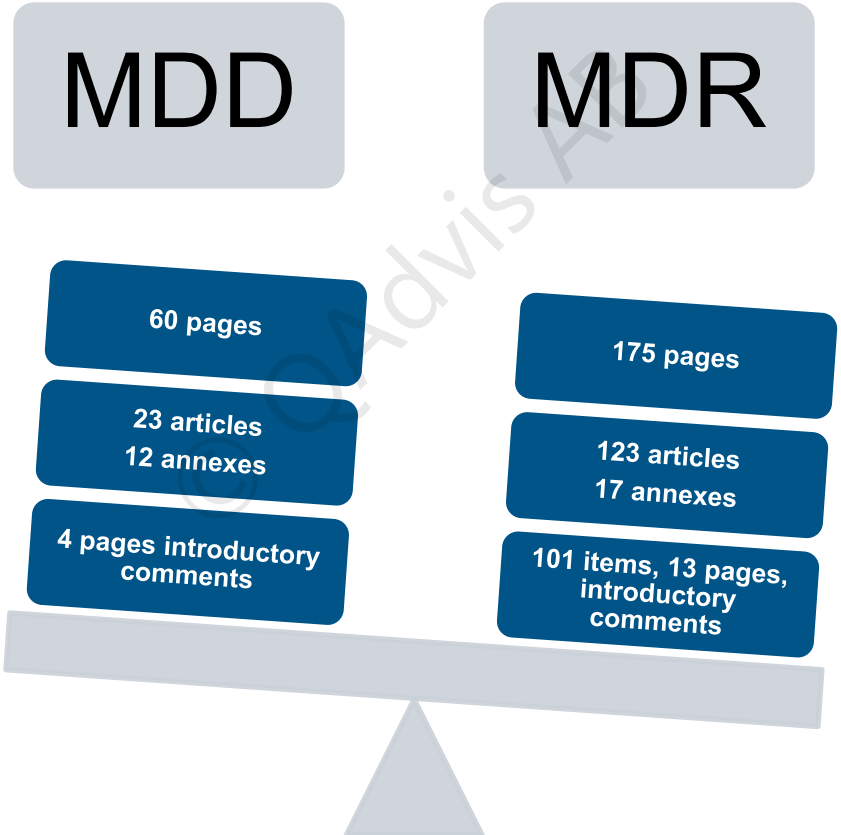
- Directives
  - AIMDD
    (90/385/EEG, LVFS 2001:5)
  - MDD
    (93/42/EG, LVFS 2003:11)

  MDR 2017/745

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

  IVDR 2017/746

Overview



QAdvis

MEDICAL DEVICE REGULATION NEWS

QAdvis

Delegated and implementing acts

Delegated acts

Acts used to modify and explain the WHAT in regulation implementation.

Implementing acts

Acts used to clarify and explain HOW the regulation should be interpreted and used.

(MDR/IVDR)

Common specifications (CS)

"*Means a set of technical and/or clinical requirements, other than a standard that provides a means of complying with the legal obligations applicable to a device, process or system*."

When there are no harmonized standards or the harmonized standards are not sufficient, the Commission can adopt a common specification.

(MDR Article 2 (71) / IVDR Article 2(74))

Person Responsible for Regulatory Compliance (PRRC)

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

"The person responsible for regulatory compliance shall suffer no disadvantage within the manufacturer's organization in relation to the proper fulfilment of his or her duties, regardless of whether or not they are employees of the organization."

(MDR/IVDR Article 15)

Person Responsible for Regulatory Compliance (PRRC)

- Responsibilities
  - Conformity of devices
  - Technical documentation
  - EU declaration of conformity are drawn up and kept up to date
  - Post-market surveillance obligations
  - Vigilance reporting
  - Investigational devices / Devices for performance studies

(MDR/IVDR Article 15 (3))

