The European IVD Regulation (2017/746). Frequently asked questions (FAQs).

March 2021

BD

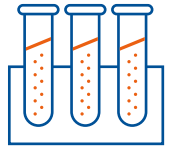
Introduction to the EU IVDR

Q. What is the remit of the EU IVD Regulation (IVDR)?

A. The EU IVD Regulation 2017/746 covers *in vitro* diagnostic medical devices. It replaces the existing European *In Vitro* Diagnostic Medical Device Directive (IVDD 98/79/EC).

Q. What is an *in vitro* diagnostic medical device (IVD)?

A. 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 to provide 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 shall also be deemed to be *in vitro* diagnostic medical devices.

Q. When did the IVDR come into force?

A. The IVDR took effect on 26 May 2017.

Q. When will the IVDR application date be?

A. After the transition period of 5 years which is in force until 26 May 2022.

Q. Should the IVDR be transposed into national laws?

A. No. Unlike directives, regulations do not need to be transposed into national laws. The IVDR will, therefore, limit discrepancies in interpretation across the EU member states.

Q. What are the main changes that are highlighted under the new IVDR?

A.

1. More in-depth evidence: Additional clinical evidence and technical documentation will be required to prove safety and performance claims. Clinical evidence should demonstrate that the information obtained from the diagnostic test is accurate and relevant

2. New risk-based classification system: The *in vitro* diagnostic medical devices will be subject to a new risk-based classification system, resulting in four risk classes

   These are:

   - Class A: Low public health risk and low individual patient risk. (Eg. Specimen receptacles, instruments)
   - Class B: Low public health risk and/or moderate individual patient risk. (Eg. Some self-tests, controls)
   - Class C: Moderate public health risk and/or high individual risk. (Eg. Cancer markers, genetic tests, Sexually Transmitted Infection (STI) tests, companion diagnostics)
   - Class D: High public health risk and high individual patient risk. (Eg. Blood grouping, transmissible agents)

3. New conformity assessment: Each risk class will have to go through a new conformity assessment route. Class B, Class C and Class D devices will be subjected to notified body (NB)* review, however to a different degree depending on the device class and type. Class A devices, except Class A sterile, are not subjected to NB review. For class D devices, an additional evaluation will be performed by an EU reference laboratory

**A notified body (NB) is a third party certification body and auditing agency that conducts conformity assessments (for those devices that are not self-certified).*

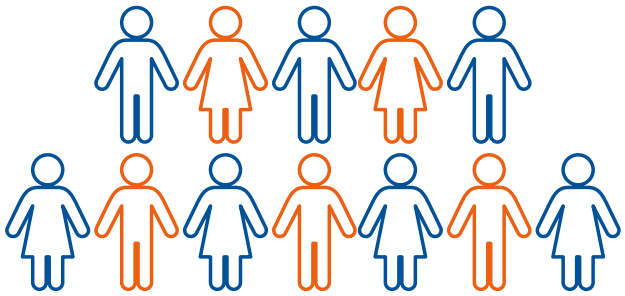
Q. What are the main changes that are highlighted under the new IVDR? continued

4. Increased oversight: Manufacturers will be subjected to increased scrutiny by NBs and competent authorities. The NBs themselves will be subjected to additional scrutiny by authorities in EU member states

5. No Grandfathering: Each *in vitro* diagnostic medical device is required to have data to support product claims

6. More transparency and traceability: EUDAMED is a sophisticated EU database for medical devices in which certain information about devices and their performance will be made public. Unique device identifiers (UDI) will be adopted to ensure clear identification and traceability

7. Increased post-market surveillance: This is achieved by notified bodies and device manufacturers systematic and proactive measures, which include post-market follow up. Post-market performance follow-up (PMPF) includes performance evaluation throughout the life of the product and reconfirmation that the benefits of the device outweigh the risks. There are also changes in incident reporting times and incident reporting times and incident reports will be uploaded into EUDAMED



