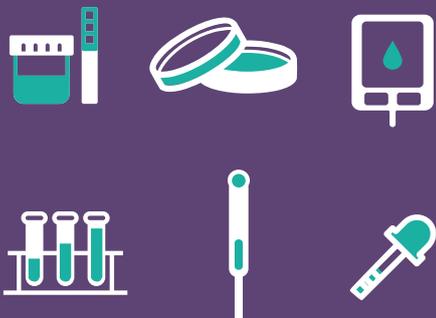




European Commission



Factsheet for Manufacturers of *in vitro* Diagnostic Medical Devices

This Factsheet is aimed at manufacturers of in vitro diagnostic medical devices. For information on the impact of the Medical Device Regulation (MDR) on manufacturers see the Factsheet for manufacturers of medical devices. References to Annexes and Articles in this factsheet refer to the IVDR (2017/746/EU).

The new Medical Devices Regulation (2017/745/EU) (MDR) and the *In Vitro* Diagnostic Medical Devices Regulation (2017/746/EU) (IVDR) bring EU legislation into line with technical advances, changes in medical science, and progress in law making.

The new Regulations create a robust, transparent, and sustainable regulatory framework, recognised internationally, that improves clinical safety and creates fair market access for manufacturers.

In contrast to Directives, Regulations do not need to be transposed into national law. The MDR and the IVDR will therefore reduce the risks of discrepancies in interpretation across the EU market.

Transitional periods are planned to smooth the application of the new Regulations. However, you should bear in mind that consultants, in-house professionals, and Notified Bodies will all get busier as the deadline draws closer.

Act now to be ready on time!

MEDICAL DEVICES CHANGE OF LEGISLATION

What you need to know!



In Vitro Diagnostic Medical Devices Regulation (IVDR) background

The IVDR will replace the existing *In Vitro* Diagnostic Medical Devices Directive (98/79/EC) (IVDD). The IVDR was published in May 2017, marking the start of a five-year period of transition from the IVDD.

During the transitional period the IVDR will come into force gradually, starting with the provisions related to the designation of Notified Bodies and the ability of manufacturers to apply for new certificates under the IVDR.

The transitional period will end on 26 May 2022, the “Date of Application” (DoA) of the Regulation. From that point the IVDR will apply fully.

To avoid market disruption and allow a smooth transition from the Directive to the Regulation, several transitional provisions are in place (Article 110). During the transition phase, products certified under the Directive and products certified under the Regulation will coexist on the market. Both will have equal status under the law, and no discrimination in eligibility criteria in public tenders may take place.

What has changed?

In terms of their impacts on manufacturers and products, the IVDD and the IVDR largely share the same basic regulatory process. No existing requirements have been removed, but the IVDR adds new requirements.

The IVDR brings more stringent requirements for the designation of Notified Bodies, with increased control and monitoring by the national competent authorities and the Commission.

The biggest change concerns the risk classification of *in vitro* diagnostic (IVD) devices and the role of Notified Bodies (NBs). The IVDR also clarifies the obligations of economic operators (manufacturers, authorised representatives, importers and distributors).

The IVDD took a list-based approach to assigning risk classes, which in turn determined the process for assessing conformity and the level of supervision required from NBs. The IVDR instead uses rules recognised at international level to assign each device to one of the four risk categories (Article 47), ranging from class A (lowest risk) to class D (highest risk). As a result, around 85% of all IVDs will need NBs oversight.

The IVDR also brings tightened requirements for clinical evidence and conformity assessment. For companion diagnostics, the NBs shall consult the competent authorities for medicinal products (Article 48).

The conformity assessment of class D devices will require the involvement of an EU Reference Laboratory (if designated for that type of device) to verify the performance claimed by the manufacturer and compliance with the applicable Common Specifications (article 48.5). In addition, for innovative class D devices where no Common Specifications currently exist, an independent expert panel must provide its views on the performance evaluation report of the manufacturer (Article 48.6).

Class D devices produced must be tested by an EU Reference Laboratory (if designated for that type of device).