Economic operator

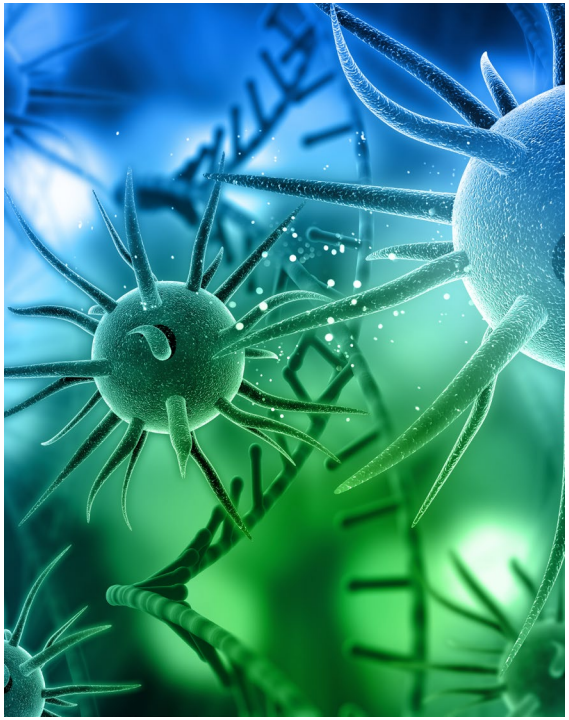
Manufacturer, importer, distributor and authorized representative

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

(MDR/IVDR Article 10, 11, 13, 14)

QAdvis

General obligations of manufacturers



Requirements on

- QMS
- Manufacturing and design
- Clinical evaluations / Performance evaluation
- UDI system
- Risk management
- Technical documentation and DoC
- Vigilance
- Post market surveillance system

(MDR / IVDR Article 10)

MEDICAL DEVICE REGULATION
TECHNICAL DOCUMENTATION

QAdvis

Intended purpose

- Shall be defined by the manufacturer
- Basis for classification
- The purpose for which a device is intended, according to;
  - Label
  - Instructions for use
  - Promotional or sales materials
  - Statements
  - As specified by the manufacturer in the clinical evaluation

(MDR Article 2 (12))

QAdvis

Technical Documentation - Overview

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

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

Technical Documentation – Annex II

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

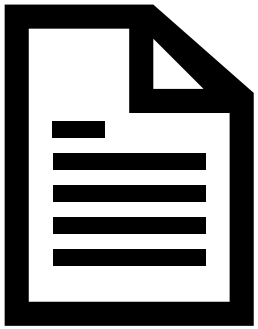
QAdvis

GSPR- Overview

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

(MDR / IVDR Annex I)

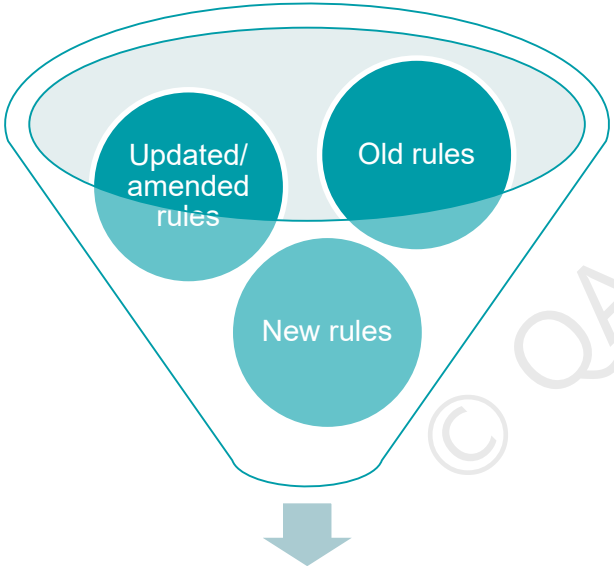
GSPR – News and update



- Labels and IFU
- Reference to regulation No 207/2012 on electronic IFU
- UDI
- Indication that the device is a medical device
- Substances composition/constituents
- Annex XVI: Information regarding absence of clinical benefit and risks
- Implant card

(MDR Annex I)

Classification rules news and updates



Classification Rules

Many devices will belong to a higher class under MDR/IVDR, leading to stricter requirements and higher level of control by NB.

