Free webinar
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How to prepare for the EU Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR)

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– Qadvis

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Introduction

QAdvis is longtime trusted providers of MedTech quality and system management, risk management, compliance, training, interim management and regulatory affairs.

QAdvis services include:
- Quality management support
- System development
- Quality and regulatory consulting
- Training
- European Authorised Representation

As compliance in the MedTech field is governed by rigidly specific requirements, developing and using a reliable quality management system is key to fulfilling and maintaining compliance. We support you in this process, using best practices based on three decades of projects in this field.

QAdvis is an active member of the European Association of Authorised Representatives, offering support and legal EU representation for non-EU companies who want to enter the European market.

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.

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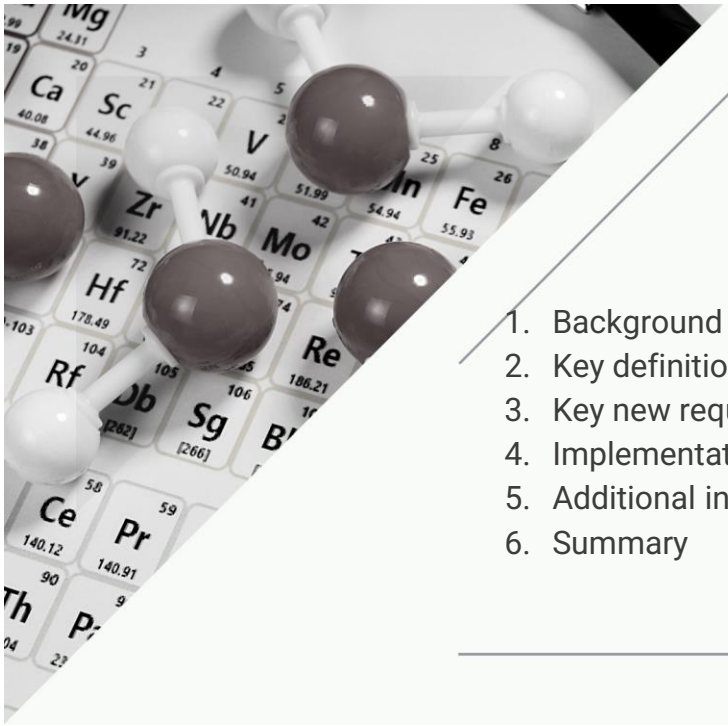

Summary of Topics

1. Background and overview
2. Key definitions
3. Key new requirements/significant changes
4. Implementation and timeline
5. Additional information
6. Summary

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1.1 Background

Directives

AIMDD Active Implantable Medical Devices Directive
(90/385/EEG, LVFS 2001:5)

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

IVDD In Vitro Diagnostic Medical Devices Directive
(98/79/EG, LVFS 2001:7)

Regulation

MDR
Medical Devices Regulation
EU 2017/745

IVDR
In Vitro Diagnostic Medical Devices Regulation
EU 2017/746

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European market

- Medical Devices, In Vitro Diagnostic Medical Devices
- EU: **27** countries
  Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden
- EEA : includes EU countries and also **Iceland, Liechtenstein** and **Norway**. It allows them to be part of the EU's single market.
- UK, Switzerland, Turkey

- CE-marking, EU requirements
- European Authorized Representatives (EAR)
- UK Responsible Person, CE-marking & UKCA
- Swiss AR (MDR & IVDR)

} For non-EU/EEA manufacturers

- DoC, or/and EC Certificate
- EU National Competent Authority (NCA), Notified Body (NB)
- Technical Documentation (TD)

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1.2 Overview

Conformity Route (MDR Article 52 / IVDR Article 48)

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

Technical Documentation (MDR/IVDR)

- Intended purpose (Article 2(12))
- Technical Documentation (Annex II)
- Technical Documentation on PMS (Annex III)
- Declaration of Conformity (Annex IV)
- General Safety and Performance Requirements (Annex I)
- Clinical Evaluation / Performance evaluation (Annex XIV/XIII)

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General obligations of manufacturers
(MDR / IVDR Article 10)

Requirements on the following aspects:

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

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2. Key definitions

MDR/IVDR Art. 2 Definitions

- Medical Devices (MD)
- In Vitro Diagnostics Medical Device (IVD)

Accessory for MD/IVD, Custom-made device, single-use device, procedure pack, system, device for self-testing, companion diagnostic… …