The IVDR calls for increased transparency, with information on IVD devices and ‘higher risk’ performance studies being made public. The new European Database for Medical Devices (EUDAMED) will play a central role in providing more complete, accurate and accessible data.

The introduction of a unique device identifier (UDI) for every IVD device will significantly enhance traceability and support post-market safety activities.



More about the timing

NBs may continue to issue certificates under the IVDD until the Date of Application (DoA) of the Regulation. Under certain conditions, devices with valid certificates issued under the Directive may continue to be placed on the market¹ until 27 May 2024 and made available² until 27 May 2025 (Article 110 paragraph 4).

Manufacturers can place their products on the market under the IVDR before the Date of Application if they comply with the Regulation.

Some articles also have a specific date of application. For example, Article 100 on EU reference laboratories for IVDs applies from 25 November 2020 (Article 113 paragraph 3d).

1 For definition see Article 2 paragraph 21
2 For definition see Article 2 paragraph 20



What does this mean in practice?

IVD definitions (Article 2)

The IVDR definition of an IVD has been broadened and clarified to cover tests intended to predict a medical condition or a disease, “companion diagnostics” (see below), and software.

The IVDR also introduces some new definitions. For example, devices for “near-patient” testing (definition 6) are designed for use by health professionals but outside a laboratory environment. “Companion diagnostics” (definition 7) are those required for the safe and effective use of a corresponding medicinal product.

IVD devices and testing services offered over the internet (“information society services”) that are accessible to European citizens must comply with the IVDR at the moment they are offered for use in the EU (Article 6).

Risk classes (article 47 and Annex VIII)

The new rule-based risk classification system is more flexible than the list-based system it replaces, allowing the IVDR better to keep pace with technological progress and the need to address emerging medical conditions.

Instead of naming specific IVD devices or medical conditions, the risk classification of a device is determined by its intended purpose and takes into consideration not only the risk to the individual but also the risk to public health. To classify their device, the manufacturer should consult the rules listed Annex VIII of the Regulation. If more than one rule applies, the rule resulting in the highest classification should be followed. In line with the international principles of classification, the four classes are:

- 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 high public health risk.

Class A devices will be self-certified by their manufacturers unless they are sold as sterile. Devices in Classes B, C and D will require conformity assessment by a Notified Body.

The classification of a device is the responsibility of the legal manufacturer in the first instance. If the Notified Body disagrees with the manufacturer’s classification, the matter should be referred to the Competent Authority (CA) of the country in which the manufacturer (or its authorised representative) is located. Two CAs may become involved if the manufacturer and the NB are located in different countries and are therefore under the authority of different CAs (Article 47).

Obligations of manufacturers

The obligations of the different actors and their relations are now clearly stated in the Regulation.

According to Article 10, manufacturers shall have systems for risk management (paragraph 2) and quality management (paragraph 8); conduct performance evaluations (paragraph 3); build up and keep updated the technical documentation (paragraph 4); and apply a conformity assessment procedure (paragraph 5). Manufacturers are also responsible for their devices once they are on the market, by taking appropriate corrective actions, recording and reporting incidents, and by providing appropriate evidence of conformity to authorities (paragraphs 11, 12, 13). They must have systems in place to cover their financial responsibility for harm caused by defective devices (paragraph 15).

Every manufacturer shall have a designated person responsible for regulatory compliance (Article 15).

Once they have completed all their obligations, manufacturers shall draw up a declaration of conformity (Article 17) and apply CE marking to their devices (Article 18).

Manufacturers outside the EU/EEA³ shall have an appropriate contract with an authorised representative based inside the EU/EEA (Article 11).

The obligations of authorised representatives (Article 11), importers (Article 13) and distributors (Article 14) are also clearly described.

Life-cycle approach

Compared to the IVDD, the IVDR places more emphasis on the life-cycle management and continuous evaluation of products.

The IVDR requires manufacturers to show that they have an effective quality management system (QMS) in place.

