

Your
Regulatory
Partner

IVDR breakfast seminar 2019-09-05

- Fundamentals you need to know
- Latest updates
- How to prepare

*QA***dvis**

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

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)

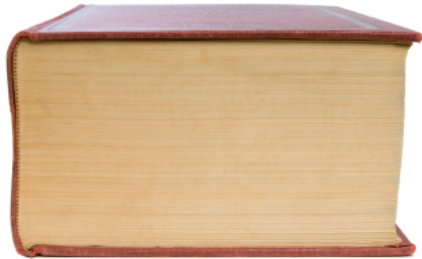
BACKGROUND

Background



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

Background



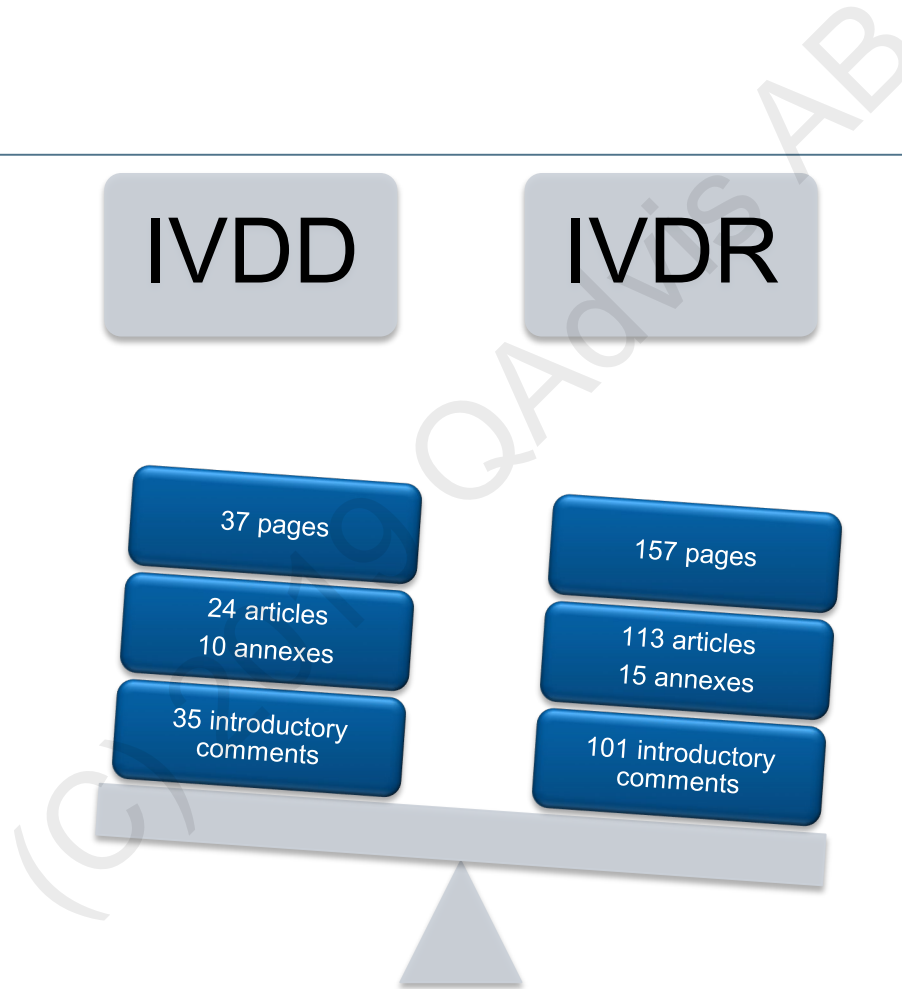
- Directives
AIMDD
(90/385/EEG, LVFS 2001:5)
MDD
(93/42/EG, LVFS 2003:11)

MDR 2017/745

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

IVDR 2017/746

Overview



IN VITRO DIAGNOSTIC REGULATION (IVDR)

Definition

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)

Definition

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.

Definition

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.”

