MDR IVDR Webinar 2021-03-10 09.00 – 10.00

- The new requirements at a glance – what are the main differences, common topics
- Some of the current hot topics in IVDR and MDR
- Status regarding designation of Notified Bodies
- How to proceed to MDR and IVDR?

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- This presentation is based on information gathered from MDR and IVDR, official websites from the Commission, Competent Authorities, and Notified Bodies, participation in and information from European seminars, the European Association of Authorized Representatives, standardization groups etc.
- To understand what is applicable for your products, and to get the complete text, please refer to MDR and IVDR.

Presentation of the speaker – Anna-Karin Areskog

Senior Quality and Regulatory Consultant

Experiences:

- QA Manager
- IVDD/IVDR and MDD/MDR
- GMP, ISO13485, QSR 21CFR 820
- Internal and external audits

Presentation of the speaker – Anneli Wiedenkeller

Senior Quality and Regulatory Consultant

Experiences:

- QA&RA, R&D, manufacturing (Worked within the medical device industry since 1988)
- Former MDD NB product assessor (active and non-active devices)
- Member of SIS TK 355 (Kvalitetsledning- och riskhanteringssystem samt andra tillhörande standarder för medicinteknik)
- MDD/MDR and IVD/IVDR

QAdvis – Key competence areas

eQMS

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-X
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 evidence

Your Regulatory Partner

THE NEW REQUIREMENTS AT A GLANCE
BACKGROUND

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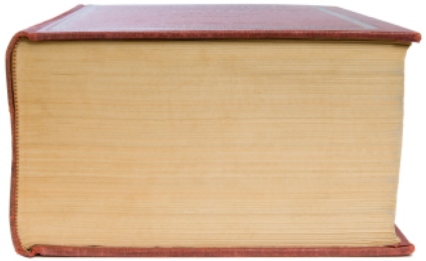
Background



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

  MDR 2017/745

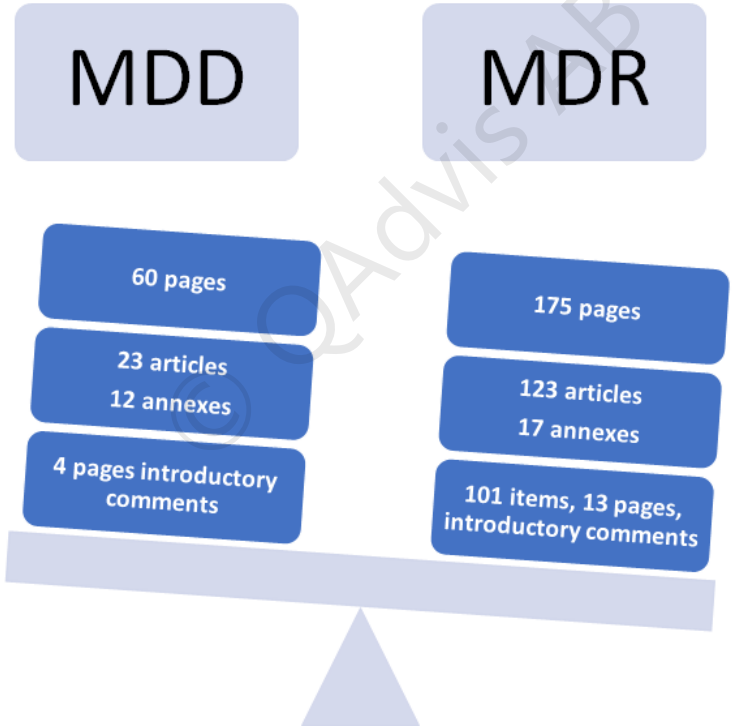
- Directive
  - IVDD
    (98/79/EG, LVFS 2001:7)