Device identification

A system of unique device identifiers (UDIs) will enhance the identification and traceability of IVDs. This is a new feature of the IVDR (Article 24).

Each IVD will have a UDI composed of two parts: a device identifier (UDI-DI) specific to the model and packaging of the device, and a production identifier (UDI-PI) to identify the point of manufacture.

Manufacturers are responsible for entering the necessary data on the European database (EUDAMED), which includes the UDI database, and for keeping it up to date.

Clinical evidence, performance evaluation, and performance studies (Chapter VI)

The level of clinical evidence needed to demonstrate the conformity of a device becomes progressively more stringent as the risk class increases. The clinical evidence for each IVD device is based on clinical data and a Performance Evaluation that demonstrates:

- scientific validity
- analytical performance
- clinical performance.

New to the IVDR is the requirement for post-market performance follow-up to update the performance evaluation when needed throughout the life cycle of the device.

The IVDR also describes the situations in which manufacturers have to conduct performance studies, and how they should do this.

Notified Bodies (Chapter IV)

The IVDR requires Notified Bodies to be designated. Compared to the situation under the IVDD, Notified Bodies will be required to meet more stringent criteria, particularly in terms of scientific and technical evaluation competence. The process of designation, which might take 12 months or more following an application by a notified body, involves assessors from both national and European authorities. This means that the first Notified Bodies designated under the new Regulation might be available by the beginning of 2019.

The database of Notified Bodies (NANDO) can be found [here](#).

As a manufacturer you must verify whether your Notified Body will be notified under the new Regulation and for which scope of products. With your Notified Body you now must plan the timing of certifications for your portfolio of products, considering the availability of your Notified Body, the need for additional data on your devices – including performance studies – and the transitional provisions set out in the Regulation.

Conformity assessment (Chapter V Section 2)

The assessment of the conformity of a device for CE marking varies according to the risk class and specific features of certain devices (Article 48). The intervention of a Notified Body is needed for all Class B, C and D devices, as well as sterile Class A devices (paragraph 10). The different routes of assessment according to the class of the device are described in Article 48 and the Annexes IX, X, XI. In some cases manufacturers have some choice regarding the conformity assessment route.

For certain Class D devices there is a new performance evaluation consultation procedure to be carried out by an independent expert panel, and when an EU Reference laboratory has been designated for this kind of Class D devices, it should verify by laboratory testing the performance claimed by the manufacturer (Article 48 paragraphs 5 and 6).

Annex I specifies the general safety and performance requirements, while Annexes II and III specify the makeup of the technical documentation.

The scope of the Quality Management System (Article 10 paragraph 8) now includes performance evaluation and post-marketing performance follow-up (PMPF). A performance evaluation plan must precede the performance evaluation itself (Annex XIII, Part A).

Common specifications defining additional requirements may be put in place for certain devices (Article 9).



Timing your transition to the IVDR

As a manufacturer, the timing of your transition to the IVDR is up to you.

From 26 May 2022, all new certificates will have to be delivered according to the IVDR. Certificates issued under the IVDD can be valid until 27 May 2024 at the latest, but the requirements of the new Regulation relating to post-market surveillance, market surveillance, vigilance, and the registration of economic operators and devices shall apply from the Date of Application (26 May 2022).

A first step is to classify your devices according to their risk classes. For those that need certification by a Notified Body, make sure you plan this in good time.

The transition period should provide plenty of time **as long as you start planning now**. Bear in mind that consultants, in-house professionals, and Notified Bodies will all get busier as the deadline draws closer.

As a manufacturer, you can start now by making sure that:

- all your products are classified appropriately;
- all product documentation and evidence of compliance will be available in time and conforms with the IVDR; and
- you have the necessary systems in place to handle clinical evidence, quality management, post-market surveillance, and liability for defective devices.

More information

For more information on any of the above topics, please refer to the Medical Devices section on the DG GROW website.