EUDAMED
EUROPEAN DATABANK ON MEDICAL DEVICES

Q. What information can I find in the EUDAMED database?

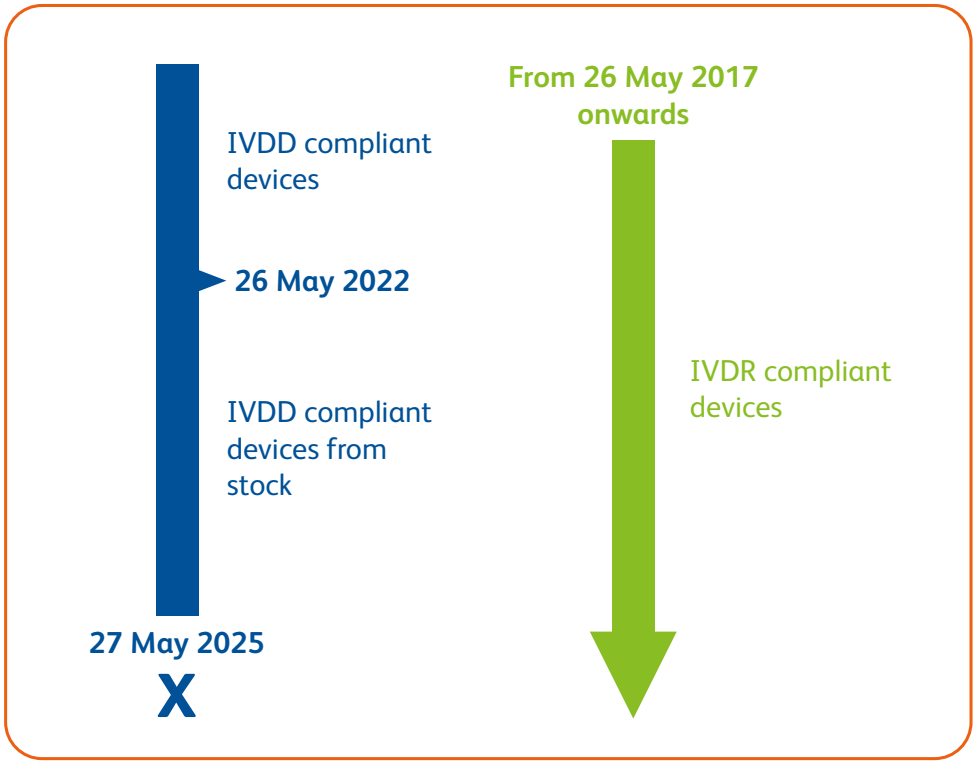
A. EUDAMED is the IT system developed by the European Commission to implement the MDR and IVDR, and to enhance transparency. The information available to the public in EUDAMED includes but is not limited to:

- The list of medical devices and IVD medical devices on the EU market
- Information about economic operators (e.g. manufacturers, authorised representatives, etc)
- Serious incidents
- Periodic safety updates for class C and class D devices
- Summary of safety and performance – a high-level overview of safety and performance of class C and class D devices

Q. Timelines and transitional provisions – which products can end up at the customer's bench?

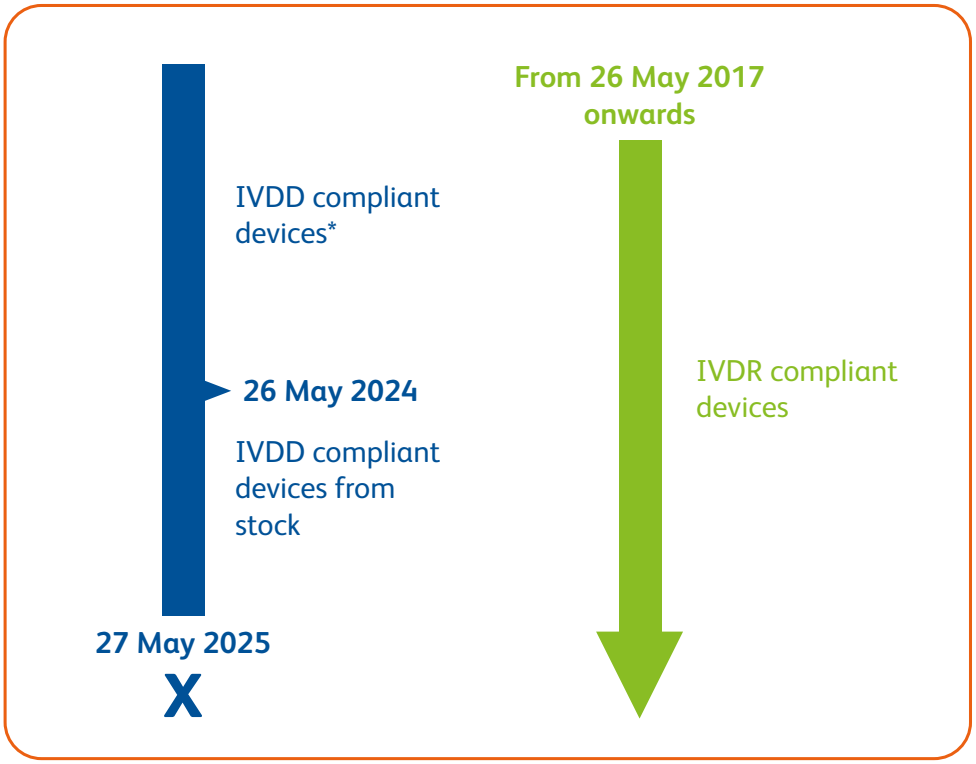
For general IVD medical devices

(= Non-Annex II IVD medical devices under IVD Directive 98/79/EC)



