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Questions and answers for manufacturers of *in vitro* diagnostic medical devices.

Version 4 (30/08/2024) (see Appendix 1 for version history)

Below, you will find specific questions and answers for manufacturers of *in vitro* diagnostic medical devices concerning the application of the new regulation on *in vitro* diagnostic medical devices (Regulation (EU) 2017/746).

For simplicity, we use the following abbreviations:

- **DoC:** Declaration of Conformity
- **EMA**: European Medicines Agency
- **Eudamed**: European database on medical devices
- **EURL**: European Union reference laboratory
- **FAMHP**: Federal Agency for Medicines and Health Products
- **IVD**: *In vitro* Diagnostic Medical Device
- **IVDD**: *In vitro* Diagnostic Medical Device Directive (Dir. 98/79/EC transposed into Belgian law via the Royal Decree of 14/11/2001)
- **IVDR**: *In vitro* Diagnostic Medical Devices Regulation - Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- **LAA**: Local Actor Administrator
- **Legacy device**: an IVD that, after the IVDR application date, is still placed on the market in accordance with the IVD Directive (IVDD), using the transitional provisions as stipulated in Article 110 of the IVDR
- **MDR**: Medical Devices Regulation - Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- **NB:** Notified Body
- **PRRC**: Person Responsible for Regulatory Compliance
- **RD**: Royal Decree
- **SRN:** Single Registration Number
- **UDI**: Unique Device Identifier

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1. When does the new IVD regulation apply?

The European regulation on *in vitro* diagnostic medical devices (IVDR, (EU) 2017/746) came into force on 25 May 2017 and became applicable on 26 May 2022. It replaces the European IVD Directive (IVDD, 98/79/EC). However, as stated in Article 113 of the IVDR, some articles are not yet applicable (e.g. concerning the placing of the unique device identifier - UDI - on the label/packaging). In addition, Article 110 of the IVDR grants manufacturers transitional periods that can be used to make certain IVDD-conform IVDs compliant with the new regulation (see question 8).

2. How to comply with the IVDR?

From 26 May 2022, IVDs must comply with the IVDR. However, transitional periods and exceptions are provided (Articles 110 and 113 IVDR, see also question 8). IVDs must meet all possible IVDR requirements, bearing in mind that the European database on medical devices, Eudamed, is not yet fully functional. IVD manufacturers must also comply with the general obligations for manufacturers set out in Article 10 of the IVDR, subject to their applicability to IVDs benefiting from a transition period (see question 8).

Requirements include (but are not limited to):

- the IVD must meet the general safety and performance requirements listed in Annex I of the IVDR (including requirements on labelling and instructions for use);
- to draw up technical documentation on the basis of Annexes II and III of the IVDR (Article 10 Paragraph 4 IVDR);
- to establish, document, maintain, update and continually improve a quality management system (Article 10 Paragraph 8 IVDR).
- the manufacturer must have at least one PRRC (person responsible for regulatory compliance) within its organisation (Article 15 IVDR);
- to affix the CE marking on the device and in its instructions for use (Article 18 IVDR);
- to assign a UDI (Article 24 Paragraph 3 IVDR);
- the manufacturer shall undertake an assessment of the conformity of its IVD according to the appropriate process(es) based on the nature and classification of its IVD (Article 48 IVDR);
- to plan, conduct and document a performance evaluation (Article 56 IVDR);
- to plan, establish, document, implement, maintain and update a post-market surveillance system (Article 78 IVDR);
- the obligations in terms of vigilance (Section 2 of Chapter VII IVDR).

This compliance with IVDR requirements is indicated by the manufacturer in the EU declaration of conformity (Article 17 IVDR).

Note: the IVDR provides for national measures to be taken via national legislation in order to implement the IVDR (e.g. Article 37 IVDR - language requirements). Therefore, Belgian national legislation has been published: the Law of 15 June 2022 on *in vitro* diagnostic medical devices and 3 Royal Decrees (the Royal Decree of 14 September 2022 implementing the preceding Law, the Royal Decree of 13 September 2022 modifying and withdrawing various provisions relating to the previous legislation on IVDs and the Royal Decree of 25 September 2022 on performance studies of IVDs).