  IVDR 2017/746

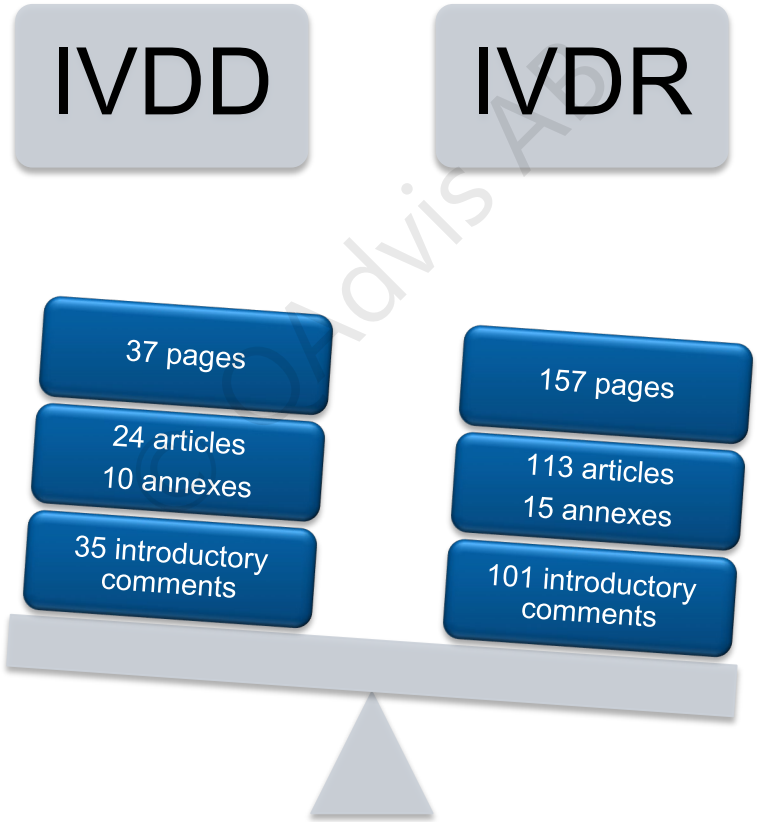
MDR 2017/745 IVDR 2017/746

WHAT ARE THE MAIN DIFFERENCES, COMMON TOPICS

Overview



Overview



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)

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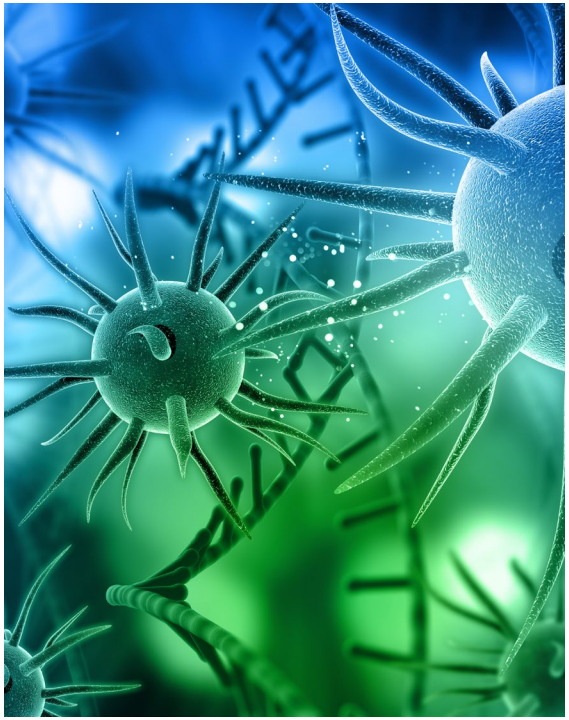
Person Responsible for Regulatory Compliance (PRRC)

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)

General obligations of manufacturers



Requirements on

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

(MDR / IVDR Article 10)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TECHNICAL DOCUMENTATION
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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/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 (IVDR Annex XIII)
- Interventional clinical performance studies and certain other performance studies (IVDR Annex XIV)

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

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

(MDR IVDR Annex I)

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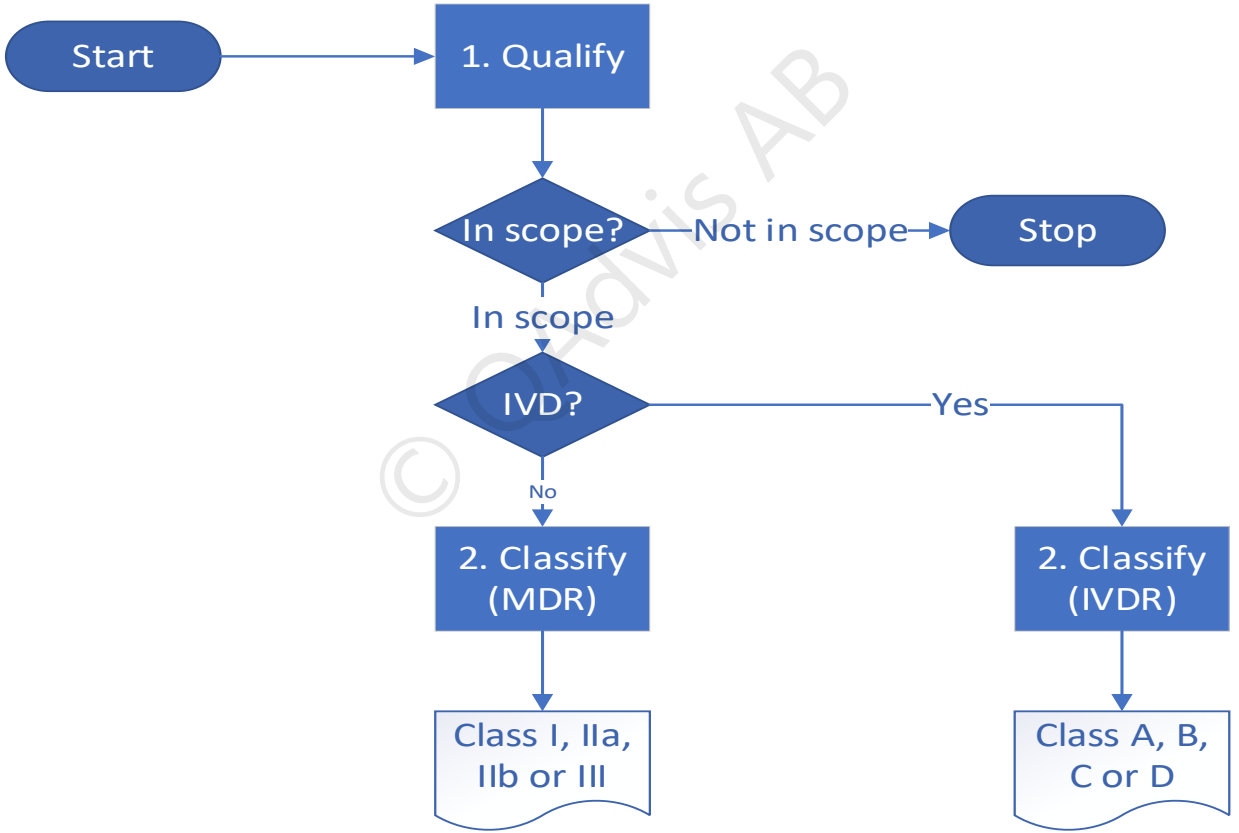
General Safety and Performance Requirements (GSPR)

