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QAdvis – IVDR breakfast seminar 2023-01-19

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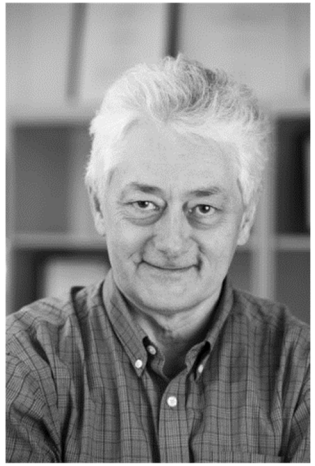


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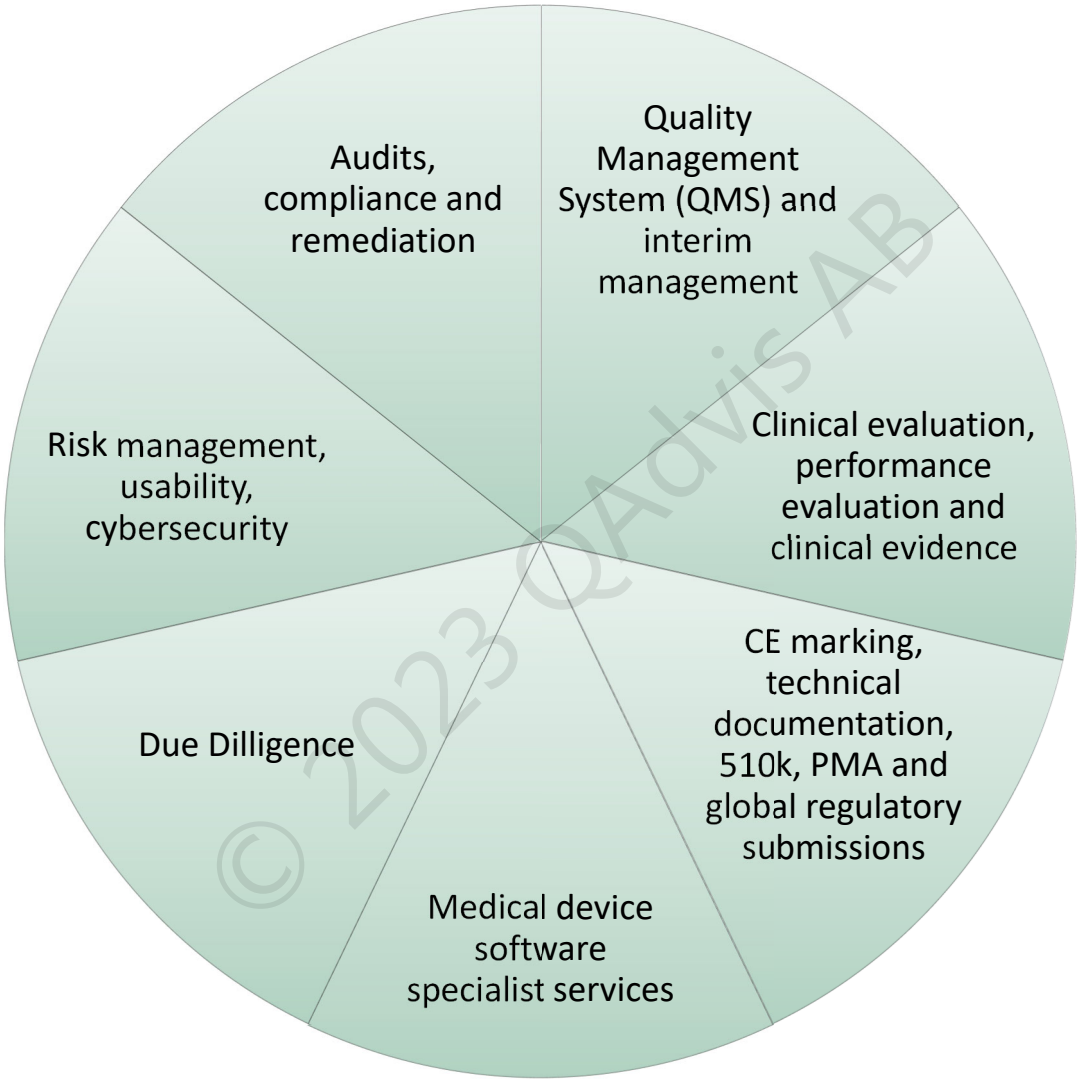
Vision
Simplify regulatory complexity to accelerate successful market availability of safe and effective medical devices for the improvement of health and human lives across the globe.



Independent European Authorized Representative (EAR)

Offers complete legal representation services for non-EU/EEA manufacturers of medical devices and in vitro diagnostics medical devices wanting to enter the EU market

Acts on behalf of manufacturers in contact with Competent Authorities and Notified Bodies

Provides additional services for Free Sales Certificates, national registrations, regulatory support, etc

Founding member of the European Association of Authorized Representatives (EAAR)

Contact: ear@qadvis.com

Independent UK Responsible Person (UKRP)

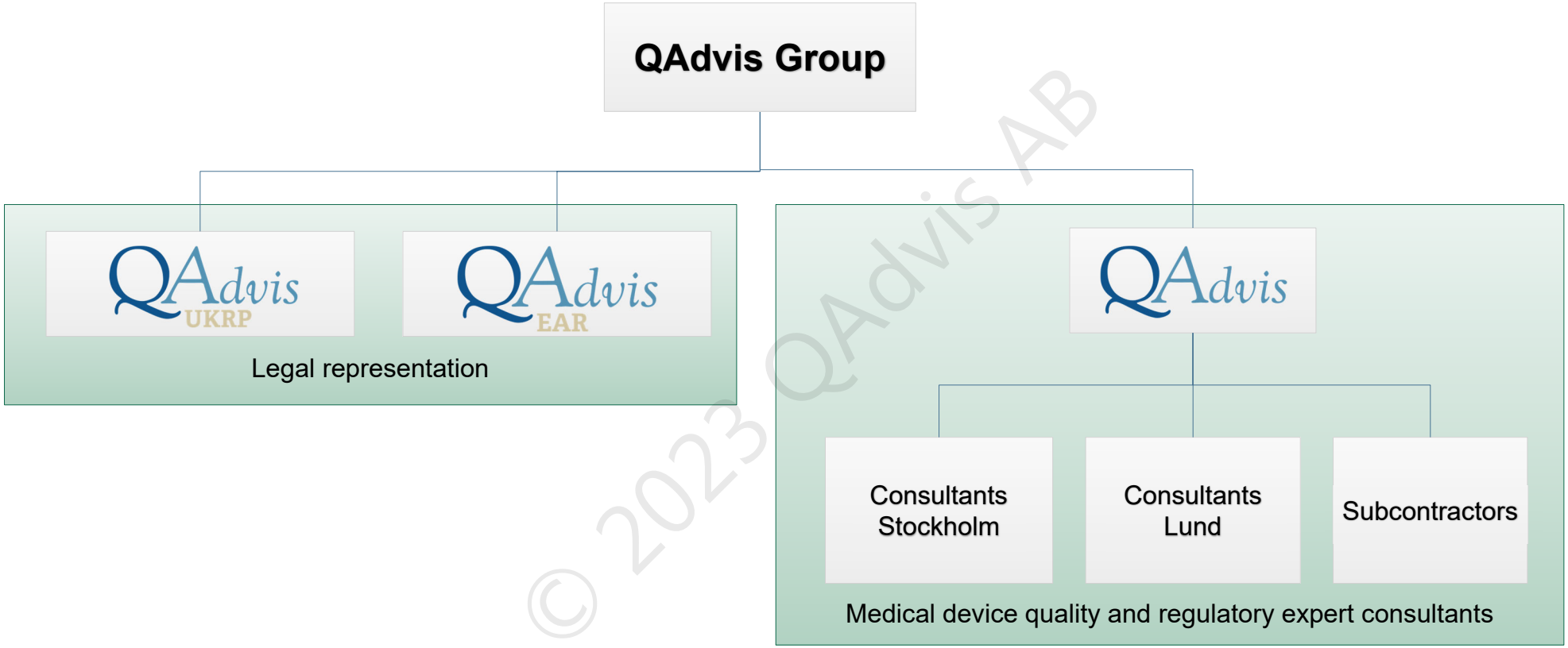
Offers complete legal representation services for non-UK manufacturers of medical devices and in vitro diagnostics medical devices wanting to enter the UK market

