GMED LNE GROUP Newsletter

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Version Française

INTRODUCTION TO THE REGULATION (EU) 2017/746

The Regulation (EU) 2017/746 (IVDR) on *in vitro* diagnostic medical devices entered into force on May 26th, 2017 and we are now 12 months away from the end of the transition period and the date of application. From May 26th, 2022, all *in vitro* diagnostic medical devices will need to comply with the new Regulation, meaning manufacturers and stakeholders will have to meet the requirements of the IVDR by this date to place *in vitro* diagnostic medical devices on the European market. This newsletter is an introduction to important steps to consider to ensure successful transition to the new Regulation.
For manufacturers intending to certify their devices under the European *in vitro* diagnostic medical device regulation, the first step would be to verify that the device is covered by the definitions of a medical device and an *in vitro* diagnostic medical device according to Regulation (EU) 2017/746 Chapter I section 1 article 2 (1) and (2).
An overview of the chapters and the annexes of the IVD regulation can be found on the next page. The chapters and annexes mentioned in this newsletter are highlighted.

A INTENDED PURPOSE

The intended purpose is defined by the IVDR in Chapter I article 2 definition (12) and the content of the intended purpose is listed in Annex II section 1.1 paragraph (c).

The intended purpose must be diligently defined as the **IVDR designation codes**[1], the **classification** and the **technical documentation content** will be based on it. In the technical documentation, the **performance evaluation** reports must include reports of the scientific validity, the analytical and the clinical performance (Annex II section 6.2). The data in these reports must support the intended purpose of the device.

In the article 7 related to "Claims", it is stated that the information included with the device or the advertising of the device should not mislead the user or patient on the use, safety, or performance of the device. Manufacturers have to keep a close eye on the public marketing of their device in regard to this requirement.

[1] Commission Implementing Regulation (EU) 2017/2185 of 23 November 2017

IVDR CHAPTERS AND ANNEXES

Double framed: Chapter and Annexes discussed in this document

Scope & Definitions

Chapter I includes, in section 1, the scope and definitions as well as general information. In section 2, regulatory status of products and counseling are addressed

Obligations

Chapter II covers obligations of economics operators and putting on the market rules as well as the common specifications. It also addresses EU Declaration of Conformity and CE marking

Identification

Chapter III Describes new identification, registration and traceability of devices. It presents the new Unique Device Identification system

Notified Bodies

Chapter IV is dedicated to the rules for notified bodies

Classification & conformity assessment

Chapter V sets the new rules of devices classification and conformity assessment routes

Clinical Evidence Performance Follow up

Chapter VI covers new performance evaluation, performance study and clinical evidence requirements

Post-market

Chapter VII is dedicated to post-market and market surveillance and post-market vigilance

Cooperation

Chapter VIII describes requirement on cooperation between member states, MDCG, EU reference laboratories and device registers

Confidentiality

Chapter IX covers confidentiality, data protection, funding and penalties

Timeline

Chapter X gives information on the transition and date of application as well as information on committee procedure and exercise of the delegation

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I Safety & Performance

Annex I sets all requirements for safety, performance, design, manufacture and IFUs are described in 3 chapters

II Technical Documentation

Annex II describes all information to be included in the technical documentation of the medical device

III Post-market plan

Annex III details requirements on the technical documentation on post-market surveillance

IV EU Declaration of Conformity

Annex IV lists the content required in the EU declaration of conformity in 10 bullet points

V CE Marking

Annex V describes the CE marking logo requirements

VI Registration & UDI

Annex VI lists the requirements for the registration of devices and economic operators and the data to be provided to the UDI database and the UDI-DI

VII Notified Bodies

Annex VII contains organizational and general requirements and requirements for QM, resources and process to be met by notified bodies

VIII Classification

Annex VIII contains the 7 classification rules to follow when classifying an in vitro diagnostic medical device

IX QMS & TD assessment

Annex IX gives information on the requirements for conformity assessment based on a QMS, the technical documentation

X Type examination assessment

Annex X is dedicated to the requirements for conformity assessment based on type-examination

XI PQA assessment

Annex XI contains the requirements for conformity assessment based on production quality assurance

XII Certificates

Annex XII gives the requirements for the certificates and their contents

XIII Performance & PMPF

Annex XIII describes the requirements for the performance evaluation, performance studies and post-market surveillance follow-up