(MDR/IVDR Annex VIII)

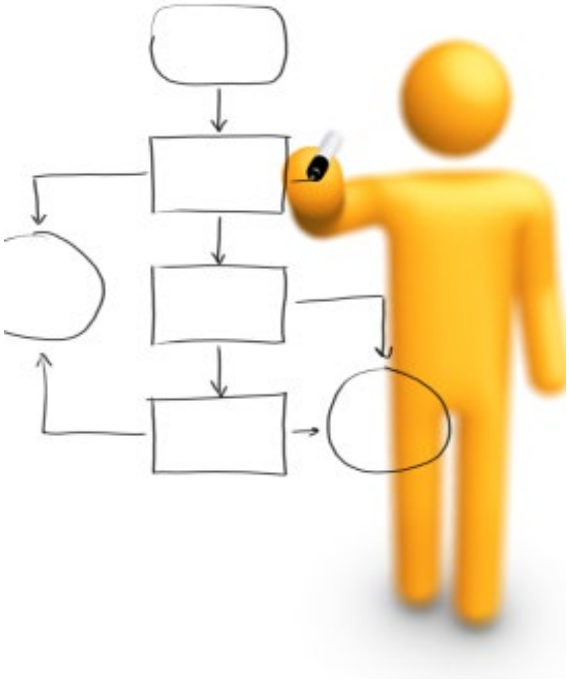
QAdvis

Classification rules overview

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

(MDR Annex VIII)

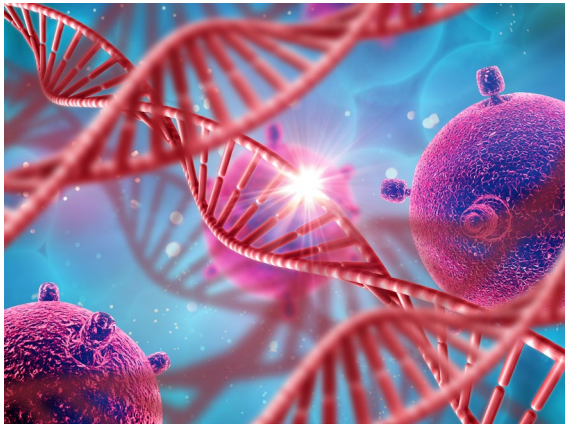
Clinical Evaluation – Requirements and overview



- Plan, continuously conduct, and document
- Clinical Evaluation Plan
- Identify clinical data
- Appraise
- Generate
- Analyze – reach conclusion: Safety, clinical performance including its clinical benefit

(MDR Annex XIV)

Post-market surveillance (PMS)