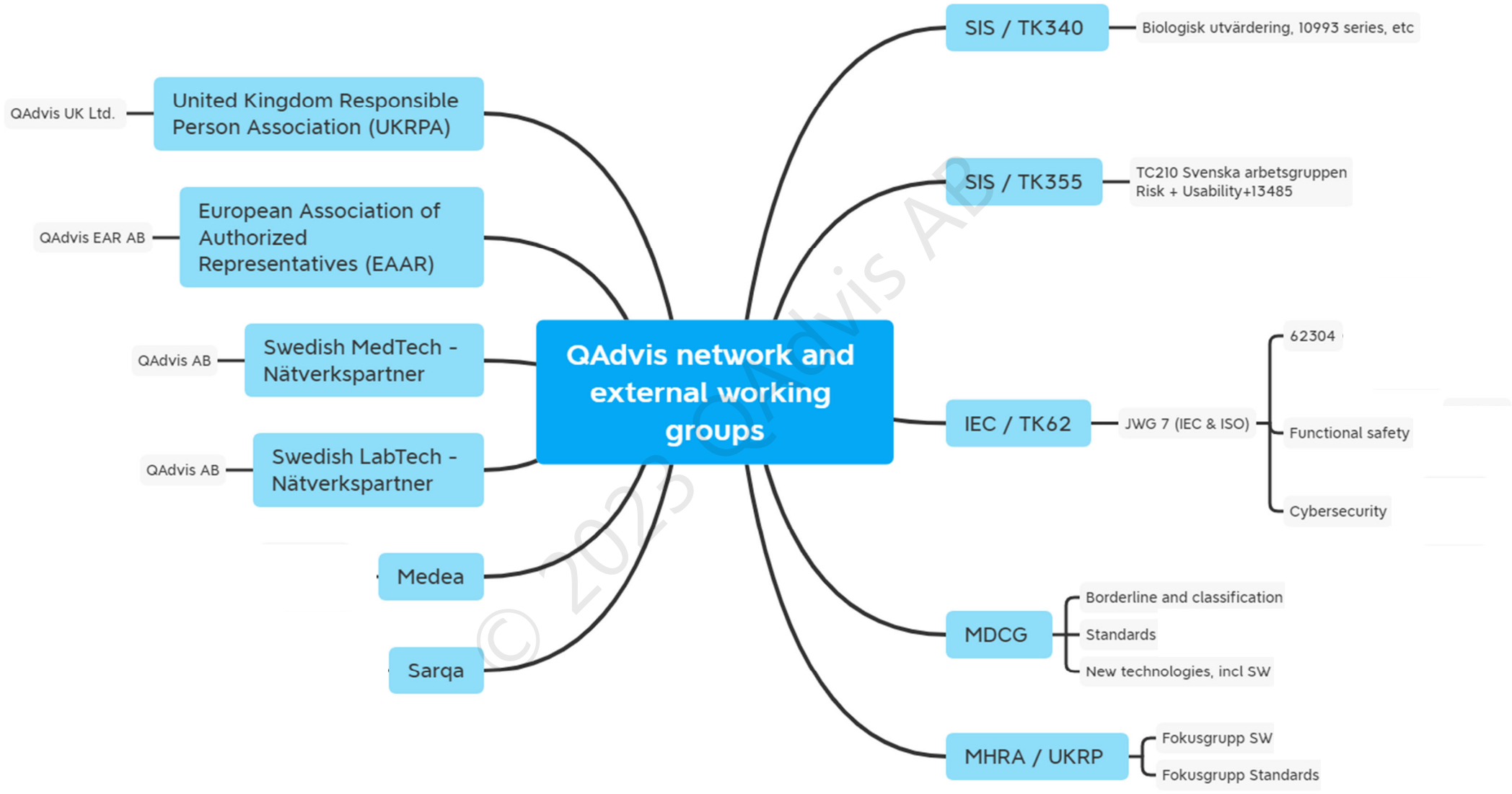
Acts on behalf of manufacturers in contact with MHRA and UK Approved Bodies

Provides additional services for Free Sales Certificates, regulatory support for e.g. UKCA-marking, etc

Founding member of the UK Responsible Person Association (UKRPA)