- Generic device group

- Manufacturer
- European Authorised Representatives (EAR)
- Importer
- Distributor

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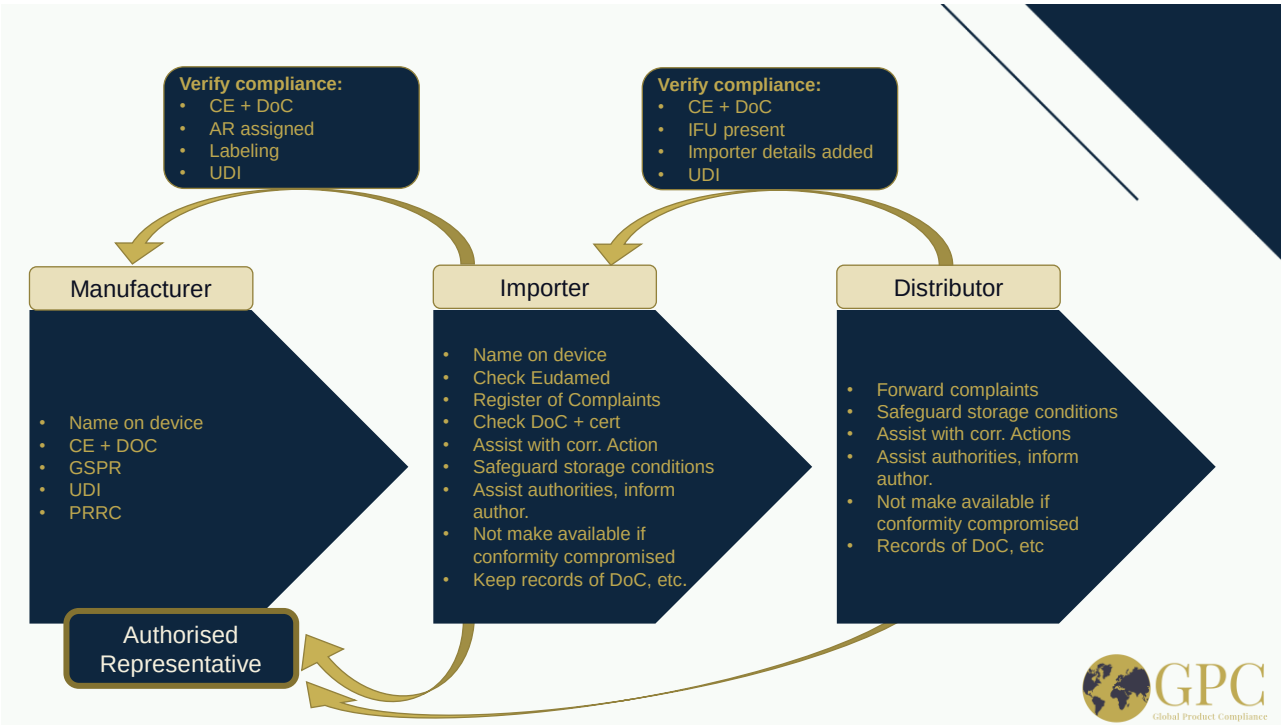

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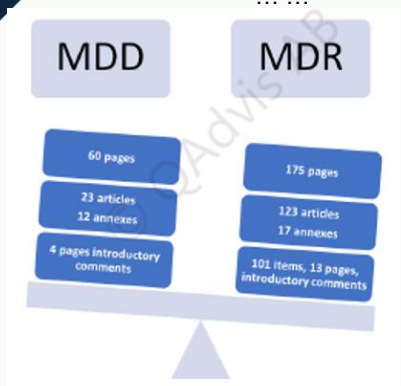
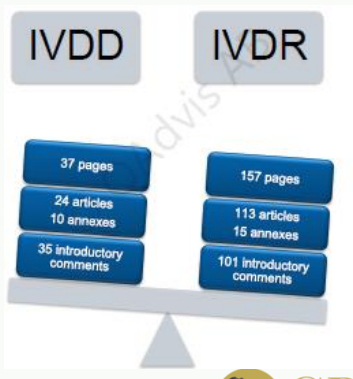
3. Key new requirements/ significant changes

- PRRC: Person Responsible of Regulatory Compliance (MDR/IVDR Art 15)
- GSPR: General Safety Performance Requirements (MDR/IVDR Annex I)
- UDI: Unique Device Identifier (MDR/IVDR Art. 2)
- CE,PE, PMS: MDR/IVDR Chapter VI & VII
- EUDAMED: MDR/IVDR Art. 33/30