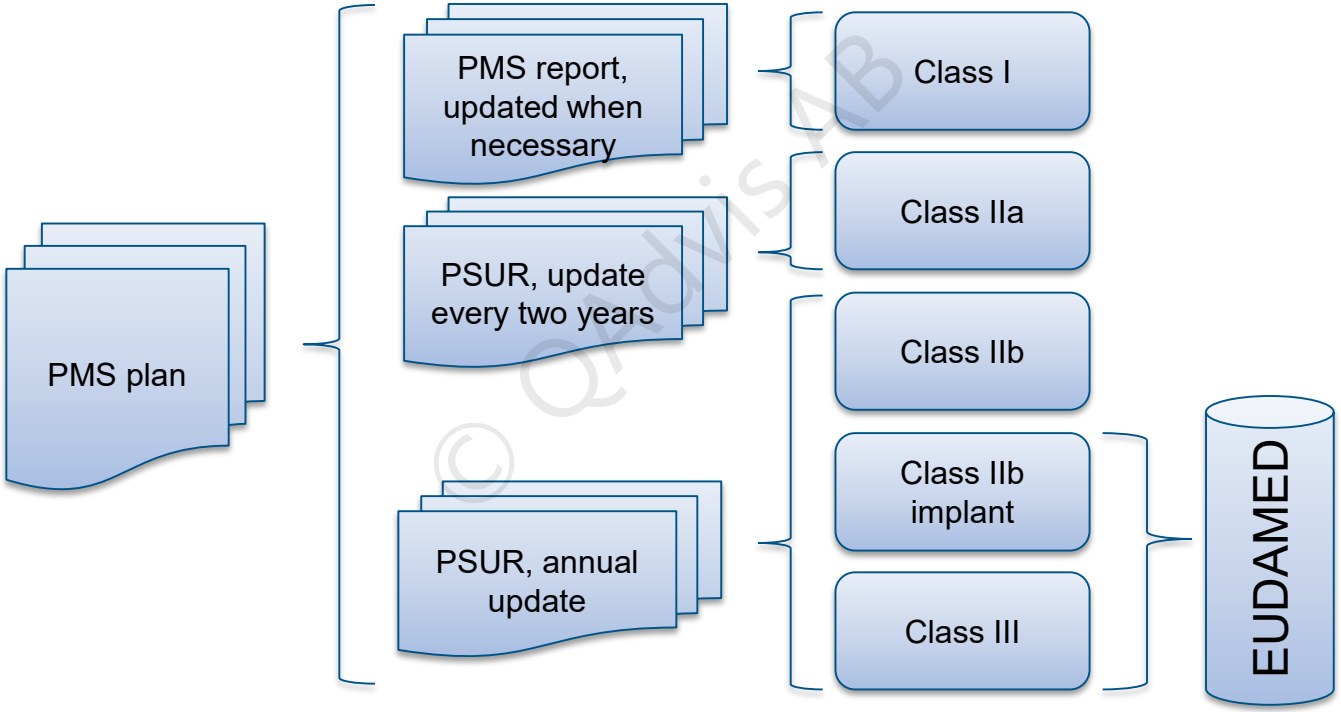


For each device the manufacturer shall

- plan,
- document,
- implement,
- maintain and
- update a post-market surveillance system
- proportionate to the risk class of the device and appropriate for the device type.

(MDR Article 83 / IVDR Article 78)

Post Market Surveillance (PMS)



(MDR Article 86)

QAdvis

Unique Device Identification (UDI)

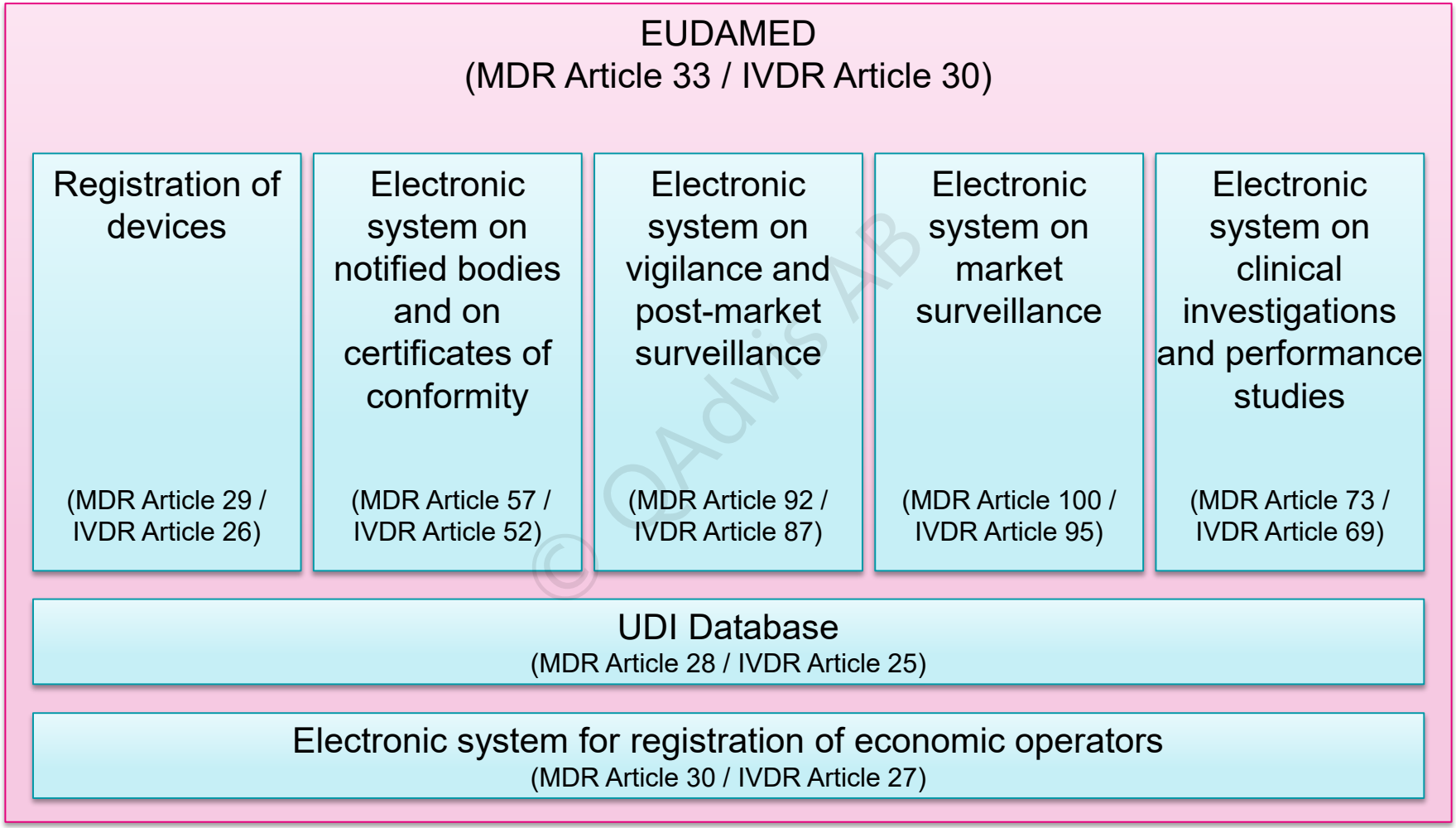
- Placed on packaging or labels for all devices placed on the market (except custom made devices)
- Used to report serious incidents and field safety corrective actions
- Basic UDI-DI shall be included in the DoC
- Reported in to Eudamed
- UDI database implementing act need to be developed for assignment of responsibility to assign UDIs