Contact: ukrp@qadvis.com





Partners

SIS

Swedish Medtech

Intertek

EAAR

Swedish LabTech

UKRPA

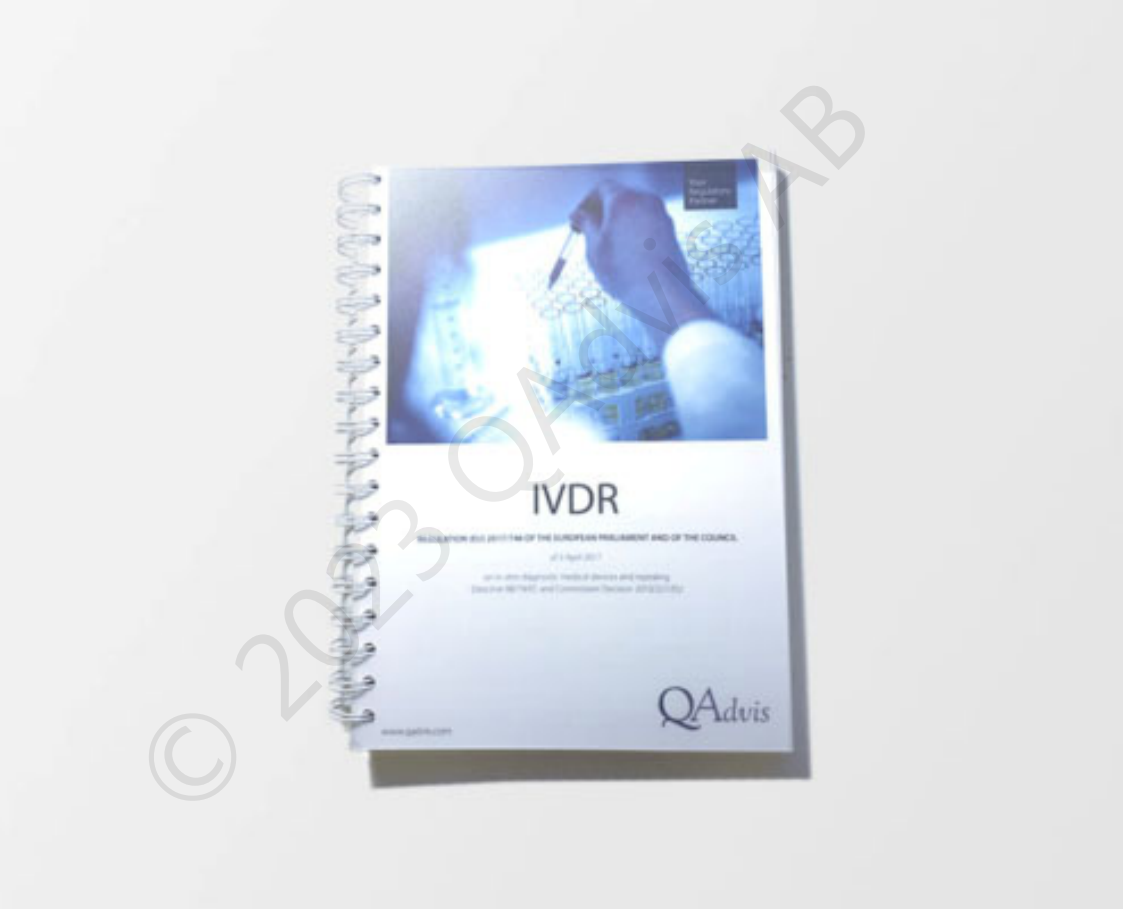
Aligned

QAdvis Academy

Open and company specific training courses:

- CE-marking
- Risk management for medical devices
- Usability according to IEC 62366-1
- Technical Documentation for medcial devices
- Clincial evaluation
- Cybersecurity for medical devices
- ISO 13458:2016
- EU In Vitro Diagnostiv Regulation (IVDR)
- EU Medical Device Regulation (MDR)
- Good Manufacturing Practice for Medcial Devices and IVD devices
- Internal audits based on ISO 13485
- Medical device software process design based on IEC 62304

IVDR-bok



RMD 2023

https://rmd2023.com/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In Vitro Diagnostic Regulation 2017/746

What's happening – latest updates – any news?

- The new requirements at a glance – what is applicable right now for you and your product?
- The current status of IVDR and MDR implementation at Notified Bodies and Competent Authorities
- IVDR implementation timelines

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Key competence areas

MDR, IVDR, CE-marking, Technical documentation

QMS
Quality Management System

Clinical evaluation, performance evaluation and clinical studies

Regulated software validation

Audits
Compliance
Remediation

Trainings
Seminars
Courses

Due diligence

Medical device software specialist

Risk management
Usability
Cybersecurity

UKRP
UK Responsible Person

Global regulatory

EAR
European Authorized Representation

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

Legal representation

European Authorized Representative, UK Responsible Person

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 Doc,
Global Regulatory Support, Clinical Evidence, Vigilance, Recalls, Post market

Anna-Karin Areskog

Senior Quality and Regulatory Consultant

Q-Manager at QAdvis

Experiences

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

IVDR transfer process

1 Qualification and classification
Qualify the device as an In Vitro Diagnostic device and based on the intended use make classificationaccording to IVDR.

2 Gap analysis and portfolio assessment
Gap analysis of device technical documentation, performance evaluation data and quality management system.

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.

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

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.

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

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

8 Conformity assessment (class A)
Sign DoC and product registration

Conformity assessment
Notified body audit and review of technical documentation.

For questions regarding our services around IVDR implementation, contact info@qadvis.com

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General obligations of manufacturers