3. What is 'Eudamed'? What modules are available?

Eudamed stands for European Database on Medical Devices and is the European database on medical devices and IVDs.

Eudamed is divided into 6 different modules, some of which are already available.

- "**Actors**" module: dedicated to identifying economic operators. These operators will have to identify themselves before making their medical devices and IVDs available on the market (Articles 27-28 IVDR). This module has been available since 1 December 2020.
- "**Devices**" module: for registering different medical devices and IVDs. UDIs will also be integrated (Articles 25-26 IVDR). This module has been available since 4 October 2021.
- "**Certificates**" module: for registering notified bodies and certificates issued by them (Article 52 IVDR). This module has been available since 4 October 2021.
- "**Clinical and performance studies**" module: for registering performance studies (Article 69 IVDR).
- "**Vigilance**" module: for all vigilance and post-market surveillance reports (Article 87 IVDR).
- "**Market surveillance**" module: for coordinating market surveillance actions between the different competent authorities (Article 95 IVDR).

The modules that are already available (Actors, Devices and Certificates) can be used on a voluntary basis and the FAMHP recommends doing so. The dates on which the use of a particular module will become mandatory, depend on different factors. More detailed information on the dates can be found on the website of the FAMHP.

Most of the information in the Actors, Devices and Certificates modules will be publicly available (already the case for data registered on a voluntary basis). Information in the other modules will have a limited public availability.

It is the responsibility of the competent authorities, notified bodies, manufacturers, authorised representatives and importers to enter and update the information in Eudamed.

More information on Eudamed can be found on the dedicated page on the European Commission website and in the European guidance documents.

4. What is the single registration number and how do I get one? How do I register in Eudamed?

The Single Registration Number (SRN) is a unique number assigned to the following economic operators:

- EU manufacturers,
- authorised representatives,
- manufacturers outside the EU, following pre-validation by their authorised representative,
- importers.

Note: a company performing different roles will therefore have several SRNs**.**

To obtain its SRN, the aforementioned economic operator must register in Eudamed using the "Actor" module. Its competent authority (the FAMHP for Belgian actors) checks and validates the registered request. Once the request has been validated, an automatic email notifies the economic operator that the SRN is available, via a link to a Eudamed page.

Registration in the "Actor" module is voluntary. **The FAMHP strongly encourages you to already register proactively.** In fact, Eudamed will be considered as the authentic source for the "actor" data and our online applications (the web portal) will communicate with EUDAMED in order to retrieve this data. This means that registration in Eudamed will be considered as registration in our online applications.

When you register in Eudamed, you will be asked to provide a number of details.

Please note the following points:

- **VAT number**: this number is used to match the data with the Crossroads Bank for Enterprises (CBE). This means that the data in Eudamed must match the data in the CBE.
- the '**signed declaration**' **document** - declaration on information security responsibilities: the purpose of this document is to appoint a Local Actor Administrator (LAA) who is responsible for the "administration" of the data in Eudamed. This declaration must be signed by a legal representative of the company.

For more information on how to register actors in Eudamed, please visit the dedicated page on the European Commission website.

Note: distributors are still required to register with our online applications (Royal Decree of 15 November 2017- FR/NL) as they do not have to register in Eudamed. More information is available on the FAMHP website.

5. In practical terms, what is the procedure in Belgium for placing an IVD on the market in accordance with the IVDR? How do I notify my IVD?

From 26 May 2022, IVDs placed on the market must comply with the IVDR. However, IVDs that are still compliant with the IVDD and which benefit from a transitional period (see Article 110 IVDR) can continue to be placed on the market. The conditions of this transitional period and the obligations are set out in question 8.