(MDR Article 27 / IVDR Article 24)

Eudamed

- European database for medical devices
- Communication between actors
- Registration of all devices by economic operators
- Accessed by
  - Economic operators
  - Competent Authority
  - Notified Body
  - The general public
- Regularly updated with post-market data and vigilance

(MDR Article 28 / IVDR Article 25)

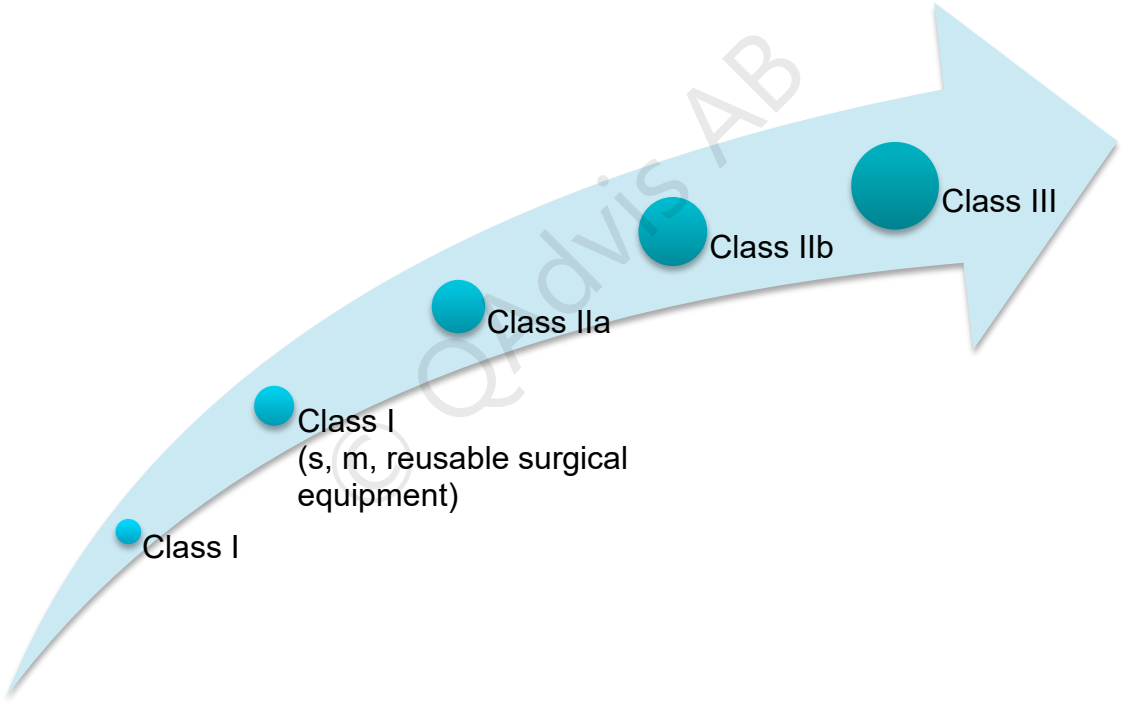

EUDAMED
(MDR Article 33 / IVDR Article 30)
Registration of devices
(MDR Article 29 / IVDR Article 26)
Electronic system on notified bodies and on certificates of conformity
(MDR Article 57 / IVDR Article 52)
Electronic system on vigilance and post-market surveillance
(MDR Article 92 / IVDR Article 87)
Electronic system on market surveillance
(MDR Article 100 / IVDR Article 95)
Electronic system on clinical investigations and performance studies
(MDR Article 73 / IVDR Article 69)
UDI Database
(MDR Article 28 / IVDR Article 25)
Electronic system for registration of economic operators
(MDR Article 30 / IVDR Article 27)

Conformity route

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

(MDR Article 52 / IVDR Article 48)