Definition

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

Definition

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)

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)

TECHNICAL DOCUMENTATION

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

(IVDR Article 2(12))

Technical Documentation - Overview



- General Safety and Performance Requirements (GSPR) (Annex I)
- Technical Documentation (Annex II)
- Technical Documentation on PMS (Annex III)
- Declaration of Conformity (DoC) (Annex IV)
- Performance evaluation, performance studies and post-market performance follow-up (Annex XIII)
- Interventional clinical performance studies and certain other performance studies (Annex XIV)

(IVDR Annex I, II, III, IV, XIII, 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

General Safety and Performance Requirements (GSPR)



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

General Safety and Performance Requirements (GSPR)

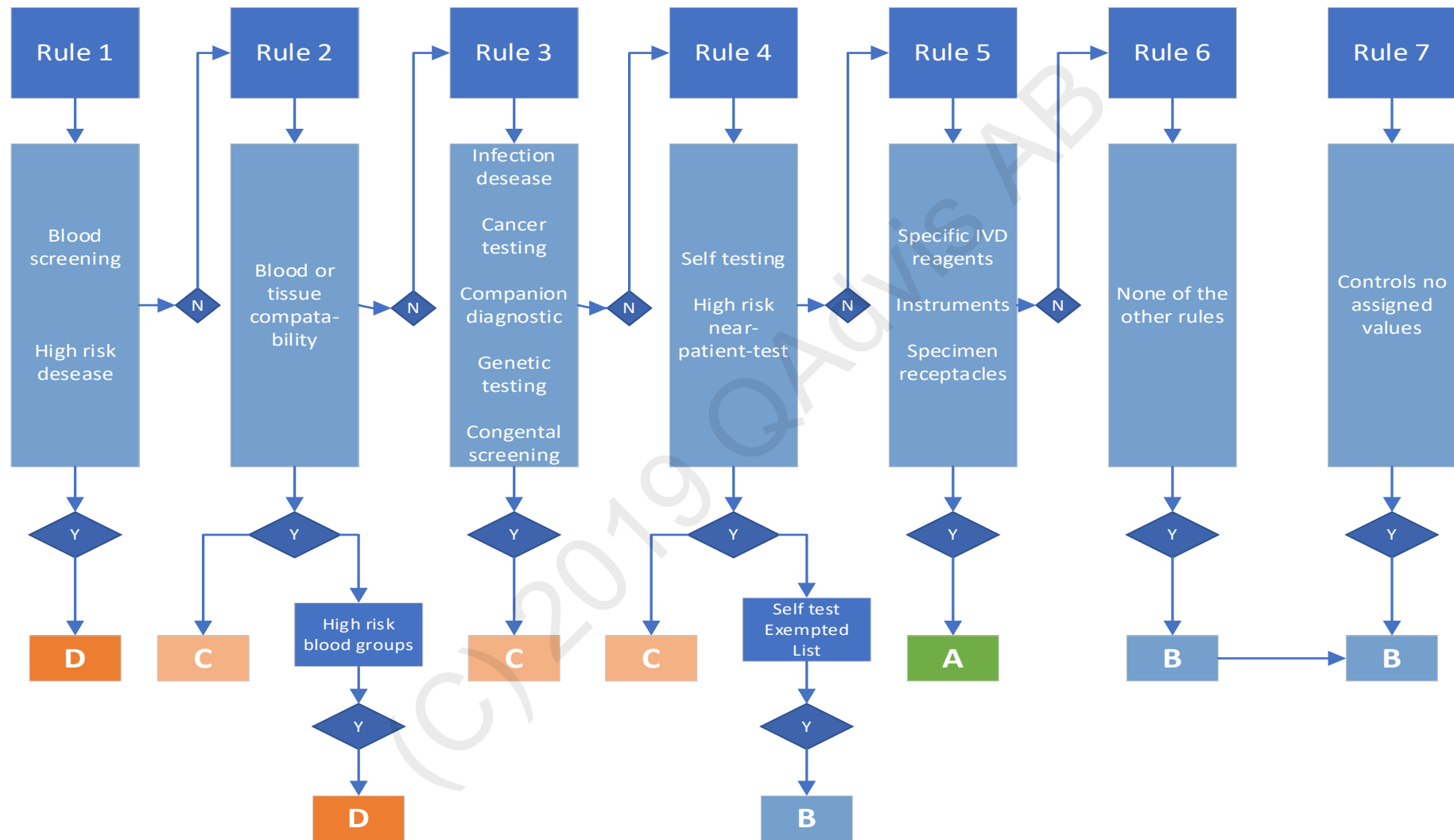


- General Requirements (GSPR 1-8)
- Requirements regarding Performance, Design and Manufacture (GSPR 9-19)
- Requirements regarding information supplied with the device (GSPR 20)