However, since registration in Eudamed for actors and devices is not yet compulsory (see question 3), the corresponding IVDD provisions transposed into national legislation continue to apply, i.e. notification of placing an IVD on the market (see the FAMHP website). **However, the FAMHP encourages Belgian manufacturers and manufacturers from outside the EU with a Belgian authorised representative to already register their IVD(s) in Eudamed using the "Devices" module.** This registration then replaces the FAMHP notification. No acknowledgement of receipt will be sent in this case. If you still wish to receive an acknowledgement of receipt, you can contact the relevant FAMHP department (see point 3 on the FAMHP web page for IVD manufacturers).

6. What are the major changes brought about by IVDR in terms of definition, classification and conformity assessment procedures?

a. Definition

Under the IVDR, the definition of an IVD has been extended and clarified.

> *"in vitro diagnostic medical device": any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, **software** or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:*
>
> *a) concerning a physiological or pathological **process** or state;*
> *b) concerning congenital physical or mental impairments;*
> *c) **concerning the predisposition to a medical condition or a disease;***
> *d) to determine the safety and compatibility with potential recipients;*
> *e) **to predict treatment response or reactions;***
> *f) to **define** or monitoring therapeutic measures.*

Specimen receptacles are also deemed to be *in vitro* diagnostic medical devices.

Note: products that meet the definition of an IVD and are offered over the internet to a natural or legal person established in the Union are also covered by the IVDR (Article 6 Paragraph 1 IVDR). This also applies to IVDs used in diagnostic or therapeutic services offered to persons established in the Union (Article 6 Paragraph 2 IVDR).

b. Classification

Under the IVDD, IVDs were divided into List A, List B, Self-test IVDs and "other IVDs". Only List A, List B and Self-test IVDs required the intervention of a notified body.

The IVDR completely changes the classification system, which is now risk-based. IVDs are divided into 4 classes: class A, B, C and D (class D being the most risky) according to 7 classification rules listed in Annex VIII of the IVDR, taking into account the intended purpose of the IVD.

Some of the requirements set out in the IVDR are directly linked to device classification, in particular the conformity assessment procedures, various post-marketing requirements, as well as the transitional provisions (Article 110 IVDR). It is therefore imperative that all manufacturers have verified the new classification of their IVD in accordance with Article 47 and Annex VIII of the IVDR.

For more information on classification rules, please consult guidance MDCG 2020-16, and for the specific case of software also guidance MDCG 2019-11.

c. IVD conformity assessment procedures

Only non-sterile Class A IVDs do not require the intervention of a notified body. In this case, the manufacturer attests the conformity of their IVD by issuing the EU declaration of conformity referred to in Article 17 and Annex IV of the IVDR, after drawing up the technical documentation set out in Annexes II and III.

All other IVDs require the intervention from a notified body. Depending on the class, the manufacturer has one or two possible tracks of having the conformity of its IVD assessed (see Article 48 of the IVDR).

Class	Track 1	Track 2
Class A sterile	Annex IX Chapters I and II	Annex XI
	EU quality management system certificate	EU production quality assurance certificate
Class B	Annex IX Chapters I and III and Sections 4.4 to 4.8 of Chapter II for at least one representative device per category of devices	/
	EU quality management system certificate and EU technical documentation assessment certificate	/
Class C	Annex IX Chapters I and III and Sections 4.4 to 4.8 of Chapter II for at least one representative device per generic device group	Annex X and Annex XI (except section 5)
	EU quality management system certificate and EU technical documentation assessment certificate	EU type-examination certificate and EU production quality assurance certificate
Class D	Annex IX: Chapters I, II (except section 5) and III	Annex X and Annex XI
	EU quality management system certificate and EU technical documentation assessment certificate	EU type-examination certificate and EU production quality assurance certificate

Please note that there are additional requirements for:

- **devices for self-testing** and **near-patient testing**: the technical documentation is assessed by the notified body in accordance with Annex IX Chapter II Section 5.1;
- **companion diagnostics**: the notified body consults a competent authority designated by the Member States in accordance with Directive 2001/83/EC or the EMA, in accordance with the procedure set out in Annex IX Section 5.2 (track 1) or Annex X Section 3, Point k (track 2);
- **class D IVDs for which an EU reference laboratory (EURL) has been designated** (Article 100 IVDR): verification by an EURL of the performance claimed by the manufacturer and of the compliance with the applicable common specifications or with other equivalent solutions chosen by the manufacturer (see question 7);
- **class D IVDs for which there are no common specifications and where it is also the first certification for that type of device**: the notified body consults the IVD expert panel (Article 106 MDR) on the manufacturer's performance evaluation report. Notified bodies can consult the MDCG 2021-22 guidance document for this procedure. On this European Commission webpage, you will also find more information on the expert panels, as well as a list of the different panels. The list of scientific opinions already issued by the IVD expert panel is available here.

Once the manufacturer has obtained the certificate(s) required for its IVD, he attests that the IVDR requirements have been met by issuing the EU declaration of conformity referred to in Article 17 of the IVDR.

Note: devices for performance study are subject to the requirements set out in Articles 56 to 77 of the IVDR. In accordance with Article 57, the manufacturer shall ensure that a device for performance study complies with the general safety and performance requirements set out in Annex I apart from the aspects covered by the performance study and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the patient, user and other persons.

Note: the list of notified bodies designated under the IVDR can be consulted on the European Commission's NANDO website.

Note: on 4 July 2022, the European Commission published implementing regulation (EU) 2022/1107 laying down common specifications for certain class D IVDs.

7. What is a European Union Reference laboratory (EURL)? What are its tasks? When will EURLs become active? What about class D IVDs for which no EURL exists?

a. Definition and tasks

EURLs are laboratories (or consortia of laboratories) designated by the European Commission to carry out the various tasks listed in Article 100 of the IVDR. These tasks can be divided in two areas:

- **Advisory tasks:** providing scientific and technical assistance, contributing to the development of common specifications, providing scientific opinions, …
- **Tasks related to the performance assessment of class D IVDs:**
  - Verification of performance (IVDR Article 48 §5)**:** as part of the conformity assessment procedure (see also question 6 c), the notified body shall request one of the EURLs to verify the performance of the class D IVD and its compliance with the applicable common specifications or other equivalent solutions chosen by the manufacturer.
  - Sample or batch testing (IVDR section 4.12 of Annex IX and in section 5 of Annex XI): the EURL must carry out appropriate tests on samples or batches of manufactured class D IVDs.

b. Which EURLs are designated?

In July 2022, the European Commission launched a call for the designation of EURLs in 8 different categories of class D IVDs. Applications were assessed based on their compliance with selection criteria (set out in particular in implementing regulation (EU) 2022/944). The European commission has also taken into account the combined capacity of all compliant laboratories in a given IVD category in order to avoid any possible saturation that could lead to potential delays in the certification of class D IVDs.

In December 2023, as a result of this call, the European Commission designated 5 EURLs covering 4 categories of **class D IVDs**:

- Detection or quantification of markers of **hepatitis or retrovirus** infection (covered by 2 EURLs)**;**
- Detection or quantification of markers of **herpesvirus** infection (covered by 3 EURLs)**;**
- Detection or quantification of markers of infection with **bacterial agents** (covered by 3 EURLs)**;**
- Detection or quantification of markers of **respiratory virus** infection (covered by 2 EURLs).

The list of designated EURLs is given in the annex to implementing regulation (EU) 2023/2713.

c. When will EURLs become active?

The implementing regulation (EU) 2023/2713 foresees a transition period that EURLs can use to get organised and prepare for the tasks assigned to them. EURLs will start carrying out their tasks from 1 October 2024.

However, class D IVDs that are already covered by an IVDR certificate or are in the process of certification (formal application for conformity assessment lodged with a notified body) before 1 October 2024, do not need to undergo a performance verification by an EURL. This performance verification step will be included during renewal of their certificate.

Note that sample or batch testing of manufactured class D IVDs, regardless of when they obtained a certificate, will start on 1 October 2024.