Requirements on

QMS

Manufacturing and design

Performance evaluation

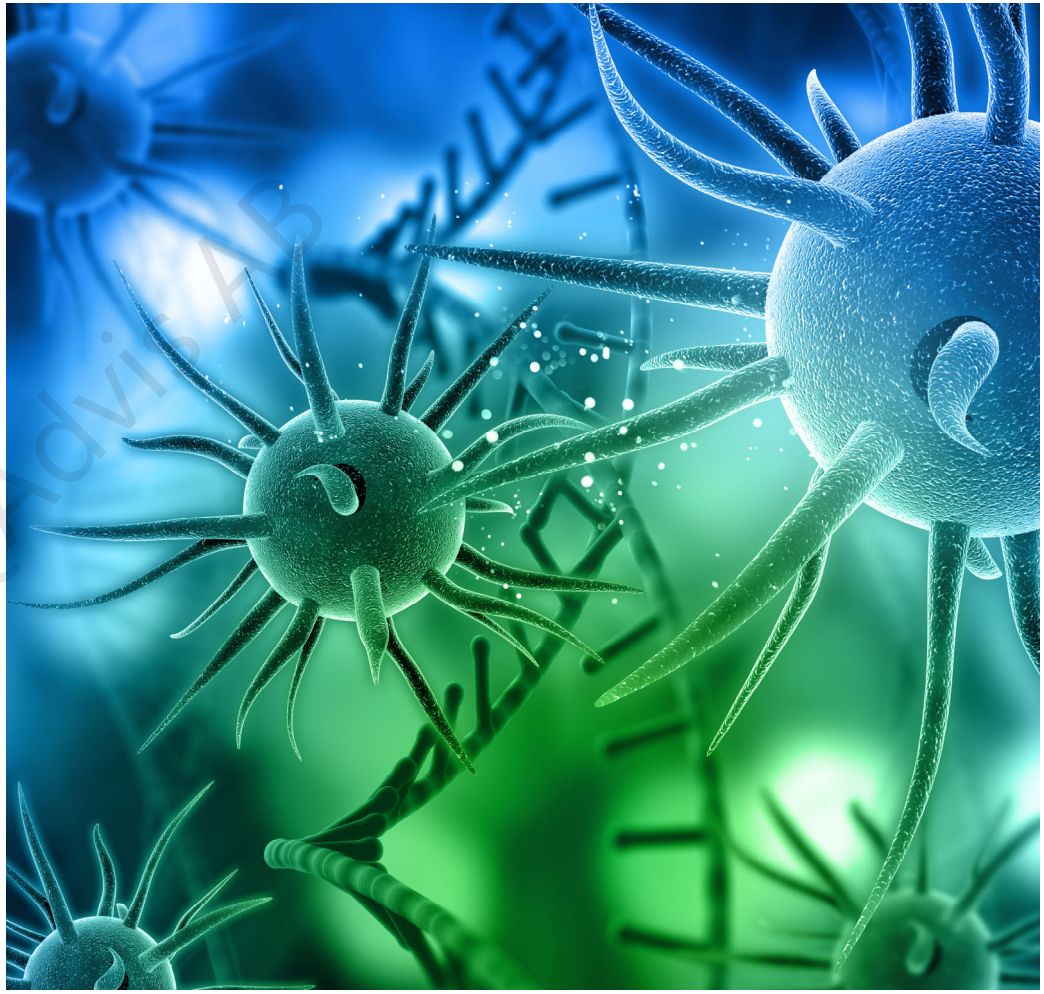
UDI system

Risk management

Technical documentation and DoC

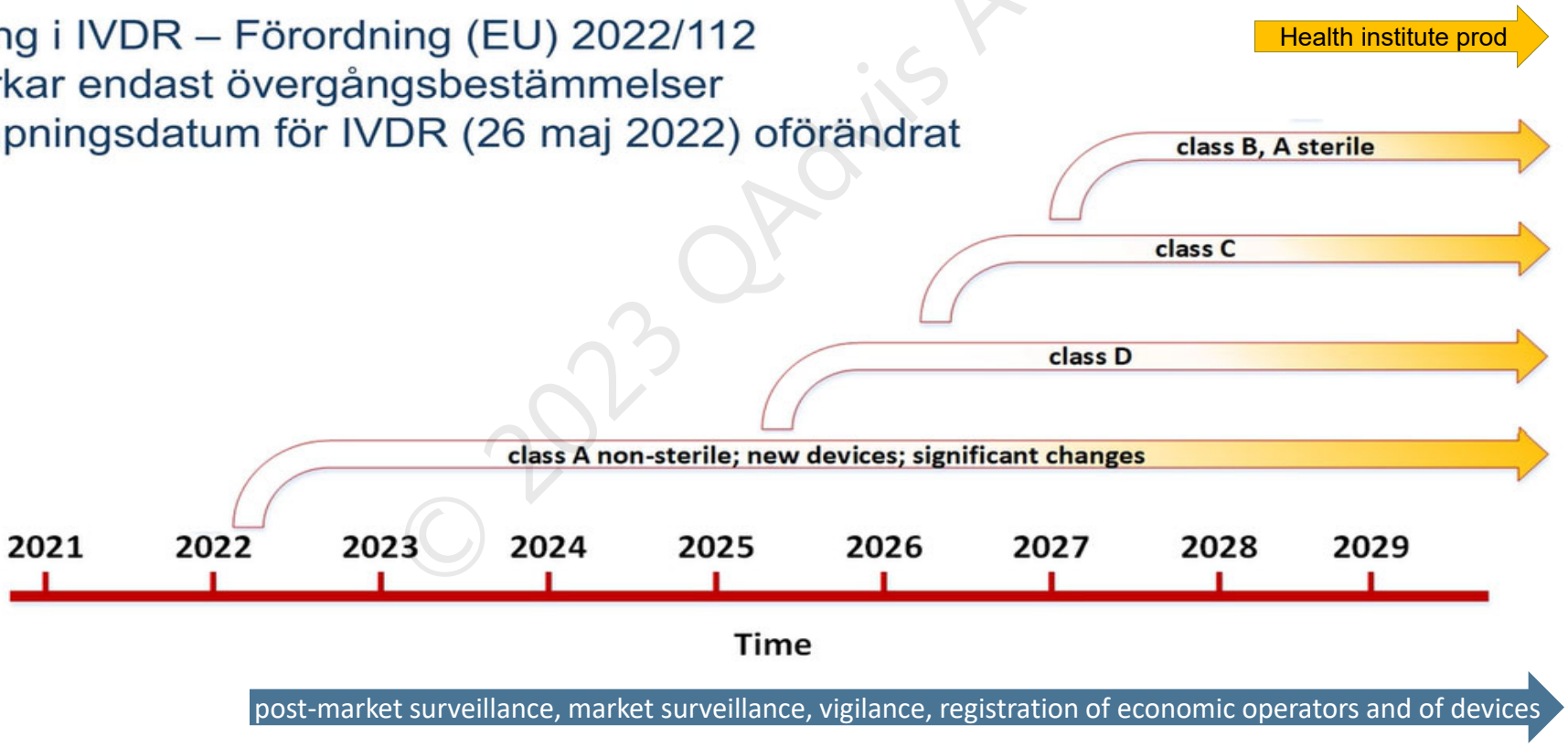
Vigilance

Post market surveillance system



Stegvis tillämpning av IVDR

- Ändring i IVDR – Förordning (EU) 2022/112
- Påverkar endast övergångsbestämmelser
- Tillämpningsdatum för IVDR (26 maj 2022) oförändrat



(https://health.ec.europa.eu/system/files/2021-10/md_2017-746-regulation_2021-amendment_en_0.pdf)

Public health: more time to certify medical devices to mitigate risks of shortages

The Commission also proposes to **remove the 'sell-off' date currently established in the Medical Devices Regulation and in the In Vitro Diagnostic Medical Devices Regulation.** The 'sell-off' date is the end date after which devices that have already been placed on the market, and remain available for purchase, should be withdrawn. Removing this 'sell-off' date will ensure that safe and essential medical devices that are already on the market remain available to healthcare systems and to patients in need.

Next Steps

The proposal now needs to be adopted by the European Parliament and the Council through an accelerated co-decision procedure.

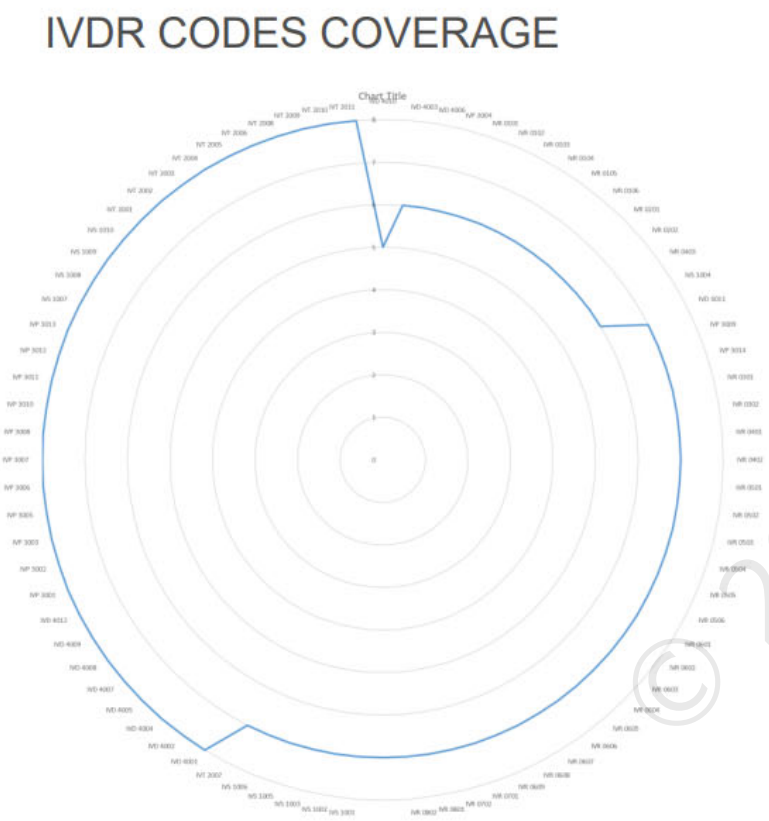
The EU commission will vote on this proposal March 5. Until then it is important to work according to the current dates

European Commission

NB with Legislation: Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Body type ▲	Name ▲	Country ▲
NB 2265	3EC International a.s.	Slovakia
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 0344	DEKRA Certification B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany
NB 0459	GMED SAS	France
NB 2962	QMD Services GmbH	Austria
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH	Germany

Summary IVDR codes coverage



- Over 80% of codes are covered by 7/8 NBs;
- Only one code is covered by 5/8 NBs:
  - IVD 4010: In vitro diagnostic devices which require knowledge regarding mycology

European Commission

What's already required (2022-05-26)?