Classification rules - 7 rules and 4 classes



- A. Low individual risk and low public health risk
- B. Moderate individual risk and/or low public health risk
- C. High individual risk and/or moderate public health risk
- D. High individual risk and/or high public health risk




In Vitro Diagnostic Regulation (IVDR)



- Many SaMD will get a classification of Class B or higher
- Need of a Notified Body
- No transition time for Class General

Warning for confusion between IVDR classification A/B/C/D and Software Safety Classification A/B/C in IEC 62304

Relevant standards for SaMD according to IVDD

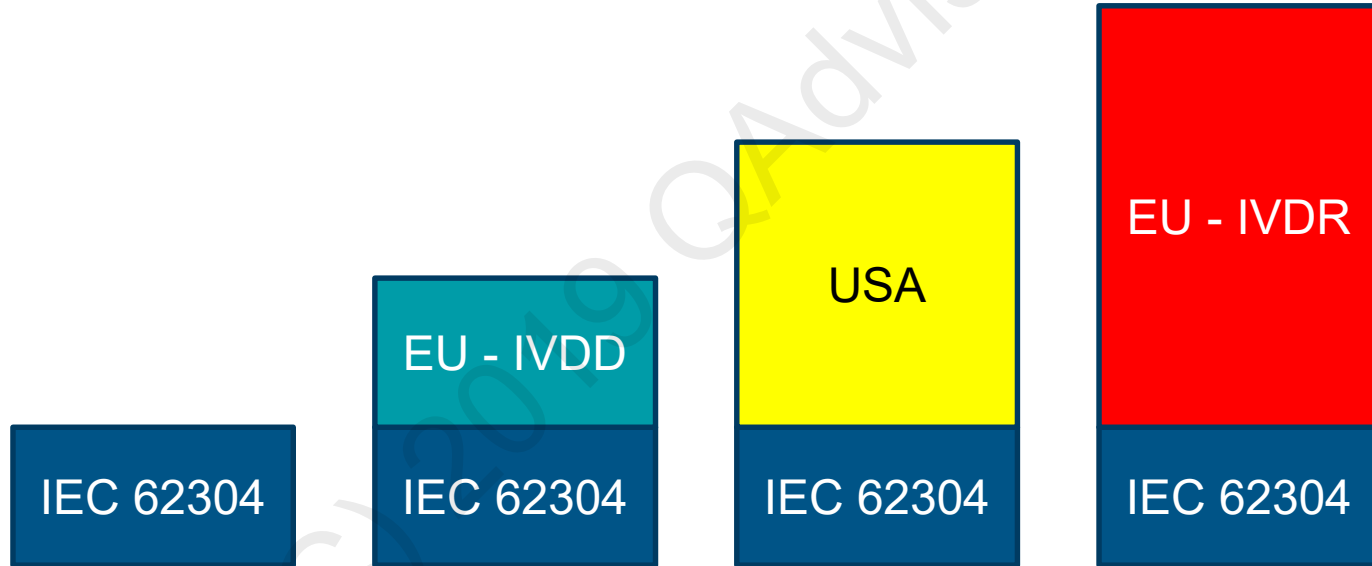


A Venn diagram on the left side of the table consists of three overlapping circles. The largest circle is dark blue and represents the 'Company' level. Inside it is a medium-sized blue circle representing the 'Product' level. Inside the product circle is a smaller light blue circle representing the 'Software' level. The table to the right lists standards for each level.