Below is a summary table of the tasks related to the performance assessment of class D IVDs for which EURLs have been designated:

Status of the class D IVD at 01/10/2024	**When does the EURL task apply?**	
	Sample/batch testing	**Verification of performance**
IVD covered by an IVDR certificate	From 01/10/2024	When renewing the certificate
IVD not covered by an IVDR certificate, but a formal application for conformity assessment is lodged with a notified body before 01/10/2024	Upon certification	When renewing the certificate
IVD not covered by an IVDR certificate and the formal application for conformity assessment is lodged with a notified body from 01/10/2024	Upon certification	During the first conformity assessment

d. What about class D IVDs for which no EURL has been designated?

Class D IVDs for which no EURL has (yet) been designated, can still be certified by a notified body and placed on the marked under the IVDR. In this case, the notified body simply does not have to apply Article 48 §5, i.e. verification of the IVD performances by an EURL. For further information, please consult the MDCG 2021-4 guidance (questions 5 and 6).

Note: with regard to sample/batch testing of manufactured class D IVDs, the absence of a designated EURL doesn't exempt the manufacturer from complying with the requirements relating to his own sample/batch testing. Only testing by an EURL is not required.

Note: the European Commission is considering further calls for EURL designations. For more information on EURLs, please consult the dedicated page on the European Commission website.

8. How does Article 110 of the IVDR (transitional provisions) apply?

a. Which IVDs benefit from a transitional period under Article 110 and under which conditions?

Originally, the IVDR provided a transition period (until May 26, 2024) only for IVDD-compliant IVDs that had a certificate from a notified body. No transition period was provided for IVDD-compliant IVDs without a certificate, being the majority of IVDs under the IVDD.

A first amendment ((EU) 2022/112) to the IVDR transitional provisions was published in January 2022. This amendment extended the initially planned transitional period for IVDs with a certificate under the IVDD to 26 May 2025 and added transitional periods for "other" IVDs under the IVDD, which require the intervention of a notified body under the IVDR.

A second amendment ((EU) 2023/607) to the IVDR transitional provisions was published early 2023. This amendment removes the deadline that was provided for the distribution of IVDD-compliant IVDs. With this amendment, IVDD-compliant IVDs already in the distribution chain can continue to be supplied to customers.

Finally, a third amendment ((EU) 2024/1860) to the IVDR transitional provisions was published in June 2024. This amendment again extends the transition periods and imposes additional conditions for using the transition periods.

The general conditions for using the transition periods for IVDD-compliant IVDs are now:

- the concerned IVDs must continue to comply with IVDD; however, manufacturers must already comply with the requirements of the IVDR regarding registration of economic operators and devices, post-market surveillance, vigilance and market surveillance;
- no significant changes may be made to the design or intended purpose of the IVD (for more information on significant changes, see MDCG 2022-6);
- the IVDs do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
- no later than 26 May 2025, the manufacturer has put in place a quality management system in accordance with the IVDR (Article 10 §8);
- no later than 26 May 2025, 2026 or 2027 (depending on the IVD class under the IVDR, see table below), the manufacturer or his authorised representative has lodged a formal application with a notified body for conformity assessment of the IVD[1];
- no later than 4 months later (26 September 2025, 2026 or 2027, depending on the IVD class under the IVDR, see table below), the manufacturer has signed a written agreement with the notified body.

[1] Or an application for conformity assessment of an IVD intended to replace the IVDD-compliant IVD.

Overview of different transition periods and additional specific conditions:

			Deadline with regard to NB		
Class under the IVDD	**Class under the IVDR**	**Deadline for placing on the market**	**Formal application**	**Written agreement**	**Specific conditions**
List A List B Self-test	D, C, B	31/12/2027	26/05/2025	26/09/2025	The certificate remains valid until 31/12/2027 depending on conditions *
Other	D	31/12/2027	26/05/2025	26/09/2025	DoC drawn up prior to 26/05/2022
	C	31/12/2028	26/05/2026	26/09/2026	
	B	31/12/2029	26/05/2027	26/09/2027	
	A sterile				

* Additional specific conditions for extending the validity of the certificate until 31/12/2027:

- on 26 May 2022, the certificate was still valid;
- after 26 May 2022, the certificate was not withdrawn;
- if the certificate had expired before 09/07/2024 (the publication date of the third amendment), the manufacturer must also comply with one of the following conditions:
  - a written IVD conformity assessment agreement must have been signed with a notified body[2] before the expiry date of the certificate ; or
  - a competent authority of a Member State has granted a derogation from the conformity assessment procedure (IVDR Article 54) or has required the manufacturer to carry out the applicable conformity assessment procedure (IVDR Article 92).