XIV Other Performance studies

Annex XIV is about interventional clinical performance studies and certain other performance studies

XV Correlation with directive

Annex XV describes the correlations between the directive 98/79/EC and the regulation in a table

B IVDR CODES

The designation scope of notified bodies is based on IVDR codes and conformity assessment procedures.
A list of codes and corresponding types of devices has been drawn up by the European Commission[2]. The lists of codes and corresponding types of devices takes into account various device types which can be characterised by design and intended purpose, manufacturing processes and technologies used. The lists of codes should provide for a multi-dimensional typology of devices which ensures that conformity assessment bodies designated as notified bodies are fully competent for the devices they are required to assess.

In vitro diagnostic medical device list of codes can be found in Annex II of the document mentioned, and reads as follows:

- Codes reflecting the design and intended purpose of the device: **IVR**.
- Horizontal codes: **IVS, IVT, IVP and IVD**.
  - **IVS** are codes specific for *in vitro* diagnostic medical devices with **S**pecific characteristics,
  - **IVT** are for *in vitro* diagnostic medical devices for which specific **T**echnologies are used,
  - **IVP** for *in vitro* diagnostic medical devices which require specific knowledge in examination **P**rocedures for the purpose of product verification,
  - **IVD** are for *in vitro* diagnostic medical devices which require specific knowledge in laboratory and clinical **D**isciplines for the purpose of product verification.

In addition, an explanatory note for the IVDR codes is being drafted and is expected to be published as a MDCG guidance in Q2 2021.

[2] Commission Implementing Regulation (EU) 2017/2185 of 23 November 2017

C CLASSIFICATION

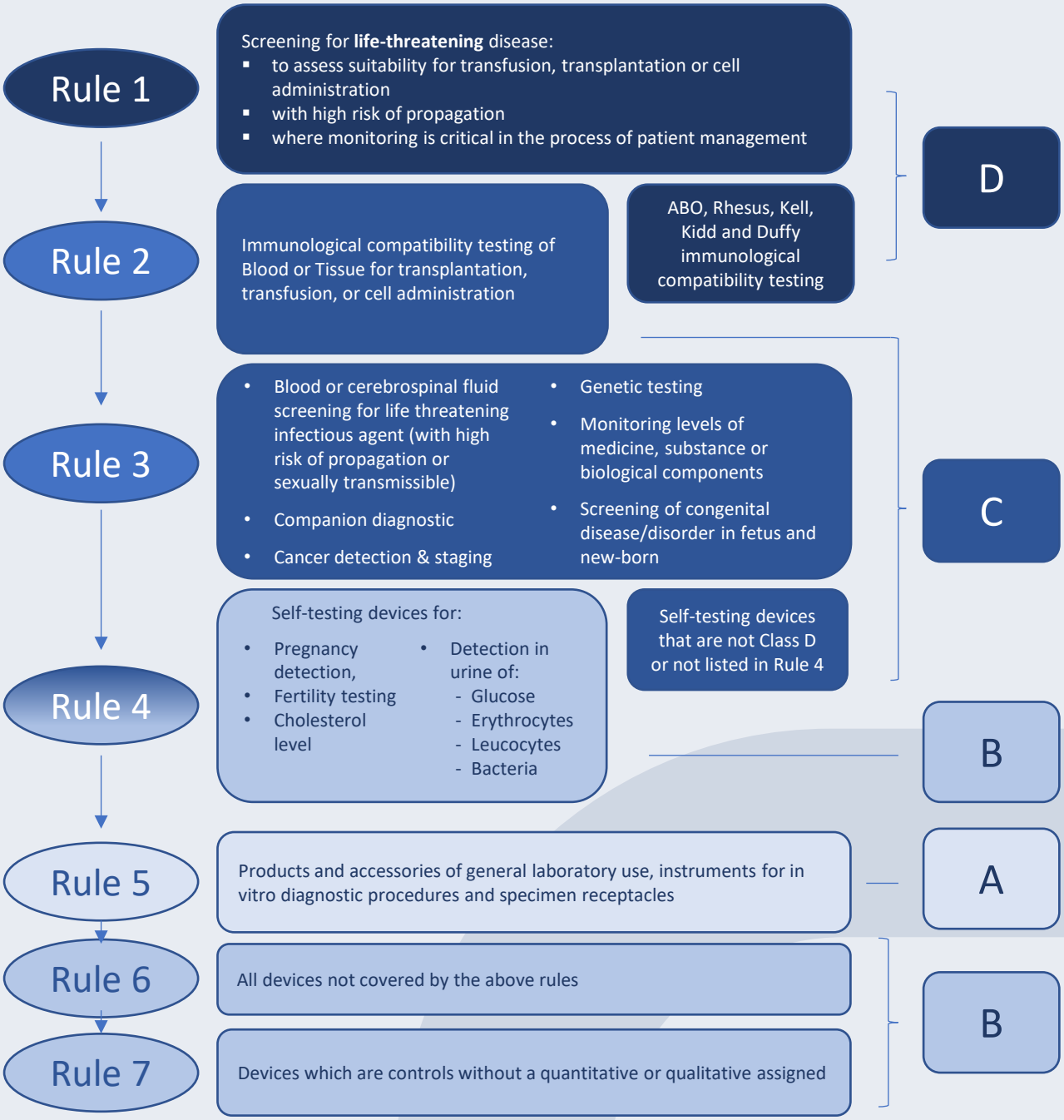
One of the most significant change between the IVDR and the directive 98/79/EC is the classification system. Previously based on a list of devices, it is now conducted through a risk-based approach classification of the devices with 4 classes: Class A devices being of lower risk and Class D being of higher risk.
Once manufacturers have defined the intended purpose and the IVDR codes of their *in vitro* diagnostic medical device, they can classify it according to Annex VIII Classification rules listed in section 2, there are 7 rules to determine the classification. We represented these rules in the following infographic on the next page.