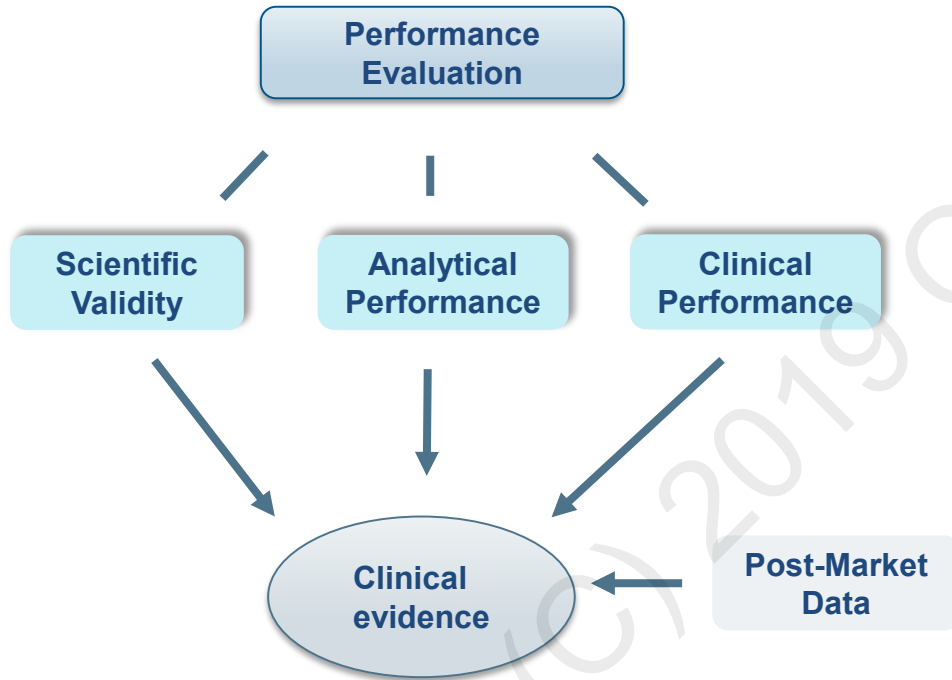
Company	<ul style="list-style-type: none">• ISO 13485• [QSR]
Product	<ul style="list-style-type: none">• IEC 82304-1• ISO 14971• IEC 62366-1
Software	<ul style="list-style-type: none">• IEC 62304

IEC 82304-1: Health Software – Part 1: General requirements for product safety

ISO 14971 and IEC 62304 are only setting a minimum level of requirements for software



Performance evaluation - concept overview



- Intended purpose and intended use
- Assessment and analysis of data to establish or verify the scientific validity, the analytical, and, where applicable, the clinical performance of a device
- A continuous process
- Extent according to e.g. risks, device classification and intended use

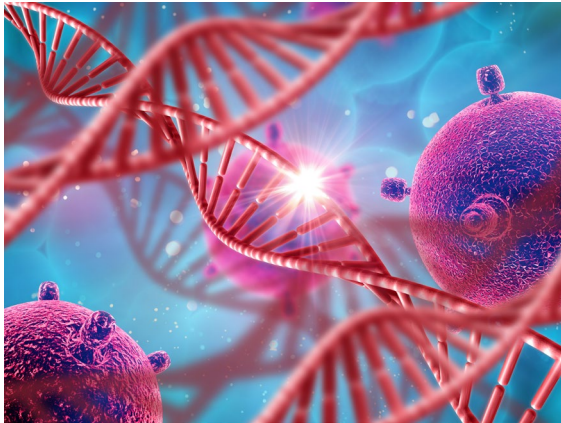
Performance evaluation – Content according to IVDR

1. Performance evaluation plan
2. Demonstration of scientific validity
3. Demonstration of analytical performance
4. Demonstration of clinical performance
5. Performance evaluation report = documentation of the clinical evidence



(IVDR Annex XIII)