Post Market Surveillance

Market Surveillance

Vigilance

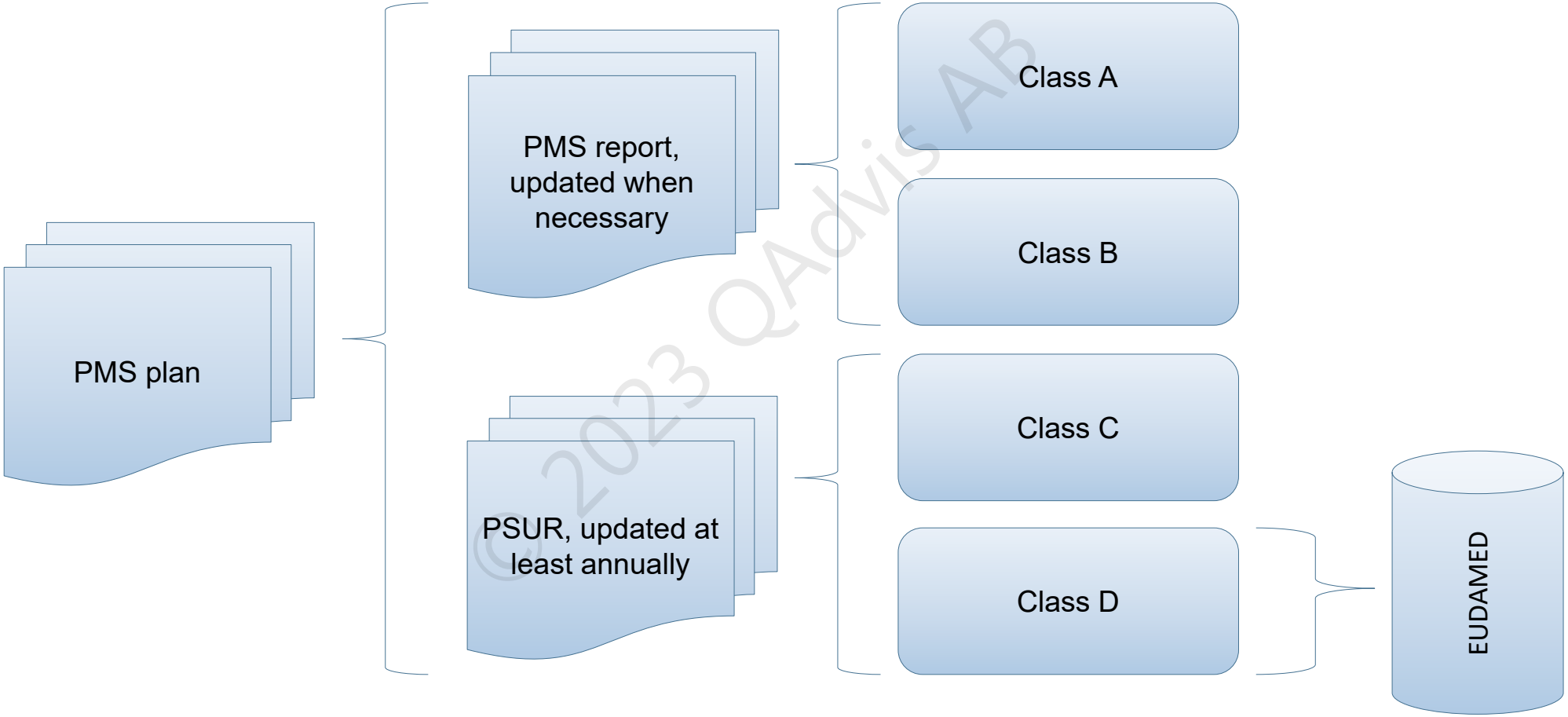
Registration of economic operators

- Eudamed/Läkemedelsverket

Registration of products

- Läkemedelsverket
- Eudamed and UDI
- IVO

Post-market surveillance



(IVDR Article 78, 79, 80, 81)

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Market surveillance

The competent authorities shall:

- perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples.
- take account of established principles regarding risk assessment and risk management, vigilance data and complaints.

How does this affect my company???

The competent authorities

a) may require economic operators to, inter alia, make available the documentation and information necessary for the purpose of carrying out the authorities' activities and, where justified, to provide the necessary samples of devices or access to devices free of charge; and

b) shall carry out both announced and, if necessary, unannounced inspections of the premises of economic operators, as well as suppliers and/or subcontractors, and, where necessary, at the facilities of professional users.

Vigilance

Reporting of serious incidents and field safety corrective actions.

In addition, Member States shall take appropriate measures, such as organising targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to the competent authorities on suspected serious incidents occurring with devices (MDR Article 87(10) and IVDR Article 82(10)).

Europeiska kommissionen

SV svenska

Sök

Public Health

Den här sidan finns inte på svenska.

Stäng meddelandet

Välj ett annat språk

Översätt den här sidan

Home > Medical Devices - EUDAMED

Medical Devices - EUDAMED

Overview

EUDAMED is the IT system developed by the European Commission to implement Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746…

Actors registration

On 1 December 2020 the European Commission has made available the Actor registration module.It is the first of six EUDAMED modules.EUDAMED…

UDI/Devices registration

Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices introduce an EU device identification…

The EUDAMED deadlines

An overview of the next milestones: here are the most important dates and facts.

*with exceptions for the UDI module

EUDAMED/UDI within QMS

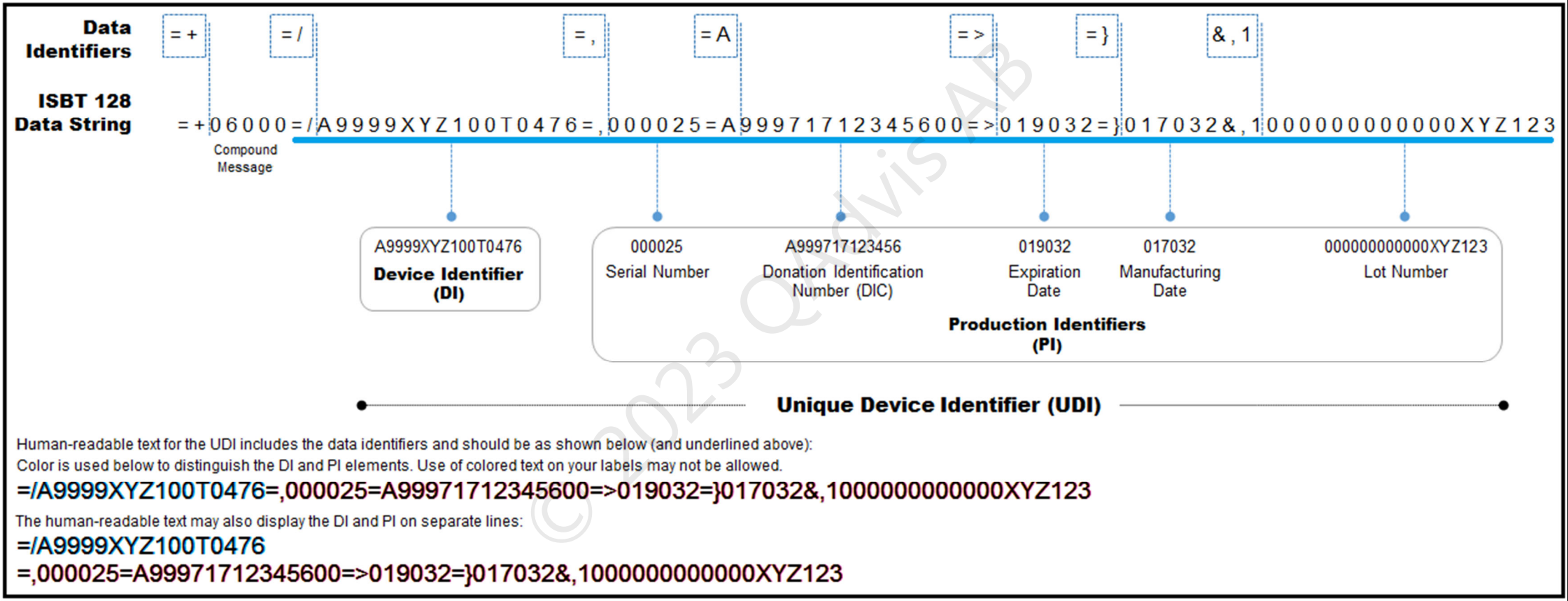
- Introduction of Eudamed - procedures for assigning and managing all UDI
- Procedure for economic operator registration, including updating of information
- Procedure for device registration, including updating of information
    - A lot of data to be submitted – Annex VI

UDI – What? How?