The MDCG has published a guidance on devices classification that can bring complementary clarity.[3]

[3] Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746

CLASSIFICATION RULES

The rules must be read from the 1st to the 7th.



D CONFORMITY ASSESSMENT PROCEDURES

Once the intended purpose, the IVDR codes and the classification of the device have been established it is time to determine which annex the manufacturer is going to use to assess the conformity of the device in a view to obtain a certificate of conformity. The different assessment procedures are laid out in **Chapter V section 2 "conformity assessment" article 48** and detailed in **Annexes IX to XI** of the IVDR. The infographics on the next pages give an overview of those conformity assessment procedures depending on the class of the device.

The scope of the notified body designation includes, in addition to the codes described above, the conformity assessment procedures as defined in the Regulation (article 38 section 3). Manufacturers have to select their notified body based on the designation scope and conformity assessment procedure included.

The technical documentation assessment by the notified body is based on the classification as well. For class D devices, technical documentation of all devices will be assessed. For class C and class B devices, according to Annex IX conformity assessment procedure, the technical documentation of at least one representative device per generic device group (for Class C) and for each category of devices (for Class B) will be assessed. For self-testing, near-patient testing and companion diagnostics devices, all devices' technical documentation will be assessed.

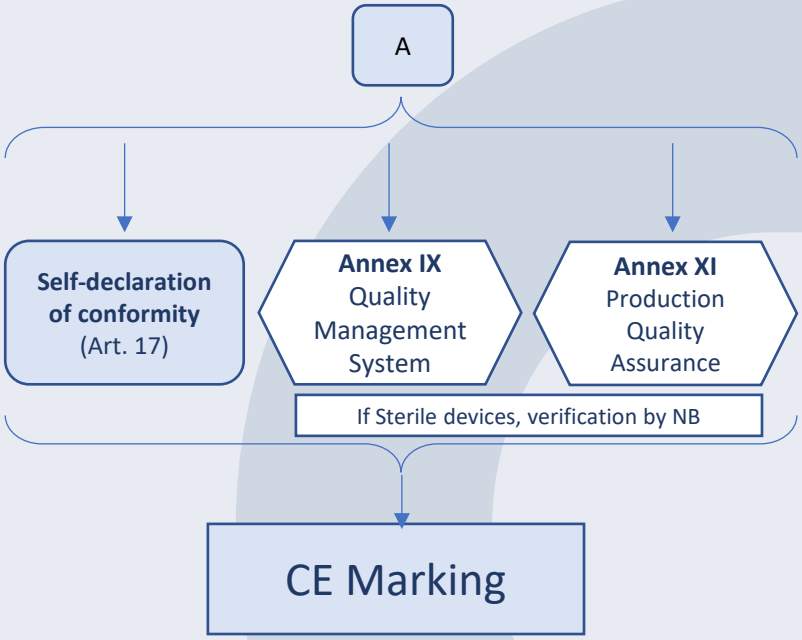
E TRANSITIONAL PROVISIONS

For manufacturers that have devices already on the EU market under a certificate issued by a notified body in accordance with the Directive 98/79/EC (IVDD) prior to May 25th, 2022, the certificate remains valid until the expiration date indicated on said certificate according to Article 110 paragraph 2 under specific conditions. However, all IVDD certificate will be void on May 27th, 2024.
Devices that have been lawfully placed on the market under IVDD before May 26th, 2022, with a certificate from a notified body, can continue to be made available on the market or put into service until May 27th, 2025.

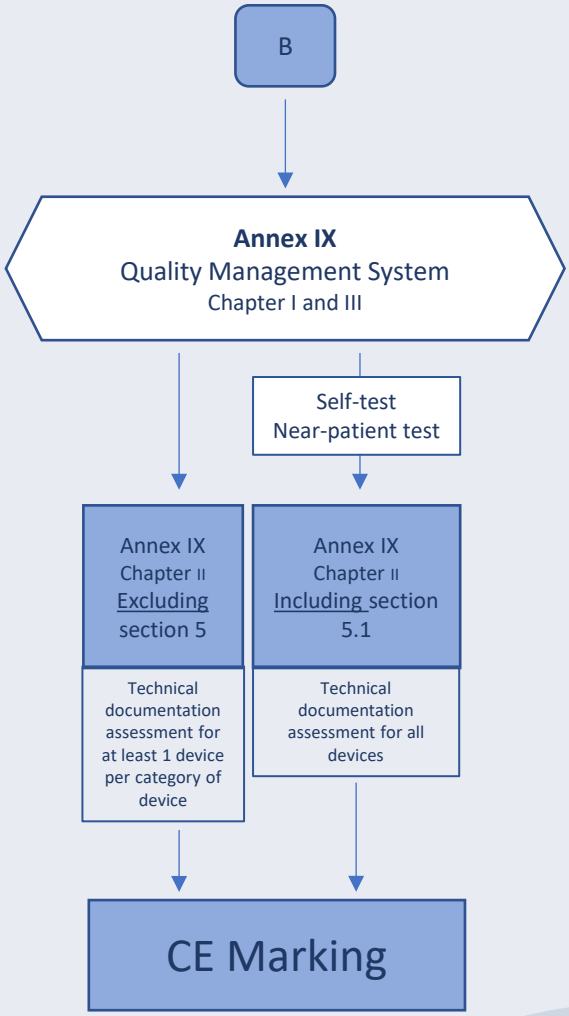
The maintenance of the certificate past the date of application (May 26th, 2022) and until May 25th, 2024 is subjected to two conditions. Firstly, there can be no significant change in the design and intended purpose of the devices covered by the certificate. And secondly, the manufacturer's quality system must include the requirements of Regulation (EU) 2017/746 relating to post-market surveillance, market surveillance, vigilance and registration of economic operators and devices.

All *in vitro* diagnostic medical devices currently self-declared will have to comply with the IVDR starting on May 26th, 2022 and manufacturers will need obtain a certificate, delivered by a notified body, depending on the classification of the device and conformity assessment procedure.