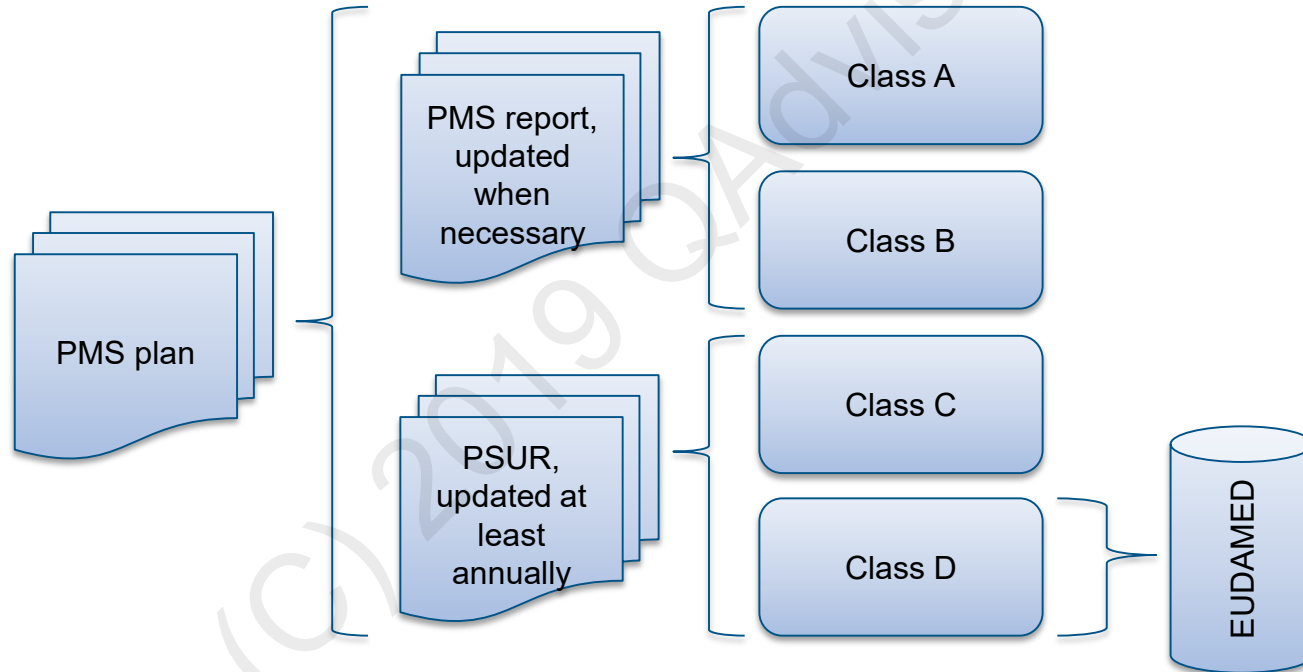
Post-market surveillance (PMS)



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.

Post-market surveillance



(IVDR Article 79, 80, 81)

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

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

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

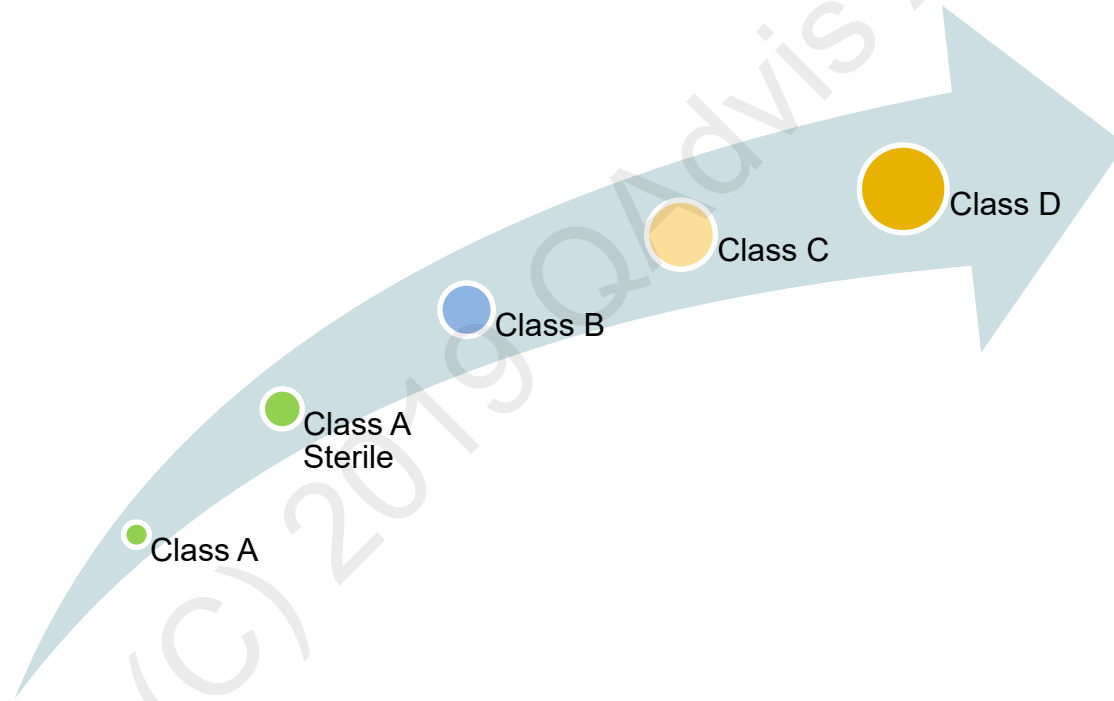
(MDR Article 30 / IVDR Article 27)