- General Requirements (GSPR 1-8(1-9))
- Requirements regarding Performance, Design and Manufacture
- Requirements regarding information supplied with the device (GSPR 20 IVDR and 23 MDR)

(MDR IVDR Annex I)

Qualification MD / IVD



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MDR Classification rules overview

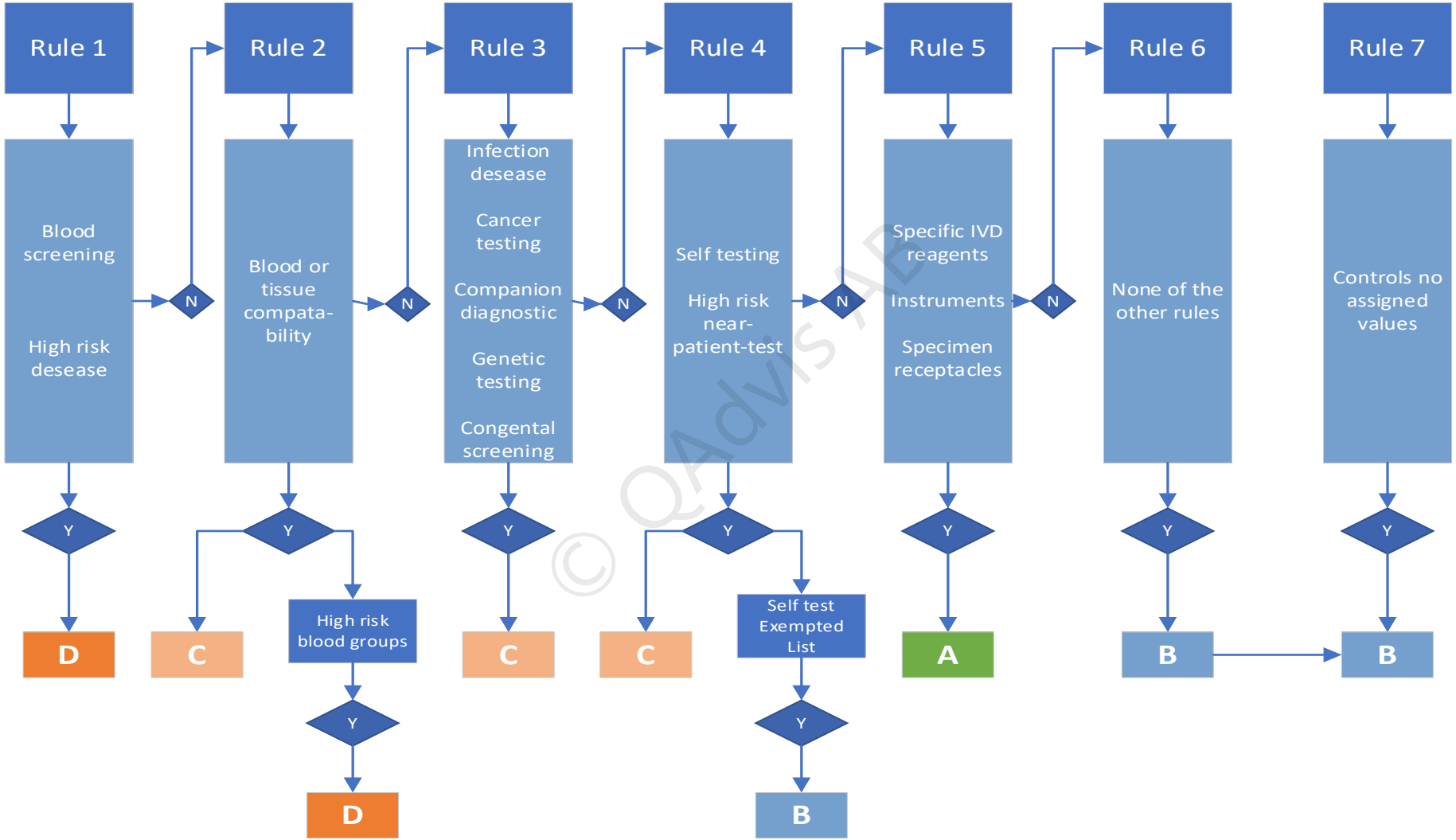
- Non-invasive devices
  - Rule 1-4
- Invasive devices
  - Rule 5-8
- Active devices
  - Rule 9-13
- Special rules
  - Rule 14-22