Conformity route – involvement of Notified Body



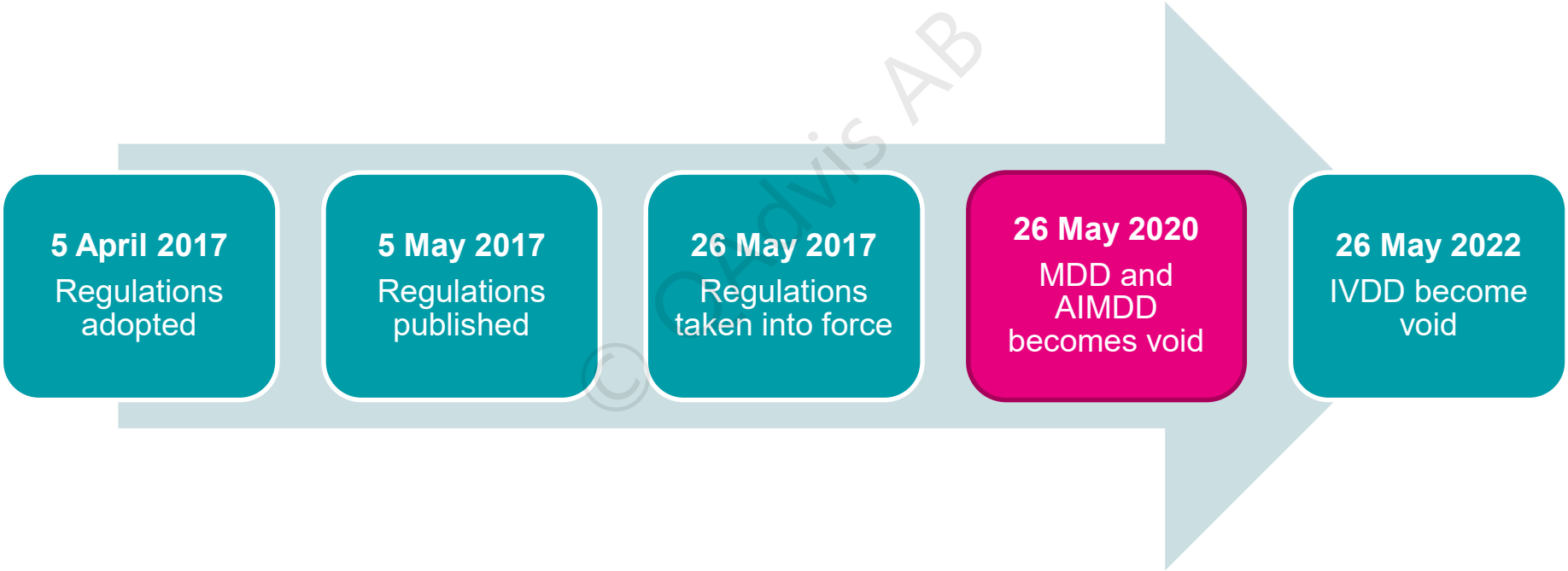
QAdvis

Your Regulatory Partner

TIMELINE AND IMPLEMENTATION

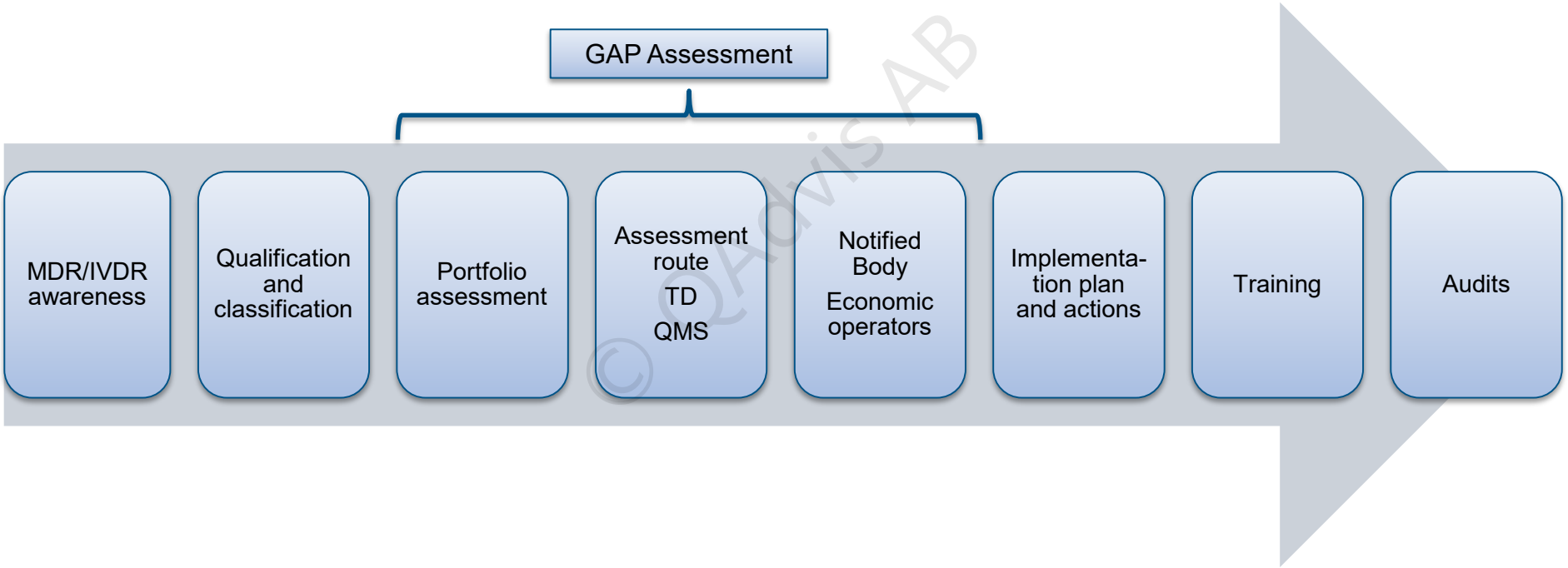
QAdvis

Transitional provisions



QAdvis

Implementation

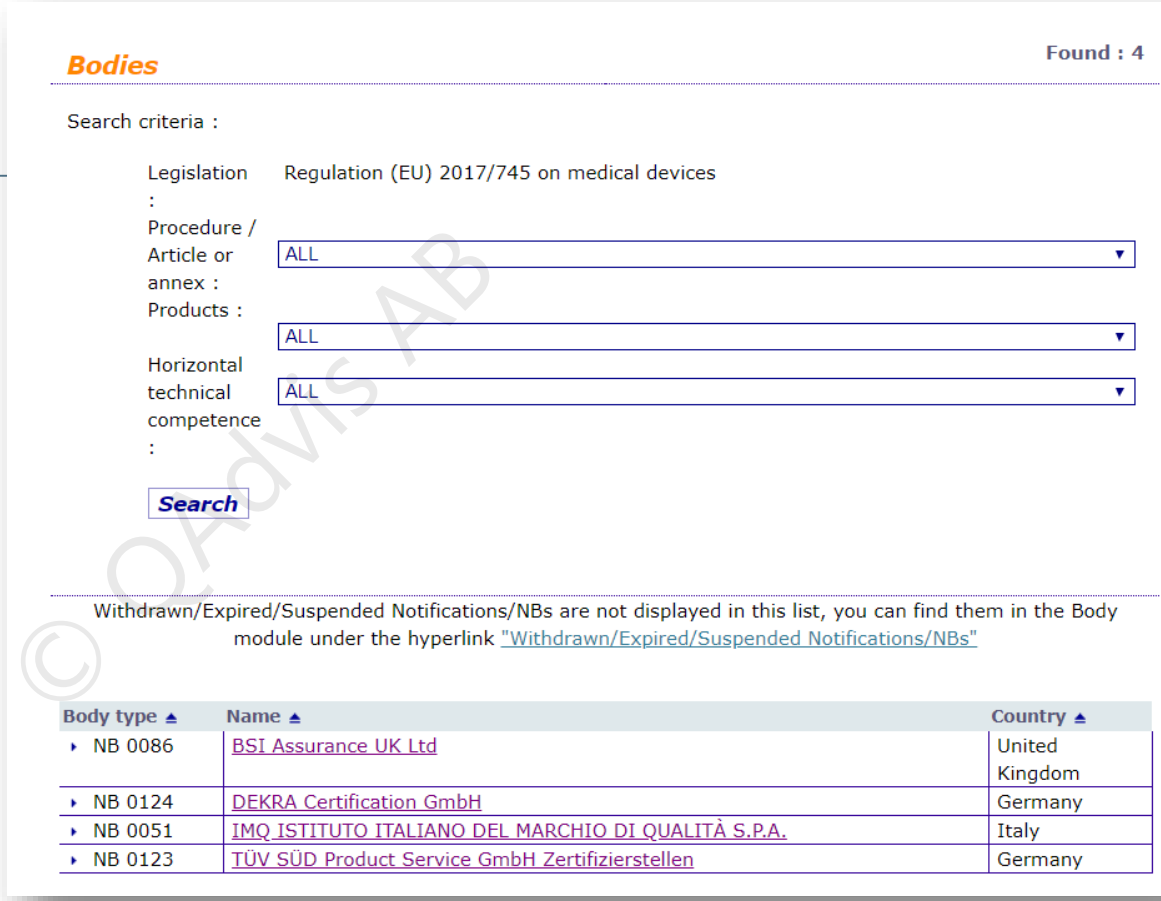


CURRENT STATUS

QAdvis

NB status

- 4 notified bodies designated under MDR
- 0 notified bodies designated under IVDR



Bodies Found : 4

Search criteria :

Legislation : Regulation (EU) 2017/745 on medical devices

Procedure / Article or annex : ALL

Products : ALL

Horizontal technical competence : ALL

Search

Withdrawn/Expired/Suspended Notifications/NBs are not displayed in this list, you can find them in the Body module under the hyperlink "Withdrawn/Expired/Suspended Notifications/NBs"

Body type	Name	Country
NB 0086	BSI Assurance UK Ltd	United Kingdom
NB 0124	DEKRA Certification GmbH	Germany
NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany

(https://ec.europa.eu/growth/tools-databases/nando/index.cfm)

QAdvis

Implementing act/decision

- List of codes and corresponding types of devices for notified bodies
- UDI issuing entities
- Expert panels
- Reprocessing of single use devices (draft)

(https://eur-lex.europa.eu/homepage.html)

MDCG guidelines

- MDCG 2018/2019 UDI guidance documents
- MDCG 2019-4/5 Eudamed registration
- MDCG 2019-7 guidance person responsible for regulatory compliance
- MDCG 2019-8 Implant card
- MDCG 2019-3 Interpretation on article 54(2)b

(https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en)

What is going on?

- Notified Bodies application and designation process ongoing
- Medical Device Coordination Group (MDCG) work ongoing
- CND nomenclature
- Harmonization of standards
- Implementation in national law
- EU work groups

Concerns

- A lot of work for Notified Bodies and Competent Authorities
- Decreasing number of Notified Bodies
- More devices and manufacturers in need of a Notified Body
- EUDAMED not running in time
- Common Specifications necessary for implementation not published in time
- Necessary Implementing Acts not ready in time
- Brexit
  - NB in UK not possible
  - EAR in UK not possible

Conclusions

- 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 data necessary
- Many products will be up-classified

Thank you for your attention!
Questions & Answers

QAdvis

QAdvis services

- Courses
  - IVDR / MDR
  - Risk management,
  - SW risk management
  - ISO 13485:2016
- Product specific workshop
- Internal trainings
- GAP analysis and implementation plan
- Quality Management System
- Auditing
- Risk management
- Clinical evaluation

Kurs MDR
2019-10-22 Stockholm
2019-10-24 Malmö

(www.qadvis.com)

QAdvis