Conformity route



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

Conformity route – involvement of Notified Body



(IVDR Article 48)

Transitional provisions

5 April 2017

Regulations
adopted

5 May 2017

Regulations
published

26 May 2017

Regulations
taken into force

26 May 2020

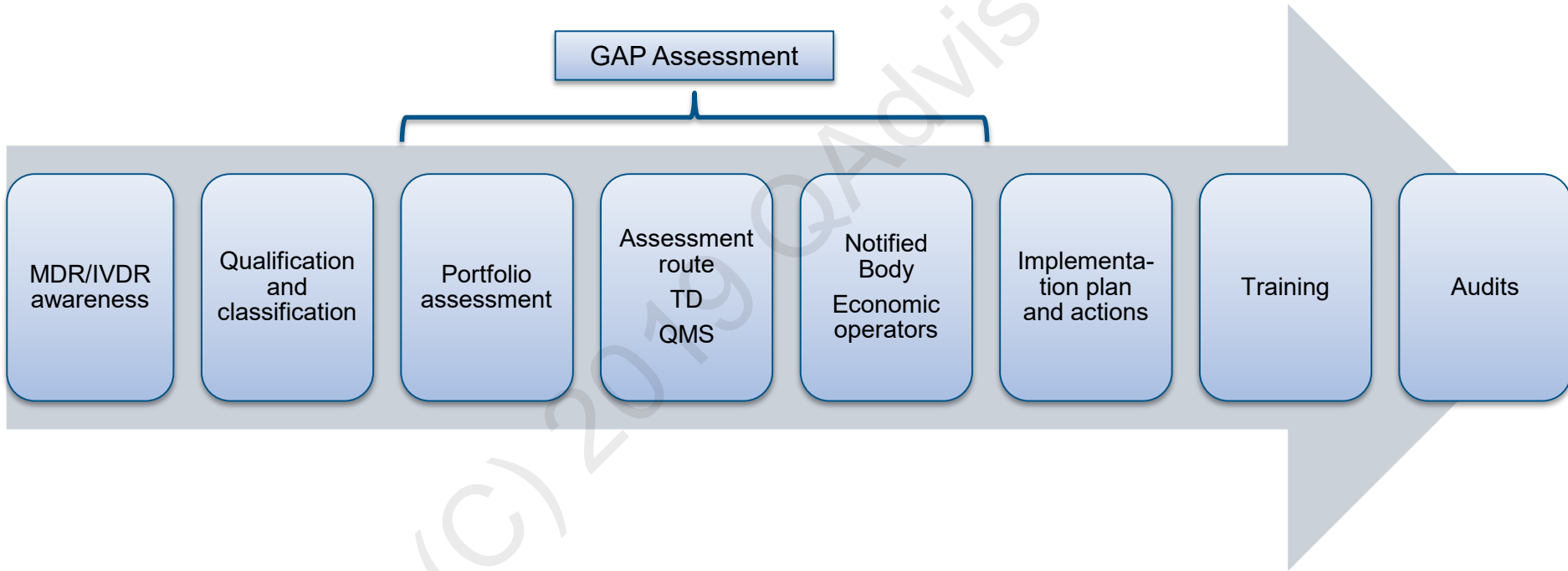
MDD and
AIMDD
becomes void

26 May 2022

IVDD become
void

IMPLEMENTATION

Implementation



LATEST UPDATES

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 :

Products :

ALL

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

Implementing acts



- List of codes and corresponding types of devices for notified bodies
- UDI issuing entities
- Reprocessing of single use devices

MDCG guidelines



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

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

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

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

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 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 IVDR
2019-09-30 Stockholm
2019-10-02 Malmö

QA_{dvis}

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