Basic UDI-DI

A series of numeric or alphanumeric characters that is created within one of the following sites:

- GS1 AISBL
- Health Industry Business Communications Council (HIBCC)
- International Council for Commonality in Blood Banking Automation (ICCBBA)
- Informationsstelle für Arzneispezialitäten (IFA) GmbH



Human-readable text for the UDI includes the data identifiers and should be as shown below (and underlined above):
Color is used below to distinguish the DI and PI elements. Use of colored text on your labels may not be allowed.

=/A9999XYZ100T0476=,000025=A99971712345600=>019032=}017032&,1000000000000XYZ123

The human-readable text may also display the DI and PI on separate lines:

=/A9999XYZ100T0476
=,000025=A99971712345600=>019032=}017032&,1000000000000XYZ123

UDI – When?

Medicintekniska produkter för in vitro-diagnostik enligt IVDR

Riskklass	UDI-bärare på förpackningar
Klass A	26 maj 2027
Klass B och C	26 maj 2025
Klass D	26 maj 2023

Basic UDI-DI – Where?

- Certificates (Notified Body)
- Declaration of Conformity
- Technical documentation
- GSPR Conclusion
- Clinical Performance
- Free sales certificates

Eudamed

Before placing a device, on the market,

Product:

the manufacturer shall,

Assign a Basic UDI-DI to the database

Provide it to the UDI Data base

Economic operator:

Registration of manufacturers, authorised representatives and importers

Note: The functionality is available in Eudamed. The system may be used (on voluntary basis) for registration of devices even before the notice of full functionality of Eudamed has been published.

The competent authority shall:
obtain a single registration number ('SRN') from the electronic system referred to in Article 27 and issue it to the manufacturer, the authorised representative or the importer.

MDCG 2022-12
Guidance on harmonised administrative practices and alternative technical solutions until Eudamed is fully functional (for Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices)

July 2022

The manufacturer shall use the SRN when applying to a notified body for conformity assessment and for accessing Eudamed in order to fulfil its obligations under Article 26

Economic operators

Manufacturer, importer, distributor and authorized representative

- Responsibilities and authorities
- Control of each other
- Eudamed

Importers – name and address on device, packaging or accompanying documentation

IVDR

Ref. Ares(2019)2967275 - 03/05/2019

Basic UDI-DI & UDI-DI attributes

Basic UDI-DI set of data in UDI database

Principle: Each UDI-DI inherits the attributes of its linked Basic UDI-DI and devices DI

Basic UDI-DI

Applicable legislation (IVDR) (*)
- 2. Basic UDI-DI value (*)
- 2b Basic UDI-DI Issuing entity (*);
- 6. Manufacturer SRN (*)
- 5. Name and address of manufacturer
- 7. Name and address and SRN of AR
- 9. Risk class (*)
- A.2.14 Intended for self-testing (Y/N) (*)
- A.2.14 Intended for near-patient-testing (Y/N) (*)
- Companion diagnostics (Y/N) (*)
- Intrument(Y/N) (*)
- Reagent(Y/N) (*)
- Professional testing (Y/N) (*)
- 11. A. Name and/or, if applicable, device model that identifies the device(s) with this BASIC UDI-DI in the technical documentation and/or certificate or declaration of conformity

(Name and/or model shall be provided)

UDI-DIs

- 0. UDI-DI value (*)
- 0b. UDI-DI Issuing entity (*)
- Secondary DI (value and issuing entity)
- 11.B. Reference, Article or Catalogue number (*)
- Device with Direct marking (Y/N) (*)
- Direct marking UDI-DI value (*)
- Direct marking UDI-DI issuing entity (*)
- 1. Quantity of device(s) (*)
- 3. Type of UDI-PI (*)
- 4. Unit of use UDI-DI (*)
- 13. Storage/handling conditions
- 10-14. Name(s)/Trade name(s) (including languages)
- 12. Additional product description
- 19. URL for additional information
- 15. Labelled as single use (YN) (*)
- 16. Maximum number of reuse (*)
- 17. Device labelled sterile (Y/N) (*)
- 18. Need for sterilisation (Y/N) (*)
- 20. Critical warnings or contra-indications
- 8. Medical device nomenclature (CND) code (1)
- 21. Status
- 27 (A.2.10). In the case of devices designed and manufactured by another legal or natural person as referred in Article 10(14), the name, address and contact details of that natural/legal person

UDI-DIs (container package DI)

- 0. UDI-DI value (*)
- 0b. Issuing entity (*)
- 1. Quantity per package (*)
- 21. Status

(1) Nomenclature decision: https://ec.europa.eu/docsroom/documents/34264

(*) may not be changed

- Mandatory
- Mandatory if applicable
- Optional

Other Device Data attributes

Basic UDI-DI

- *A.2.2 Certificate IDs (with NB, type .. Link);*
- *A.2.11 SSP;*
- *A.2.9 Performance study IDs (..link);*
- *A.2.5 Presence of Human tissues/Cells (Y/N) (*);*
- *A.2.6 Presence of Animal tissues/Cells (Y/N) (*)*
- *A.2.7 Presence of Substances/cells of microbial origin (Y/N) (*);*
- *Kit (Y/N) (*);*

UDI-DIs

- A.2.13 New Device (Y/N) (*);
- A.2.3 Member State of the Placing on the EU Market of the Device (*);
- A.2.4 Member State(s) were the Device is made available in the Country;

(*) may not be changed

What's happening?

During 2022: 9 Guidelines for IVDR are released

2023: 1 Guidelines

Eudamed and UDI ongoing

In Vitro Diagnostic medical devices (IVD)

Reference	Title	Publication
MDCG 2022-20 EN •••	Substantial modification of performance study under Regulation (EU) 2017/746	December 2022
MDCG 2022-19 EN •••	Performance study application/notification documents under Regulation (EU) 2017/746	December 2022
MDCG 2022-15 EN •••	Guidance on appropriate surveillance regarding the transitional provisions under Article 110 of the IVDR with regard to devices covered by certificates according to the IVDD	September 2022
MDCG 2022-10 EN •••	Q&A on the interface between Regulation (EU) 536/2014 on clinical trials for medicinal products for human use (CTR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)	May 2022
MDCG 2022-9 EN •••	Summary of safety and performance template	May 2022
MDCG 2022-8 EN •••	Regulation (EU) 2017/746 - application of IVDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC	May 2022
MDCG 2022-6 EN •••	Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR	May 2022
MDCG 2022-3 EN •••	Verification of manufactured class D IVDs by notified bodies	February 2022
MDCG 2022-2 EN •••	Guidance on general principles of **clinical evidence** for In Vitro Diagnostic medical devices (IVDs)	January 2022

In-house devices

Reference	Title	Publication
MDCG 2023-1 EN •••	Guidance on the health institution exception under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746	January 2023
MDCG 2022-21 EN •••	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745	December 2022