(MDR Annex VIII)

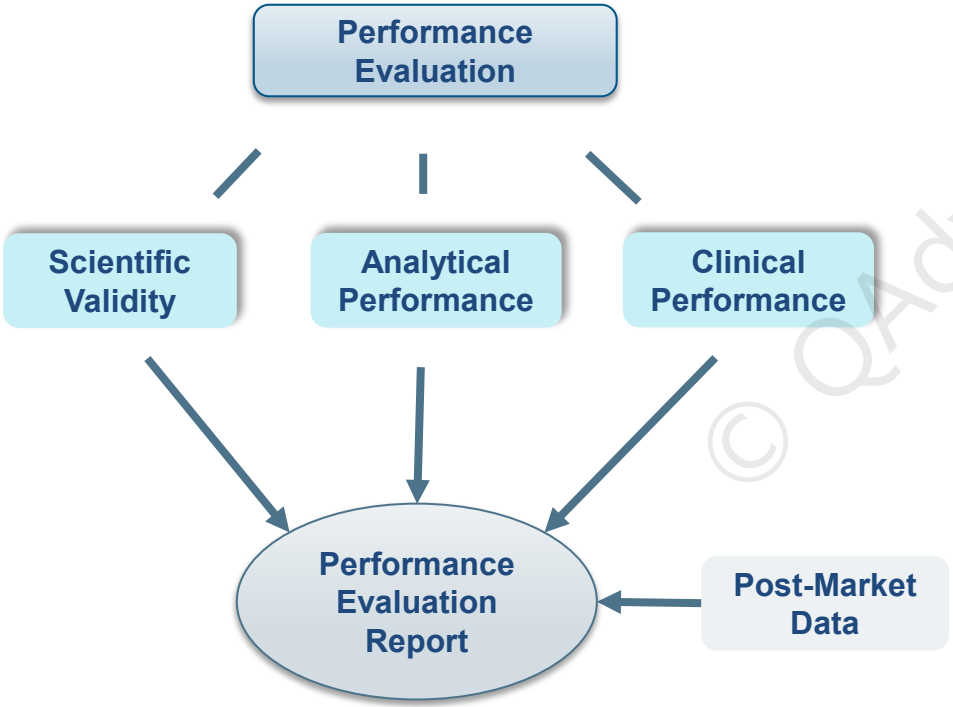
Classification rules - 7 rules and 4 classes

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

(IVDR Annex VIII)


Rule 1
Blood screening
High risk desease
Y
D
N
Rule 2
Blood or tissue compata-bility
Y
C
High risk blood groups
Y
D
N
Rule 3
Infection desease
Cancer testing
Companion diagnostic
Genetic testing
Congental screening
Y
C
N
Rule 4
Self testing
High risk near-patient-test
Y
C
Self test Exempted List
Y
B
N
Rule 5
Specific IVD reagents
Instruments
Specimen receptacles
Y
A
N
Rule 6
None of the other rules
Y
B
Rule 7
Controls no assigned values
Y
B

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

(IVDR Annex XIII)

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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)

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Clinical Evaluation (incl PM Clinical Follow-Up)-MDR

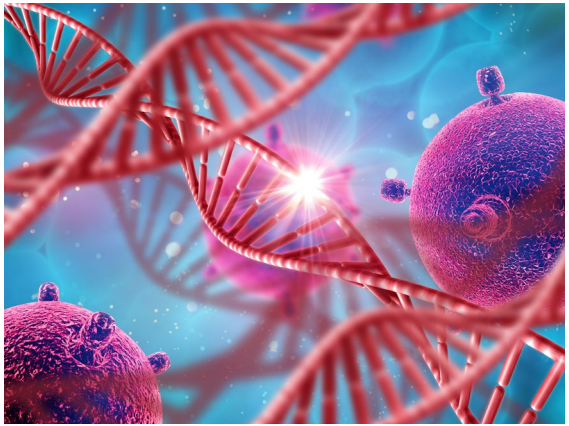
Clinical Evaluation Plan

Clinical Evaluation Report

Post-Market Clinical Follow-Up

MDR article 61, 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)