For Notified Body (NB) certified devices

(= Annex II List A, Annex II List B and self-testing IVD medical devices under IVD Directive 98/79/EC)



**only applicable in case NB-certificate is still valid but no longer than 26th of May 2024.*

Q. Can my laboratory purchase IVDR-compliant IVD devices before 26 May 2022, the date of application of IVDR?

A. Yes, but it depends on.

- Manufacturers deciding when to release the IVDR-compliant devices
- Self-certified CE marked class A devices (e.g. specimen receptacles, instruments) may be available in the EU market earlier
- Constraints in Notified Body capacity may affect the availability of class B and class C devices
- Availability of IVDR compliant class D devices, which require another entity (e.g. Reference Laboratories) in addition to NB for their conformity assessment, will take longer

Q. What should be my action plan?

Some devices on the market today will have changes to their intended use under IVDR	1) Know which devices will be discontinued or will have a different intended use under IVDR
Some devices will be discontinued	2) Organise stock management and supply to ensure business continuity
A mix of IVDD- and IVDR- compliant devices might be present in the market for some time	3) If customers wish to manufacture and use laboratory developed tests (LDTs), due to equivalent IVDR-compliant tests not being available in the market, they must ensure compliance with specific conditions and requirements as outlined in the IVDR

Laboratory developed tests (LDT) and health institutions (HI)

Q. What is a laboratory-developed test (LDT)?

A. An LDT is a diagnostic tool that is designed, manufactured, and used within a health institution (HI).

Q. What is a health institution (HI)?

A. The IVDR defines a health institution as

'an organisation, the primary purpose of which is the care or treatment of patients, or the promotion of public health.'

Q. Why are LDTs exempt from the current IVDD but now regulated under the IVDR?

A. Article 1(5) provides an exemption for LDTs from the IVDD.

IVDR prescribes certain requirements for LDTs and the HI manufacturing and using the LDT must meet certain conditions. These requirements and conditions are put in place to ensure a high level of health protection for patients.

Q. What changes will the IVDR bring to LDTs?

A. LDTs are regulated under IVDR. However, the LDTs only need to meet the relevant requirements of IVDR Annex I if the HI using and manufacturing the LDT meets certain conditions. The exemption conditions are specified in Article 5(5) and a few of them are:

- The HI should provide a justification that patients' needs cannot be met because:
  - No equivalent CE marked device is available in the EU, or
  - Performance of the equivalent CE marked device is not sufficient for the target patient group
- The device is manufactured and used within the same health institution. This use shall be understood to include measurement and delivery of results
- The device is not manufactured on an industrial scale

HIs which do not meet the conditions of Article 5(5) can only manufacture and use the LDT if it complies with all the requirements of the IVD Regulation

Q. To whom does the exemption apply?

A. Examples of HIs as indicated in the IVDR are:

- Hospitals
- Laboratories and public health institutes that support the health care system and/ or address patient needs, but which do not treat or care for patients directly

Q. To whom does the exemption NOT apply?

A. The exemption does not apply to, for example:

- HIs outside of the EU
- Wellness centres

Q. What are the main governance and enforcement rules for HIs to consider if they want to manufacture and use LDTs?

A. HIs must consider these rules:

- Development and use of an LDT is possible only in the absence of a CE-marked alternative or if the performance of the equivalent CE marked device is not sufficient for the target patient group
- HIs must adhere to Article 5(5) and Annex 1 of the IVDR
- The EU Member States will oversee devices manufactured and used within the healthcare institutions in their territory

Q. What are the key requirements for HIs?

A. The key requirements for HIs are:

- The tests or assays made by HIs shall be manufactured and used within the framework of a Quality Management System
- The laboratory of the health institution should be accredited to EN ISO 15189 (or alternate national provisions)
- LDTs must comply with the relevant General Safety and Performance Requirements (GSPR) as outlined in Annex I of IVDR
- The HI will review the experience gained from the clinical use of the device and take corrective actions if necessary
- The HI will make the declaration of conformity of the device publicly available

Q. What are the technical documentation requirements that HIs must meet to satisfy Article 5(5)?

A. There are specific documentation requirements for all LDTs in order for the exemption to apply. Specifically for class D LDTs, the HI should prepare documentation that describes:

- The intended purpose of the device
- The manufacturing facility
- The manufacturing processes
- Device design and performance data in relation to its intended purpose

The documentation should be of sufficient detail to demonstrate that all applicable general safety and performance requirements as outlined in Annex I are met.

IVDR allows the EU Member States to extend this requirement to other risk classes.

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