Remarks:

- no transition periods are foreseen for the following IVDs and consequently they should already comply with the IVDR:
  - IVDD-compliant IVDs listed above, but for which the general conditions or the specific conditions are not met;
  - IVDs that are not sterile and fall under the class A of the IVDR;
  - 'new' IVDs (IVDs not in compliance with the IVDD before 26/05/2022);
  - IVDs that were excluded from the IVDD but are now included in the IVDR.
- IVDs placed on the market from 26 May 2022 based on the transition periods presented above are commonly referred to as "legacy devices».
- for legacy IVDs with a certificate under the IVDD (List A, List B, self-tests), the notified body that issued the IVDD certificate continues to be responsible for the appropriate surveillance of all applicable requirements relating to the legacy devices it certified (unless already agreed otherwise with an IVDR notified body). By 26 September 2025, the notified body that signed the written agreement will become responsible for this surveillance. If the written agreement relates to an IVD intended to replace the IVD for which the IVDD certificate has been issued, the surveillance shall be carried out on the IVD that is replaced. The arrangements for the transfer of surveillance shall be clearly defined in an agreement between the manufacturer and the IVDR notified body, and, if practical, the notified body that issued the IVDD certificate.
- The European Commission has published a Q&A document in response to the latest IVDR amendment. This document addresses several questions regarding transition periods, conditions and demonstration of compliance, as well as the obligations and modalities of the notified bodies involved. The appendix to this document contains a flowchart to help determine whether and until when an IVD can make use of a transition period.

[2] Or a signed conformity assessment agreement of an IVD intended to replace the IVDD-compliant IVD.

b. What IVDR requirements apply to legacy devices?

Legacy devices must continue to comply with the IVDD. However, according to Article 110 Paragraph 3d, the IVDR requirements relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and devices, apply and replace the corresponding IVDD requirements.

If these requirements are linked to Eudamed, they are not yet applicable as long as the use of Eudamed is not mandatory. The corresponding IVDD requirements transposed into national legislation (Belgium: RD of 14/11/2001) will therefore continue to apply. For example: device registration requirements (see questions 3/4/5 that also contain information that is applicable to legacy devices).

In May 2022, the European Commission published the guidance MDCG 2022-8 on the application of IVDR requirements to legacy devices, taking into account that Eudamed is not yet fully functional.

9. How do I draw up an IVDR declaration of conformity?

Annex IV of the IVDR describes the information that must be included in the declaration of conformity:

1. name, registered trade name or registered trade mark and, if already issued, SRN of the manufacturer, and, if applicable, its authorised representative, and the address of their registered place of business where they can be contacted and their location be established;
2. a statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer;
3. the basic UDI-DI;
4. product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the basic UDI-DI referred to in point 3;
5. risk class of the device;
6. a statement that the device that is covered by the present declaration is in conformity with Regulation 2017/746 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;
7. references to any common specifications used and in relation to which conformity is declared;
8. where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued;
9. where applicable, additional information;
10. place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.

10. What is the unique device identifier (UDI)?

The UDI (for Unique Device Identifier) is a series of numeric and alphanumeric characters used to identify a device. The UDI is comprised of two parts: the UDI-DI and the UDI-PI.

- The **UDI-DI** (UDI device identifier) is specific to the device. It contains the information described in Part B of Annex VI of the IVDR (e.g. manufacturer's name, risk class, trade name, etc.).
- **The UDI-PI** (UDI production identifier) identifies the device at production unit level. It contains the information described in Part C of Annex VI of the IVDR (e.g. serial number, batch number, software identification and manufacturing or expiry date or both).