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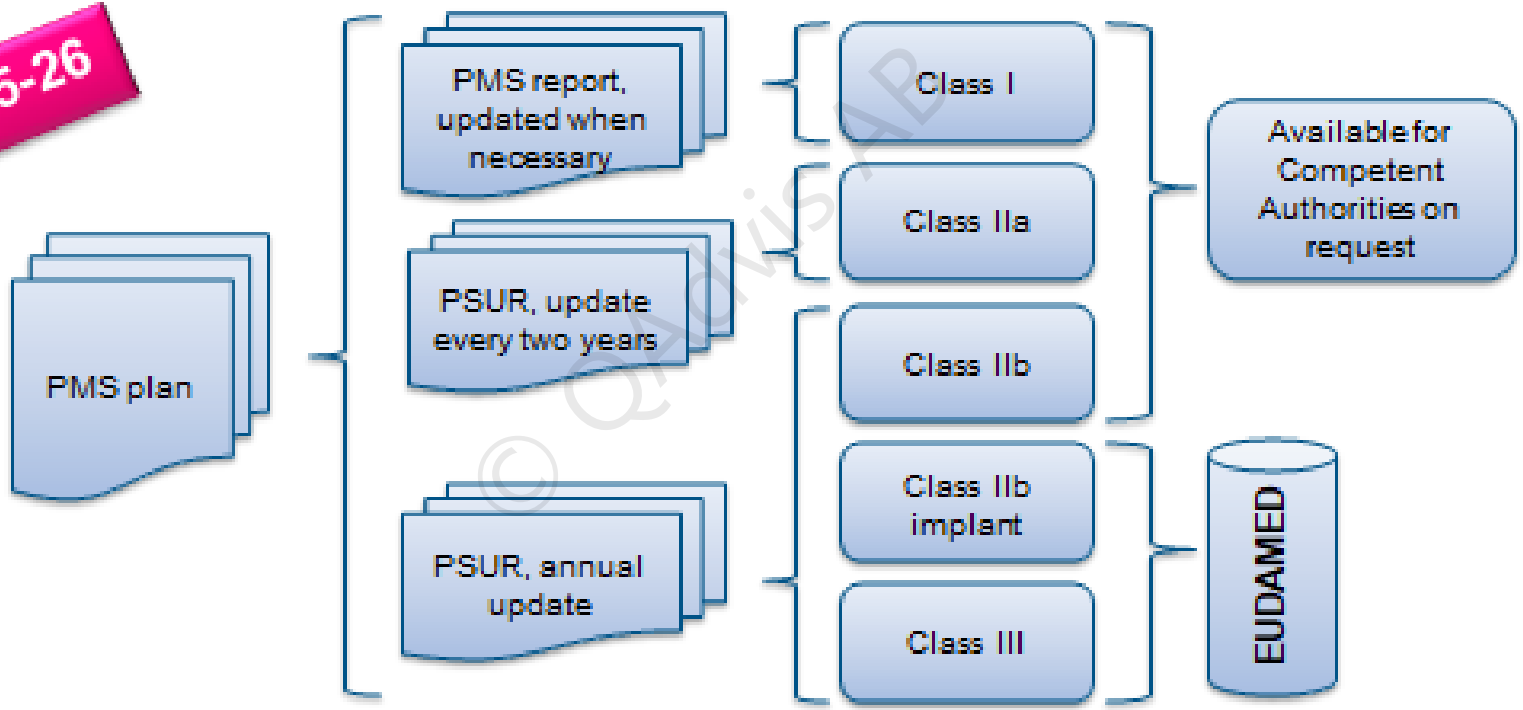
Post Market Surveillance (PMS)

2021-05-26



(MDR Article 83, 84, 85, 86)