… …





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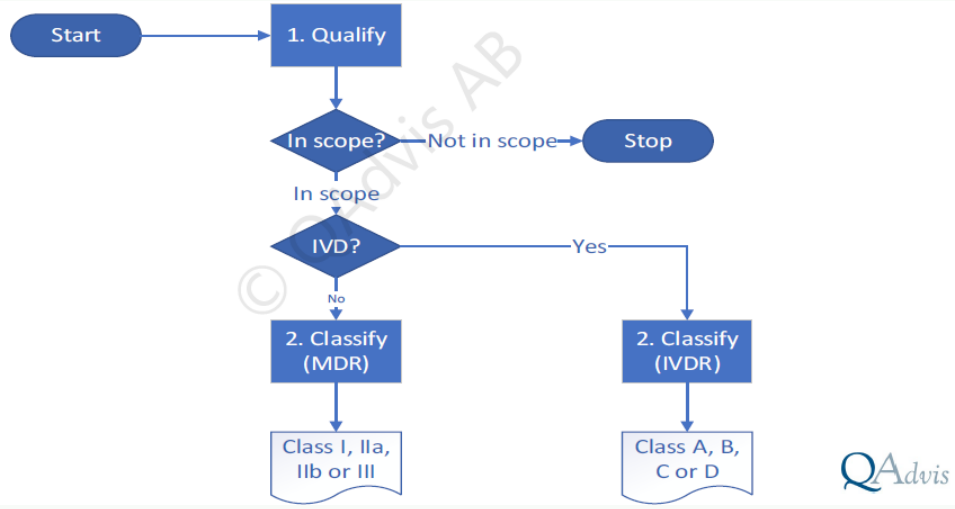
Qualification MD/IVD



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Classification rules overview

MDR/IVDR Annex VIII

For MDR:

22 rules and class I, Is, Ir, IIa IIb III

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

(MDR Annex VIII)

For IVDR:

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)

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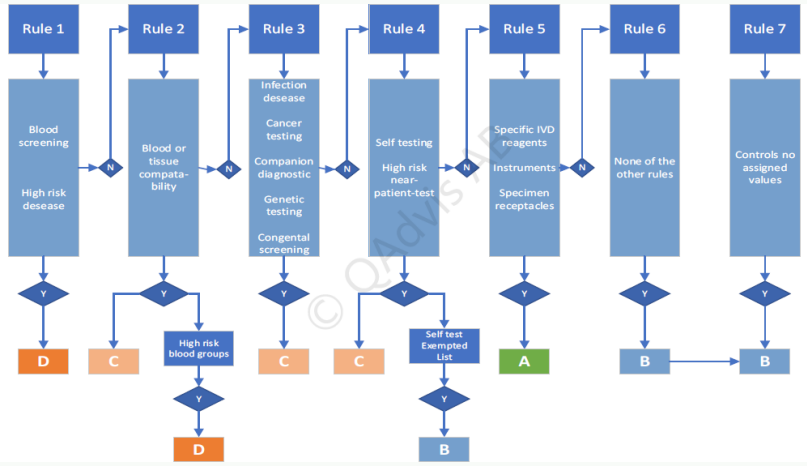
IVDR rules chart



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Clinical Evaluation (CE)

MDR Art. 61, Annex XIV

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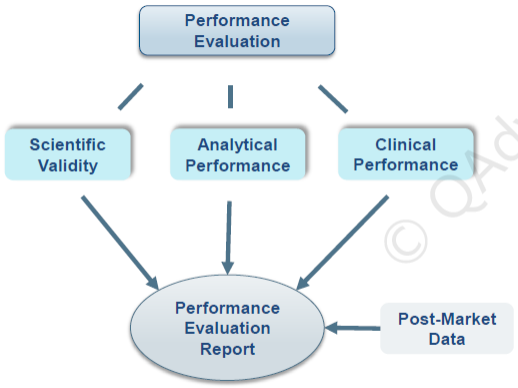
Performance Evaluation (PE)