The UDI-related requirements are applicable to IVDR-compliant IVDs, unlike legacy devices for which the manufacturer is free to apply these requirements or not.

The UDI "carrier" (consisting of an automatic identification and data capture (AIDC) system and a human-readable interpretation) must be placed on the device label and all higher levels of packaging. This obligation is staggered over time (Article 113 Paragraph 3 Section e IVDR) according to the IVD risk class (see table below).

Class D	Class B and Class C	Class A
26 May 2023	26 May 2025	26 May 2027

More information on the UDI can be found on the European Commission website, or in the European guidance.

11. How do I obtain a UDI?

"Issuing entities" supply the UDIs. Four entities have been designated by the European Commission:

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

To obtain the necessary information, please contact one of these issuing entities directly.

12. What is the "person responsible for regulatory compliance" (PRRC)?

The IVDR requires every manufacturer to appoint a person responsible for regulatory compliance (PRRC). The PRRC must be part of the company, with the exception of micro and small enterprises, which can "outsource" this function. However, this person must be permanently and continuously available.

The PRRC must meet certain requirements in terms of qualifications and professional experience (see Article 15 Paragraph 1 IVDR) and is responsible for fulfilling at least the requirements set out in the IVDR (see Article 15 Paragraph 3 IVDR), such as verifying the conformity of devices, drawing up and maintaining technical documentation and the EU declaration of conformity, checking that post-marketing surveillance obligations are complied with, etc. For more information on the PRRC, please consult the guidance MDCG 2019-7.

Note: the authorised representatives must also have at least one PRRC permanently and continuously at their disposal, who must meet certain requirements in terms of qualifications and professional experience (see Article 15 Paragraph 6 IVDR).

13. Where can I find the European guidance and other useful documents?

The European Commission publishes many documents and information concerning the world of medical devices and IVDs:

- specific information on IVDs: common specifications, IVD expert panel, EURL, etc.
- information on regulations in general: extension of transitional provisions, corrigendum, guidance documents
- guidance on UDI, Eudamed, nomenclature, notified bodies, legacy devices, etc.
- information on dialogue between the various stakeholders: MDCG, international cooperation, etc.
- information on expert panels.
- information on Eudamed.
- information on topics of interest: notified bodies, UDI, harmonised standards, etc.

Appendix I: version history

Changes from version 3 (22/12/2023):

- Contents: updated as follows: the publication of Regulation (EU) 2024/1860 amending Regulations (EU) 2017/745 and (EU) 2017/746 (questions 3, 4, 8).

Changes from version 2 (16/05/2023):

- Contents: updated as follows:
  - the postponement of the scheduled date on which Eudamed will be fully functional (question 3, question 4, question 8),
  - publication of implementing regulation (EU) 2023/2703 designating EURLs (question 7);
  - publication of the guidance MDCG 2022-15 on appropriate surveillance with regard to legacy devices (IVD) (question 8)

Changes from version 1 (applicable for the French and Dutch version)[3]:

- Editorial: addition of internal links, correction of page numbering, addition of a version number.
- Contents: updated as follows:
  - the application of Regulation (EU) 2017/746 (questions 1, 2, 5, 8);
  - the publication of national legislation to implement the IVDR (question 2);
  - the postponement of the scheduled date on which Eudamed will be fully functional (question 3),
  - clarification of the administrative notification process (question 5);
  - publication of implementing regulation (EU) 2022/1107 laying down common specifications (question 6);
  - publication of implementing regulations for EURLs and the timetable for designating EURLs (question 7);
  - publication of regulation (EU) 2023/607 amending regulations (EU) 2017/745 and (EU) 2017/746 (question 8);
  - publication of the guidance MDCG 2022-6 on significant changes to legacy devices (question 9);
  - the publication of the guidance MDCG 2022-8 on IVDR requirements for legacy devices (question 8, 10).

[3] the English translation was completed in July 2023.