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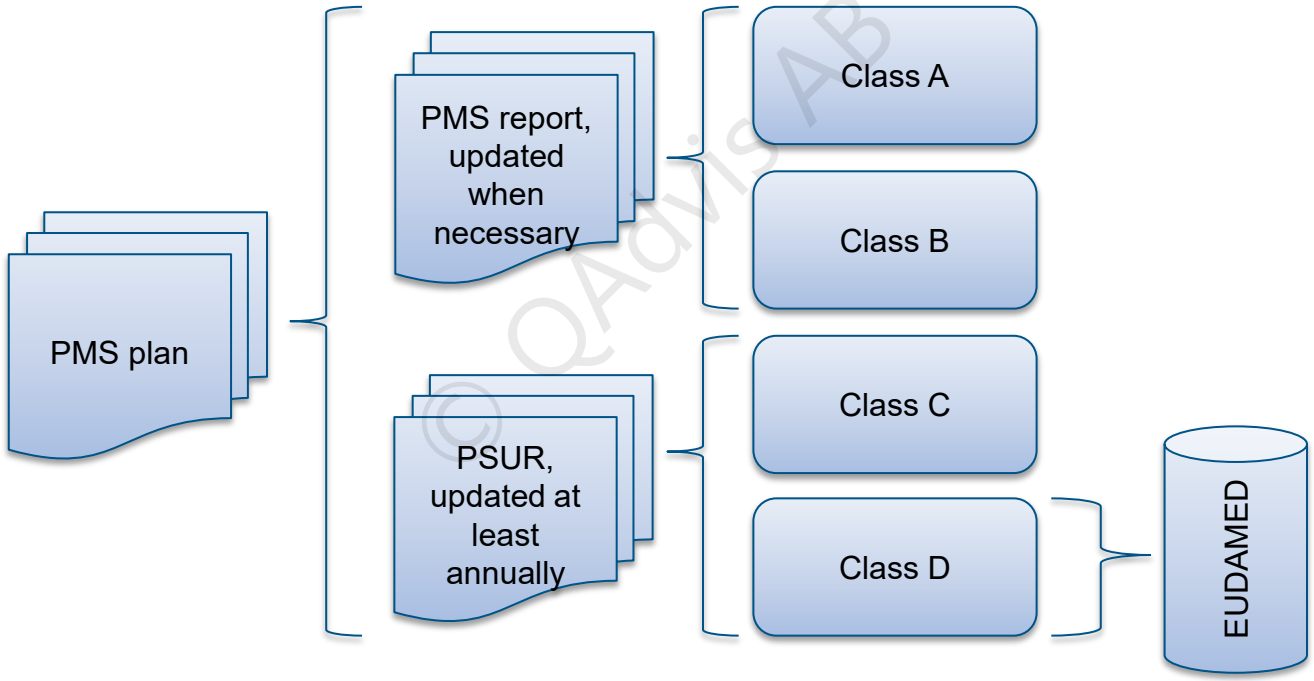
Post-market surveillance (PMS)



(IVDR Article 79, 80, 81)

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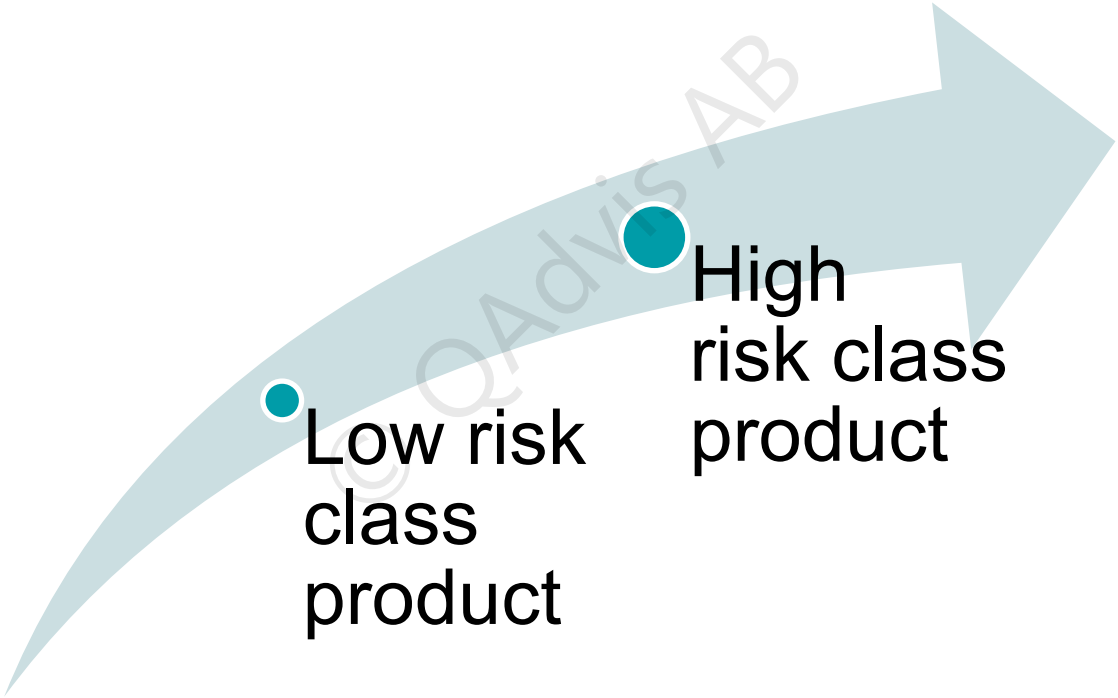
Conformity route

- 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

(MDR Article 52 / IVDR Article 48)

Conformity route – involvement of Notified Body



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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)