IVDR Annex XIII



- 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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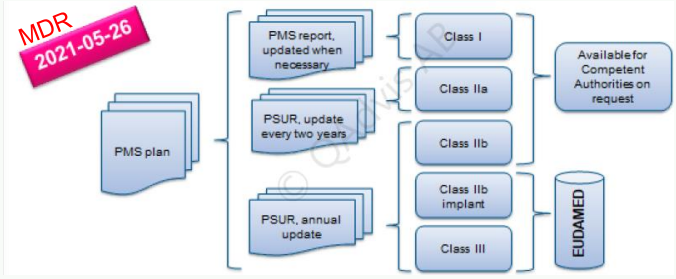
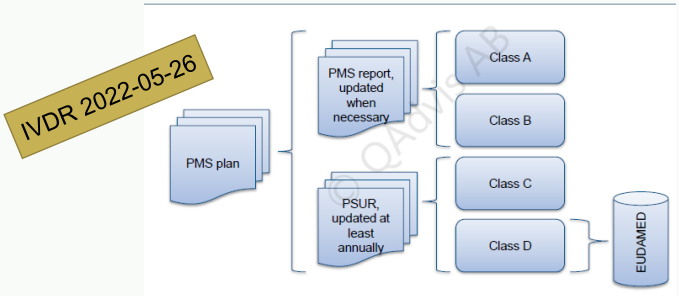
Post-Market Surveillance (PMS)

MDR Art. 83-86 /IVDR Art. 78-81





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Technical Documentation

MDR/IVDR Annex II

Example: A list of basic TD files for QAdvis EAR assessment review

For MDR/IVDR Basic Technical Documentation (TD) as part of the CE-Marking process for our review is listed below :

1. Documented product information and manufacturer information: intended use/product description (including contract manufacturer, critical sub-contractors) /specification/classification and justification
2. General safety and performance requirements (GSPR) checklist
3. Labelling/Instruction for use (IFU)
4. Risk Management documents, including procedure/plan, analysis and report
5. Verification/Validation documents including procedure/plan, report, test reports/analytical performance, clinical performance and stability documents/data
6. Clinical Evaluation/Performance documents, including procedure/plan, report…
7. QMS certificate/manual/procedures, such as Person Responsible for Regulatory Compliance (PRRC), Post Market Surveillance (PMS) plan and report, Complaint handling, Vigilance and Field Corrective Action (FSCA)
8. Declaration of Conformity (DoC)
9. Liability insurance documents

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EUDAMED

MDR Art. 33/IVDR Art. 30

EUDAMED Time line - European Commission

EUDAMED is structured around 6 interconnected modules:

- Actor registration module
- UDI/Devices module
- NBs & Certificates module
- Clinical Investigations and performance studies
- Vigilance and post-market surveillance
- Market Surveillance

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4. Implementation and timeline

- Corrigendum 1 and 2

1.Corrigendum, OJ L 117, 3.5.2019, p. 9 (2017/745)

2.Corrigendum, OJ L 334, 27.12.2019, p. 165 (2017/745)

- Amendment

MDR REGULATION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2020

IVDR REGULATION (EU) 2022/112 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 January 2022

- MDR DoA 2021-05-26
  IVDR DoA 2022-05-26

- Legacy devices
- Regulation MDR/IVDR devices

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5. Additional information

How to prepare for EU MDR & IVDR for Manufacturers?

- Process?
- Step by step?

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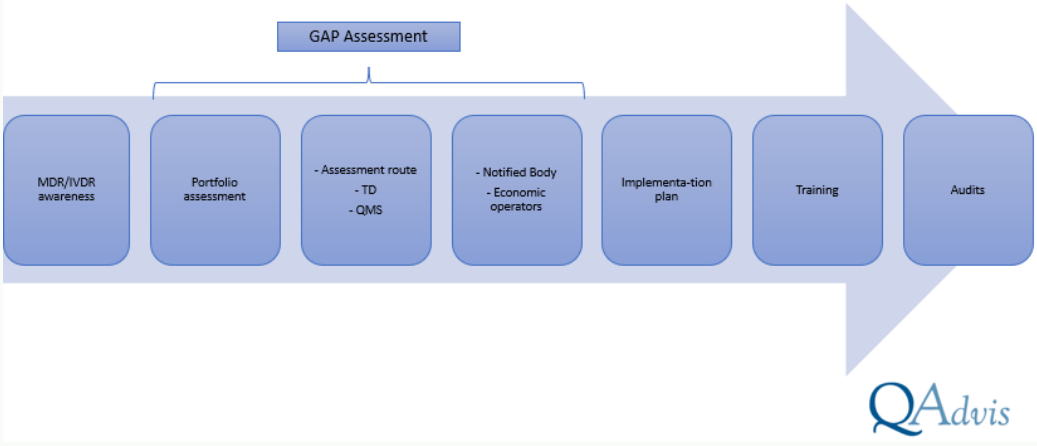
How to prepare for EU MDR & IVDR