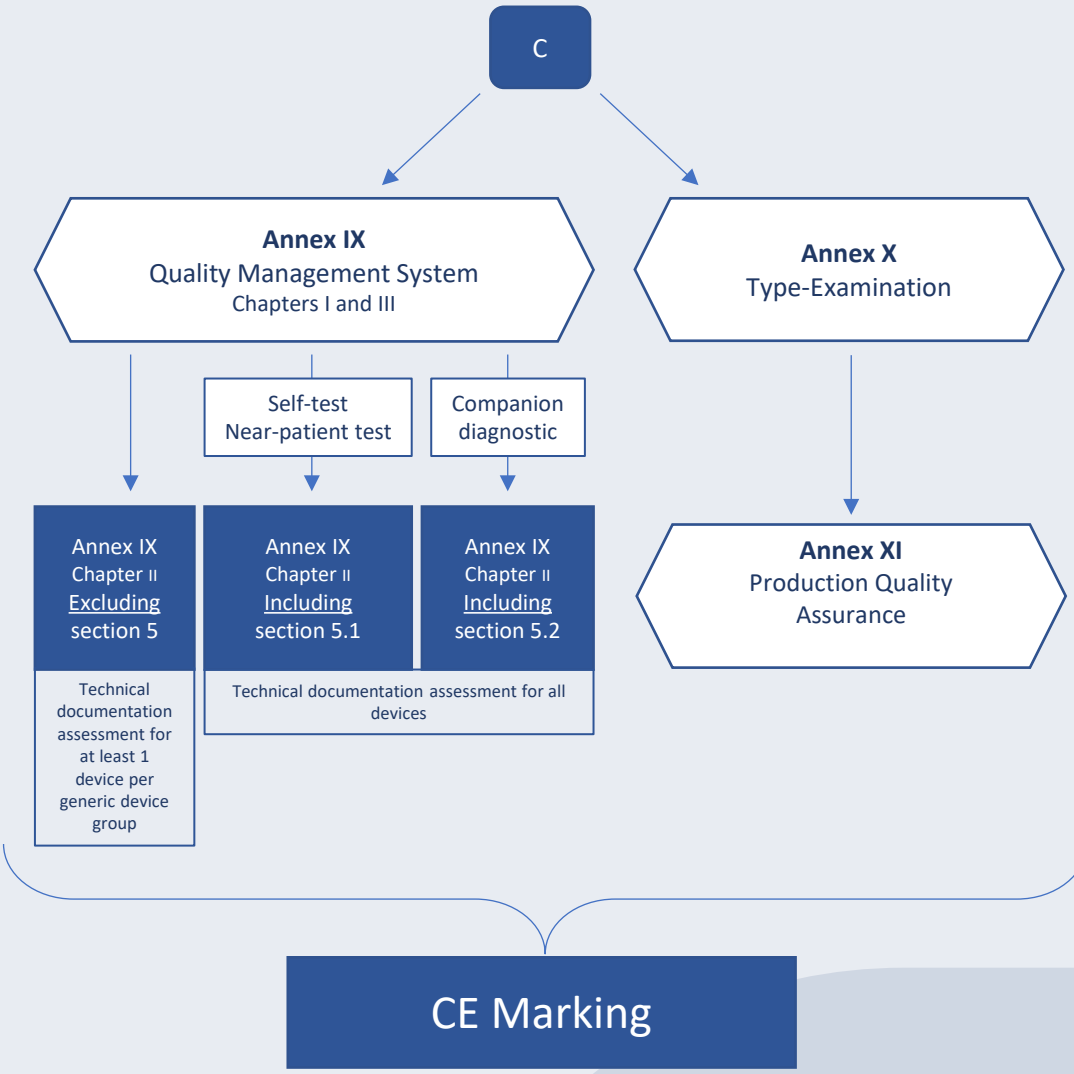
CONFORMITY ROUTES FOR CLASS A DEVICES



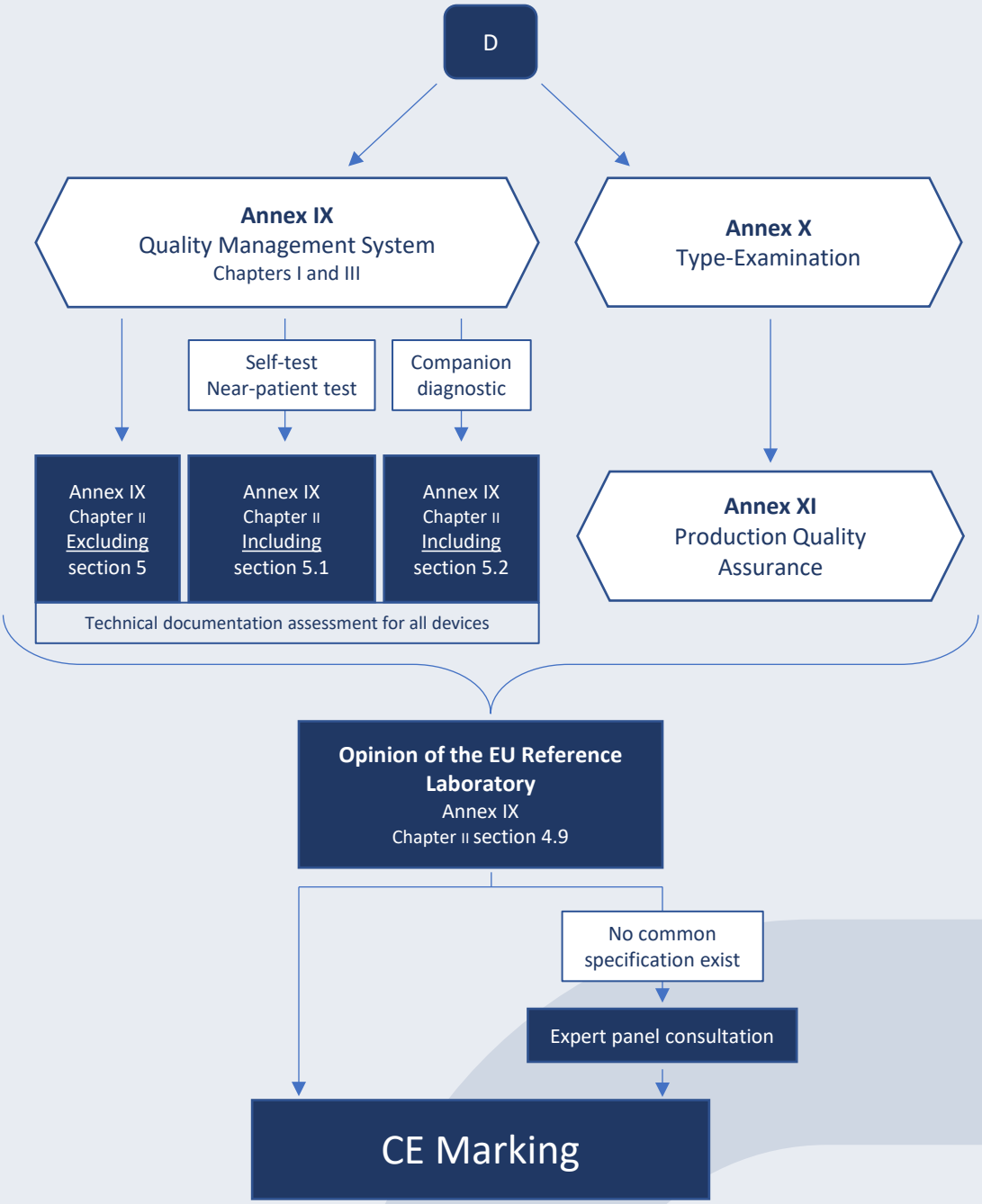
CONFORMITY ROUTES FOR CLASS B DEVICES



CONFORMITY ROUTES FOR CLASS C DEVICES



CONFORMITY ROUTES FOR CLASS D DEVICES



Conclusion

Defining the intended purpose, the IVDR codes, the classification, and the conformity procedure to assess the *in vitro* diagnostic medical device are the starting points for a successful implementation of the Regulation (EU) 2017/746 for manufacturers. However, there are other important aspects of the IVDR that need attention as well. Obligations of the different economic actors, general safety and performance requirements, content of the technical documentation, performance evaluation reports and clinical evidence, post-market surveillance, and new device registration system EUDAMED are also key elements manufacturers will need to master.

Manufacturers are encouraged to keep themselves up to date of the upcoming MDCG guidances as well as the European Commission updates regarding the state of implementation (implementing measures, rolling plans...) at this address: https://ec.europa.eu/health/md_sector/new_regulations

To go further

TRAINING FOR NORTH AMERICA REGION

Post Market Surveillance and Vigilance New Requirements under Both Regulation (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR)
1-day training session | August 5 | October 13

→ CHECK OUT THE PROGRAM

TRAINING FOR EUROPE AND OTHER PART OF THE WORLD (EXCL. US)

Implement the requirements of the European regulation on in vitro diagnostic medical devices
SA50 | 1-day training session | On demand

→ CONTACT GMED TRAINING CENTER

Comply with the new regulatory requirements for post-market surveillance and vigilance
SA45 | 1-day training session | On demand

→ CONTACT GMED TRAINING CENTER

Implement UDI (Unique Device Identification) requirements
SA66 | 0.5-day training session | On demand

→ CONTACT GMED TRAINING CENTER

Adapt your quality management system to the ISO 13485 standard, 2016 version
SA19 | 2-day training session | On demand

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