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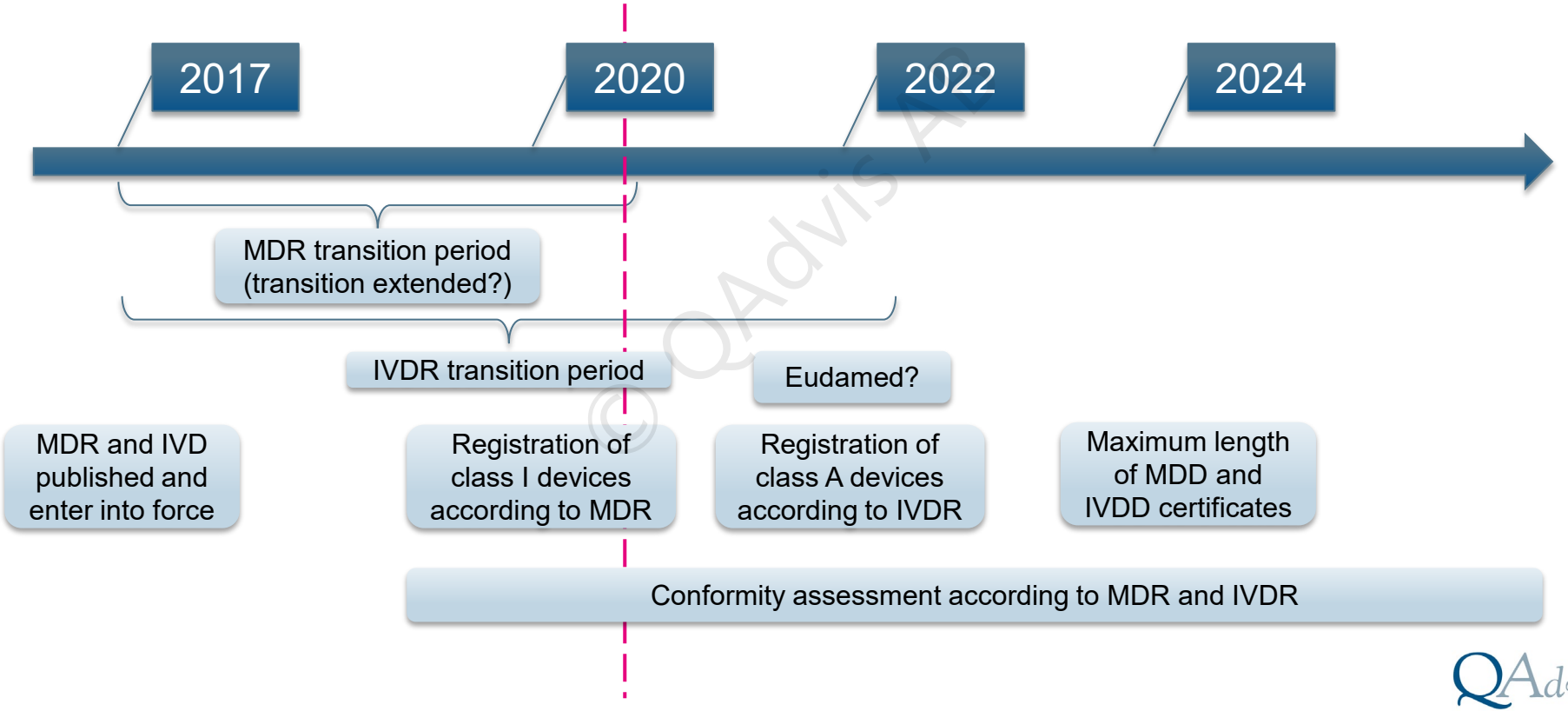
Timeline



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HOW TO PROCEED TO MDR AND IVDR?

1

Qualification and classification
Qualify the device as a medical device and based on the intended use make classification according to MDR.

Qualification and classification rational for applicable devices

2

Gap analysis and portfolio assessment
Gap analysis of device technical documentation, clinical data and quality management system.

Gap-analysis

3

Transfer strategy and time plan
Development of strategy for implementation, identification of possible conformity route, contact a notified body and creation of overall time plan.

Project plan, support in notified body contacts

4

Implementation
Detailed implementation plan, identification of resources. Execute implementation actions, development of QMS and technical documentation.

Implementation action plan as a complement to the project plan. Updated technical documentation and QMS.

5

Deploy new QMS and PRRC
Establish the role of Person Responsible for Regulatory Compliance (PRRC) in the organization. Implementation and training in new QMS procedures.

MDR and QMS training sessions. Role description and implementation in organization for PRRC

6

Technical documentation – pre-assessment
Pre-assessment of the updated technical documentation to ensure MDR requirements are covered and allow for a faster review time by the notified body.

Review report with identified proposed actions and non-conformities

7

Internal audits and mock audit
Internal audit to ensure successful implementation of MDR requirements and a mock-audit to prepare the company for the certification audit.

Audit report with identified proposed actions and non-conformities

8

Conformity assessment (class I)
Sign DoC and product registration

Conformity assessment
Notified body audit and review of technical documentation.

Support regarding response handling and non-conformities. EC-certificate – products are approved to be placed on the market.