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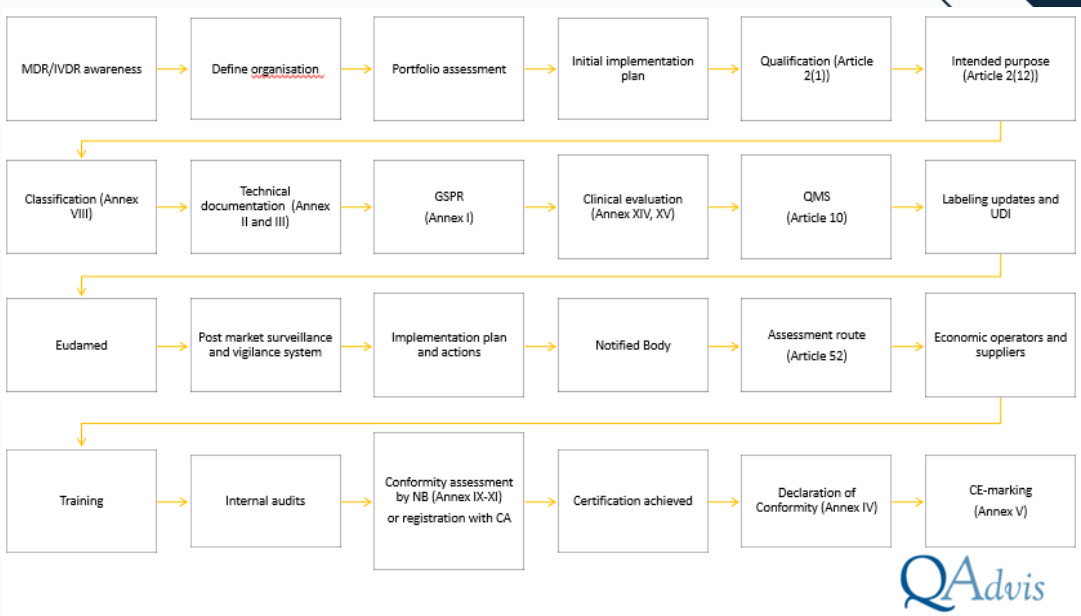

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For non-EU/EEA Manufacturers

EAR services for CE marking

- EAR
- EAR agreement
- Mandate/letter of Authorization by Manufacturer

- TD assessment review
- EAR on behalf of non-EU/EEA Manufacturers, apply for CE-registration with NCA
- Confirmation letter from the NCA & EAR-Certificate

- Language requirements
- Additional registration/notification

UKRP services for UKCA

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Useful links

European Commision webpage

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

Medical Devices - Sector (europa.eu)

DocsRoom - European Commission (europa.eu)

MDCG guidance

Guidance - MDCG endorsed documents and other guidance (europa.eu)

Harmonized Standards

Medical devices (europa.eu)

IV diagnostic medical devices (europa.eu)

Common Specification (CS)

Manufacturers of devices without an intended medical purpose (europa.eu)

In vitro diagnostic medical devices - common specifications (europa.eu)

IMDRF and GMDN

Documents | International Medical Device Regulators Forum (imdrf.org)

GMDN Agency

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NCA & NB

• NCA Contact points
Additional registration/notification
National languages requirements

• NANTO NANDO web site
Until June 3, 2022
30 notified bodies designated under MDR
7 notified bodies designated under IVDR
NB code, scope… …

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6. Summary

- Don't wait for clarifications – act now – the clock is ticking!
- Make a migration plan, get management buy in, secure resources and budget
- Assess your qualification and classification
- Many products will be up-classified
- Stand in line for a NB – if needed
- Stricter requirements on all players (Authorities, Notified Bodies and Manufacturers)
- Sufficient clinical data necessary

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Questions & Answers

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Q&A

- When is my medical device considered to form an integral product with a medicinal product?
- How does the notified body work?
- What are the countries that have different language requirement?
- when can the software considered as medical device? If an IVD just calculates a ratio using software , then can we consider it also as MD? Risk class of this IVD is calss C

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Thank You.

Contact us for global regulatory services


https://gpcgateway.com/


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