Use nomenclature and definitions according to the Regulations

Intended purpose

Technical Documentation

PRRC

Risk

Distributor

Clinical evidence

Clinical benefit

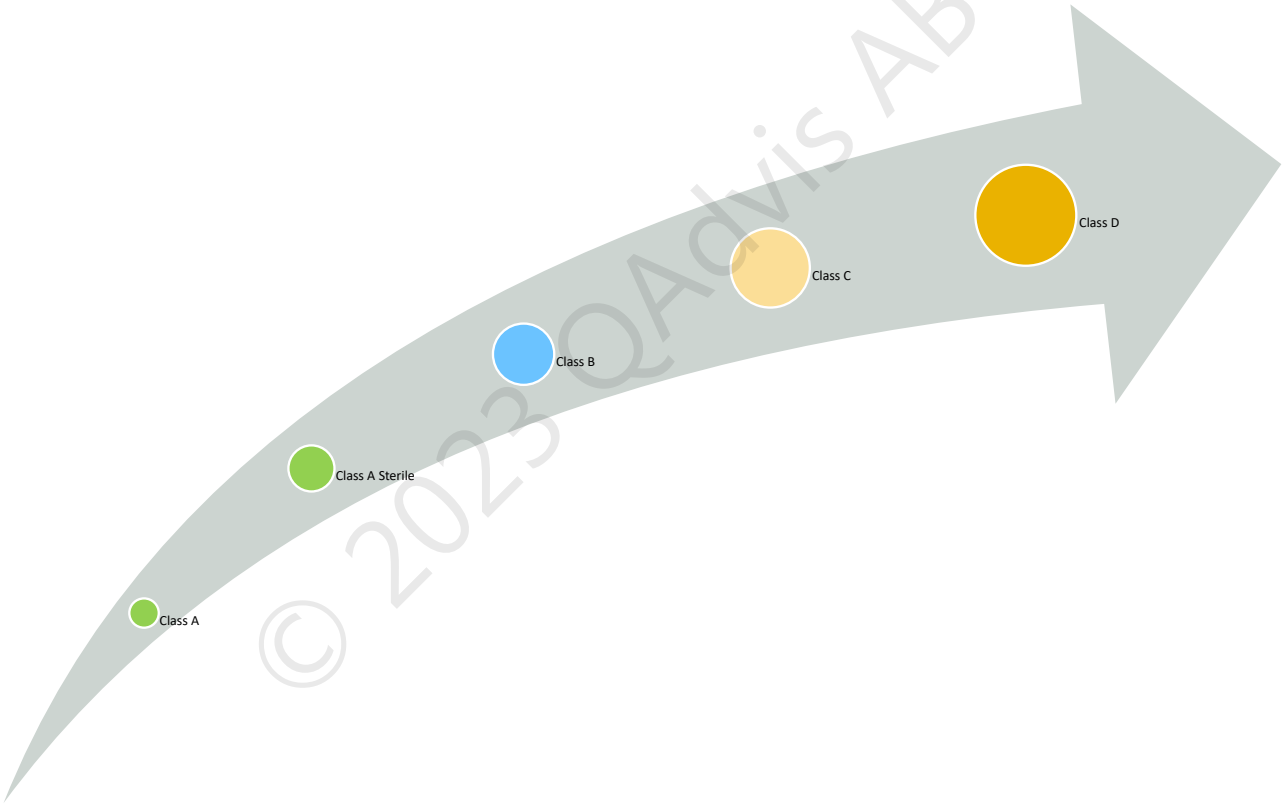
Performance evaluation

Diagnostic specificity

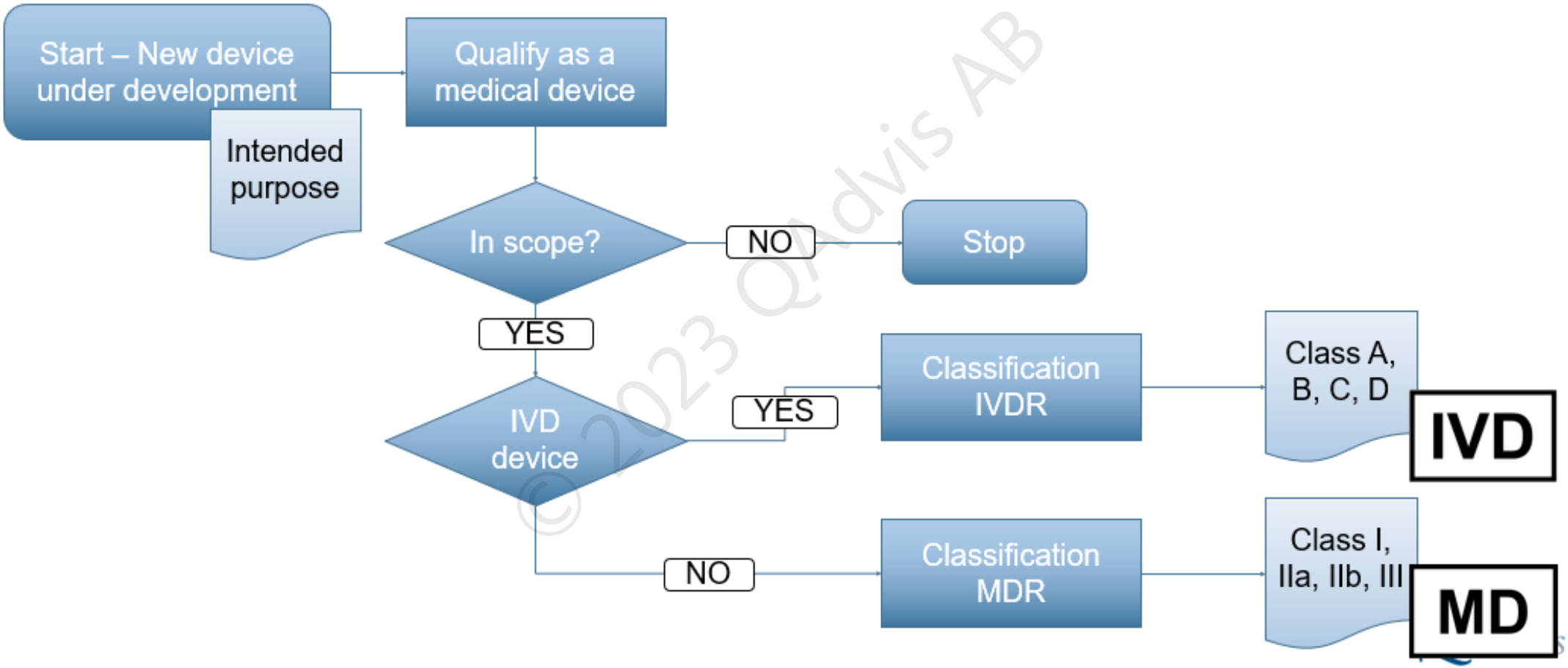
Adverse event

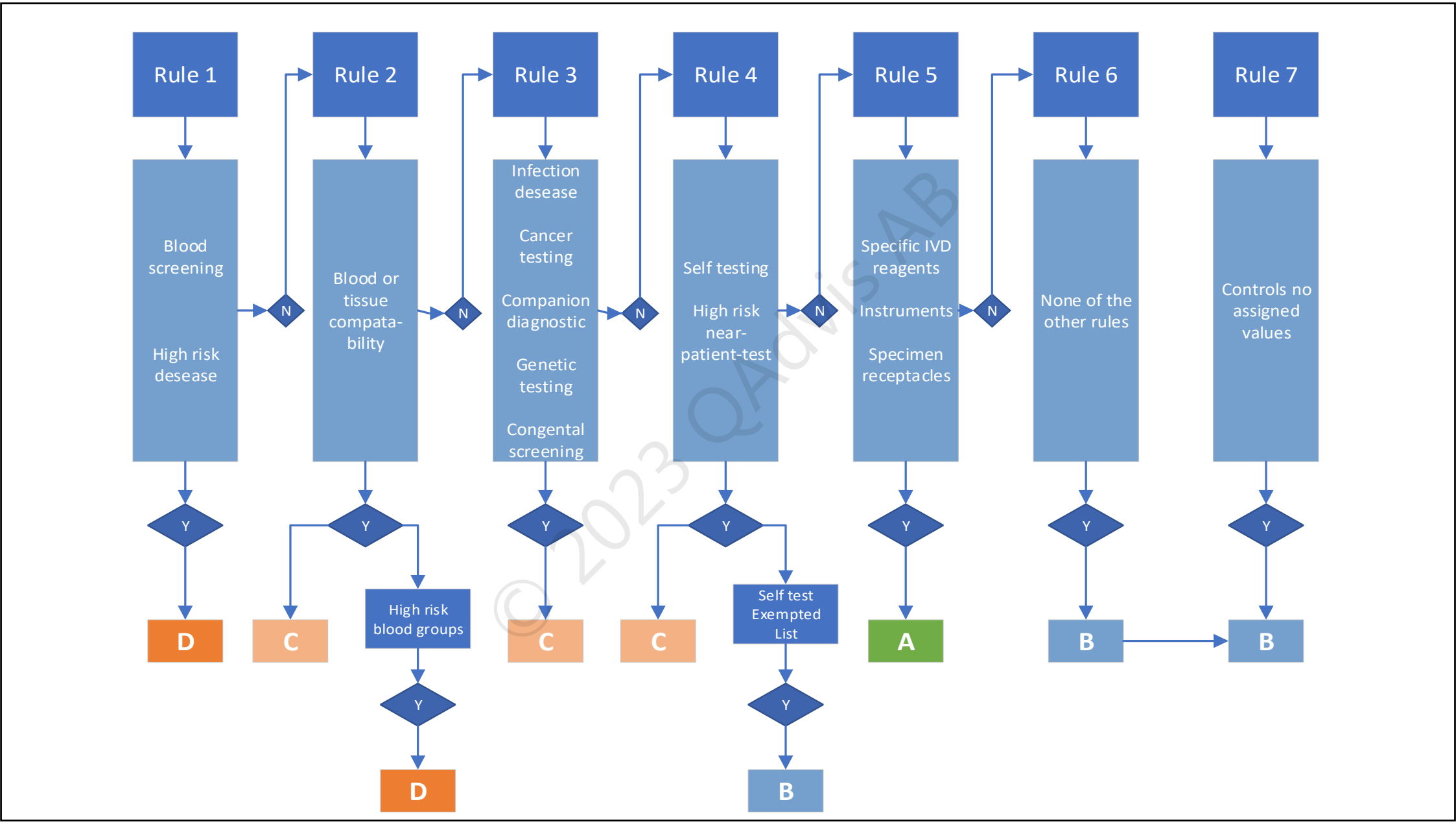
Etc…..

Conformity route – involvement of Notified Body



Qualification and classification




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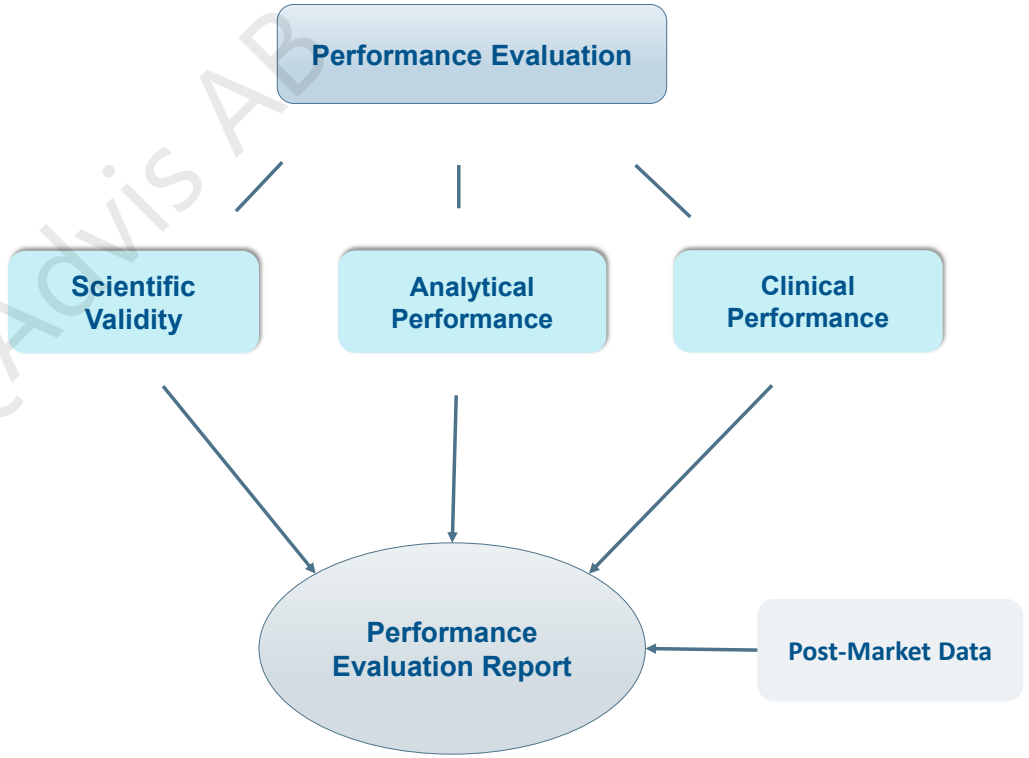
Performance evaluation - concept overview

- 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



Demonstration of scientific validity

The manufacturer shall demonstrate the scientific validity based on one or a combination of the following sources:

- relevant information on the scientific validity of devices measuring the same analyte or marker;
- scientific (peer-reviewed) literature;
- consensus expert opinions/positions from relevant professional associations;
- results from proof of concept studies;
- results from clinical performance studies.

Demonstration of the analytical performance

The manufacturer shall in relation to all the parameters demonstrate

- analytical sensitivity,
- analytical specificity,
- trueness (bias),
- precision (repeatability and reproducibility),
- accuracy (resulting from trueness and precision),
- limits of detection and quantitation,
- measuring range,
- linearity,
- cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross-reactions

Demonstration of the clinical performance

Purpose is to show

- diagnostic sensitivity,
- diagnostic specificity,
- positive predictive value,
- negative predictive value,
- likelihood ratio,
- expected values in normal and affected populations.

Sources

- clinical performance studies;
- scientific peer-reviewed literature;
- published experience gained by routine diagnostic testing.

In-house Device

Health Institutions

On a non-industrial scale

Equivalent ones not available commercially

Not transferred to another legal entity

GSPR / Annex I

- QMS (ISO15189)
- Documentation on the manufacturing process
- Design and performance data
- Intended purpose
- review the experience gained from the clinical use

IVO

RUO – Research Use Only

Manufactures use the “Research Use Only” (RUO) label **to declare that their products should not be used in diagnostic procedures**.

This enables them to avoid the time-consuming and costly documentation required for conformity-assessed in vitro diagnostic medical devices (CE-IVDs).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