CURRENT HOT TOPICS/LATEST UPDATES

Status regarding designation of NB:s

- 19 notified bodies designated under MDR

- 4 notified bodies designated under IVDR

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 2265	3EC International a.s.	Slovakia
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.	Hungary
NB 1912	DARE!! Services B.V.	Netherlands
NB 0344	DEKRA Certification B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany
NB 2460	DNV GL Presafe AS	Norway
NB 0297	DQS Medizinprodukte GmbH	Germany
NB 0459	GMED	France
NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy
NB 0373	ISTITUTO SUPERIORE DI SANITA'	Italy
NB 2862	Intertek Medical Notified Body AB	Sweden
NB 0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	Germany
NB 0482	MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH	Germany
NB 0050	National Standards Authority of Ireland (NSAI)	Ireland
NB 0598 (ex-0403)	SGS FIMKO OY	Finland
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany
NB 2696	UDEM Adriatic d.o.o.	Croatia

Body type	Name	Country
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany

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

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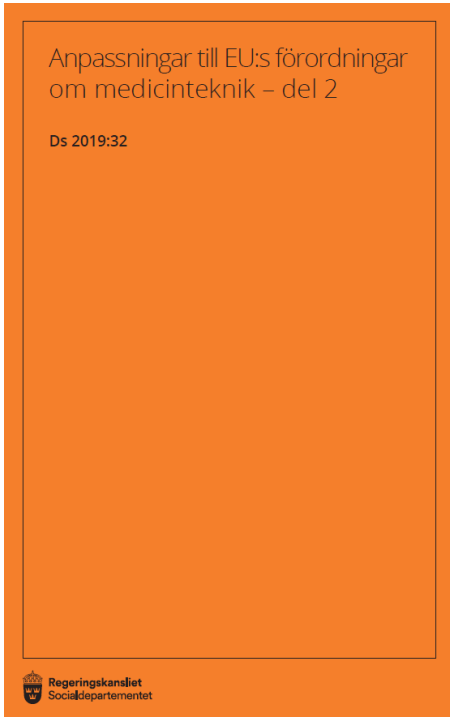

- Language requirements
- National registration
- Fees
- Sanctions and penalties
- Clinical trials
- Market surveillance

Implementing acts

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

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

MDCG guidelines – need to be controlled regularly

- UDI guidance documents
- Eudamed registration
- Qualification and classification of software
- Guidance on cybersecurity for medical devices
- Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software

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

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MDCG guidelines

Clinical investigation and evaluation

Reference	Title	Publication
MDCG 2020-13 - Word version	Clinical evaluation assessment report template	July 2020
MDCG 2020-10/2 MDCG 2020-10/1	Guidance on safety reporting in clinical investigations Appendix: Clinical investigation summary safety report form	May 2020 May 2020
MDCG 2020-8	Guidance on PMCF evaluation report template	April 2020
MDCG 2020-7	Guidance on PMCF plan template	April 2020
MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices	April 2020
MDCG 2020-5	Guidance on clinical evaluation – Equivalence	April 2020
MDCG 2019-9	Summary of safety and clinical performance	August 2019

New technologies

Reference	Title	Publication
MDCG 2020-1	Guidance on clinical evaluation (MDR) / Performance evaluation (IVDR) of medical device software	March 2020
MDCG 2019-16 rev.1	Guidance on cybersecurity for medical devices	December 2019
MDCG 2019-11	Qualification and classification of software - Regulation (EU) 2017/745 and Regulation (EU) 2017/746	October 2019

Other topics

Reference	Title	Publication
MDCG 2020-16	Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746	November 2020
MDCG 2020-9	Regulatory requirements for ventilators and related accessories	April 2020
MDCG 2020-2 rev.1	Class I transitional provisions under Article 120 (3 and 4) – (MDR)	March 2020
MDCG 2019-15 rev.1	Guidance notes for manufacturers of class I medical devices	December 2019

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

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Corrigendum MDR and IVDR

Corrigenda to the medical devices regulations

- Corrigendum of 27 December 2019 to Regulation (EU) 2017/745 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Directives 90/385/EEC and 93/42/EEC
- Corrigendum of 27 December 2019 to Regulation (EU) 2017/746 on in vitro diagnostic medical devices, repealing Directive 98/79/EC and Commission decision 2010/227/EU
- Corrigendum of 5 May 2019 to Regulation (EU) 2017/745 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Directives 90/385/EEC and 93/42/EEC
- Corrigendum of 5 May 2019 to Regulation (EU) 2017/746 on in vitro diagnostic medical devices, repealing Directive 98/79/EC and Commission decision 2010/227/EU

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

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Concerns

- A lot of work for Notified Bodies and Competent Authorities
- Lack of reference laboratories
- Decreasing number of Notified Bodies
- More devices and manufacturers in need of a Notified Body
- EUDAMED is delayed
- Common Specifications necessary for implementation not published in time
- Necessary Implementing Acts not ready in time

Conclusions

- A lot of work – start now!
- Use the Nomenclature
- No grandfathering:

  Not ready in time = products cannot 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

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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

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Our one day courses
divided in to two half-day online sessions

EU Medical Device Regulation (MDR)
and
EU In Vitro Diagnostic Regulation (IVDR)

Session one/day 1:
Joint session for both EU MDR regulation
and EU IVDR regulation

Session two/day 2:
Divided in to two tracks, one for EU MDR and one for EU IVDR specific training

More information