Frequently asked questions

Below you can find an extract from the FAQs of the Competent Authorities for Medical Devices. For a complete list, see:

<https://www.camd-europe.eu/regulatory/available-now-mdr-ivdr-transitional-faqs/>

When does the IVDR apply?

The *In Vitro* Medical Device Regulation (EU) 2017/746 (IVDR) will apply from 26 May 2022 – the “Date of Application” (DoA).

Some provisions of the IVDR will come into force earlier (e.g. regarding Notified Bodies and the Medical Device Coordination Group). Some will apply later (e.g. regarding UDI labelling).

When does the existing Directive cease to apply?

In general, the IVDD will be repealed with effect from 26 May 2022 (the DoA). However, there are some exceptions, such as:

- for the continued marketing of devices that comply with the IVDD (see below); and
- to serve as a backup in case EUDAMED is not fully functional by the DoA.

What is the applicable legislation up to 26 May 2022?

Until the DoA, the laws and regulations adopted by Member States in accordance with the IVD Directive will continue to apply. However, there are some exceptions.

Is it possible to place devices on the market that are compliant with the IVDR prior to the DoA?

Yes, you may certainly place IVDR-compliant devices on the market before the end of the transitional period. This applies to devices in all risk classes, if the requirements set by the IVDR are in place.

However, devices in Class D may not be placed on the market before the expert panels and the EU reference laboratories have been established.

Depending on the risk class of the device, conformity assessment may involve an appropriate Notified Body. This requirement will delay starting conformity assessment until an appropriate Notified Body is available.

As a manufacturer, which obligations of the Regulation do I need to fulfil in order to place compliant devices on the market before the DoA?

You should meet as many obligations as possible, bearing in mind that the complete IVDR infrastructure, including EUDAMED, may not be fully functional before the Date of Application.

Both the device and the manufacturer must comply with the IVDR. You should assess the conformity of your device – a process that may require the involvement of a Notified Body. Other important points include:

- performance evaluation
- risk management
- QMS
- responsibilities of economic operators
- post-market surveillance
- technical documentation and other reports
- liability for defective devices.

Until EUDAMED is fully operational, some parts of the IVDD will have to substitute for the corresponding requirements of the IVDR. These include the registration of devices and economic operators.

A person responsible for regulatory compliance needs to be available but not necessarily registered until EUDAMED is operational.

Do certificates issued by Notified Bodies under the existing Directive remain valid after the DoA?

Yes, IVDD certificates will generally remain valid until their indicated expiry dates or until 27 May 2024, whichever is the earlier.

After 27 May 2024 there will be no more valid IVDD certificates.

Valid IVDD certificate types include:

- EC Design-Examination Certificate
- Certificate of Conformity
- EC Type Examination Certificate
- EC Certificate Full Quality Assurance System
- EC Certificate Production Quality Assurance

An IVDD declaration of conformity is not a certificate issued by an NB and is therefore not valid under the IVDR.

Is it possible to have valid IVDR and IVDD certificates in parallel until 27 May 2024?

Yes.

Can manufacturers still place on the market/put into service Directive-compliant devices after the end of the transition period?

Yes, under certain conditions there will be an option to continue placing on the market/putting into service devices that comply with the IVDD until their existing certificates expire (or 27 May 2024 at the latest). This may avoid the immediate need for new certificates under the IVDR.

To use this option, all the existing certificates will have to be valid (including for example QMS), the purpose and nature of the device must not change, and you must follow the new IVDR rules for registration, surveillance and vigilance.

Devices not listed in Annex II of the IVDD may not remain on sale after the DoA, even though they are otherwise compliant with the Directive. They must be re-certified under the IVDR, except for self-test.

What is the “sell-off” provision about?

The “sell-off” provision is intended to limit the time during which devices that are compliant with the Directive and have already been placed on the market may be made available.

Any devices that are still within the supply chain and that have not reached their final user as being ready for use, for example a hospital, on 27 May 2025 are no longer marketable and must be withdrawn.

Once a Directive-compliant device has been made available to the final user by the deadline, the further making available of this device is not subject to/covered by the Regulation.

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