

# The transition to a new regulatory framework for *in vitro* diagnostic medical devices in the European Union

**This document provides an overview of the transition period from the IVD Directive 98/79/EC to the IVD Regulation (EU) 2017/746. It explains the impact for *in vitro* diagnostic (IVD) medical devices being placed on the market during the transition period.**

## Summary:

- From May 2017 to May 2022, IVDs will start to transition from being CE marked under the current IVD Directive 98/79/EC to being CE marked under the new IVD Regulation (EU) 2017/746.
- However, the transition may last until at least May 2024 for those IVDs that are certified by a Notified Body under the current Directive. No new certifications under the current Directive can take place after 26 May 2022.
- EU Member State authorities and Notified Bodies will continue to oversee the EU market, ensuring that all IVDs are fit for purpose and reliably provide information to be used for diagnostic purposes, regardless of whether they are CE marked under the current Directive or the Regulation.
- An IVD is not inferior simply because it is CE marked under the current Directive instead of under the new Regulation.
- Regulatory documentation - such as Declarations of Conformity, certificates, labels and instructions for use – issued under the current Directive, may remain valid until up to approximately May 2024, and can both continue to be used and will lawfully remain in circulation.

## The European Union regulatory framework for IVDs

Since 1998, Directive 98/79/EC has regulated *in vitro* diagnostic (IVD) medical devices that are placed on the European Union (EU) market. This legislation, which aims to ensure that IVDs are fit for purpose and reliably provide information to be used for diagnostic purposes, is currently being replaced by a new EU IVD Regulation: Regulation (EU) 2017/746.

The system for ensuring that IVDs meet the necessary standards, specifications, quality, safety and performance requirements is complex. This is reflected in the several years given to allow a smooth transition from the Directive to the Regulation.

EU Competent Authorities, Notified Bodies (i.e. conformity assessment bodies), manufacturers and other supply chain operators will need time to smoothly transition to the new EU Regulation. They therefore have a clearly-defined transition period in the Regulation.

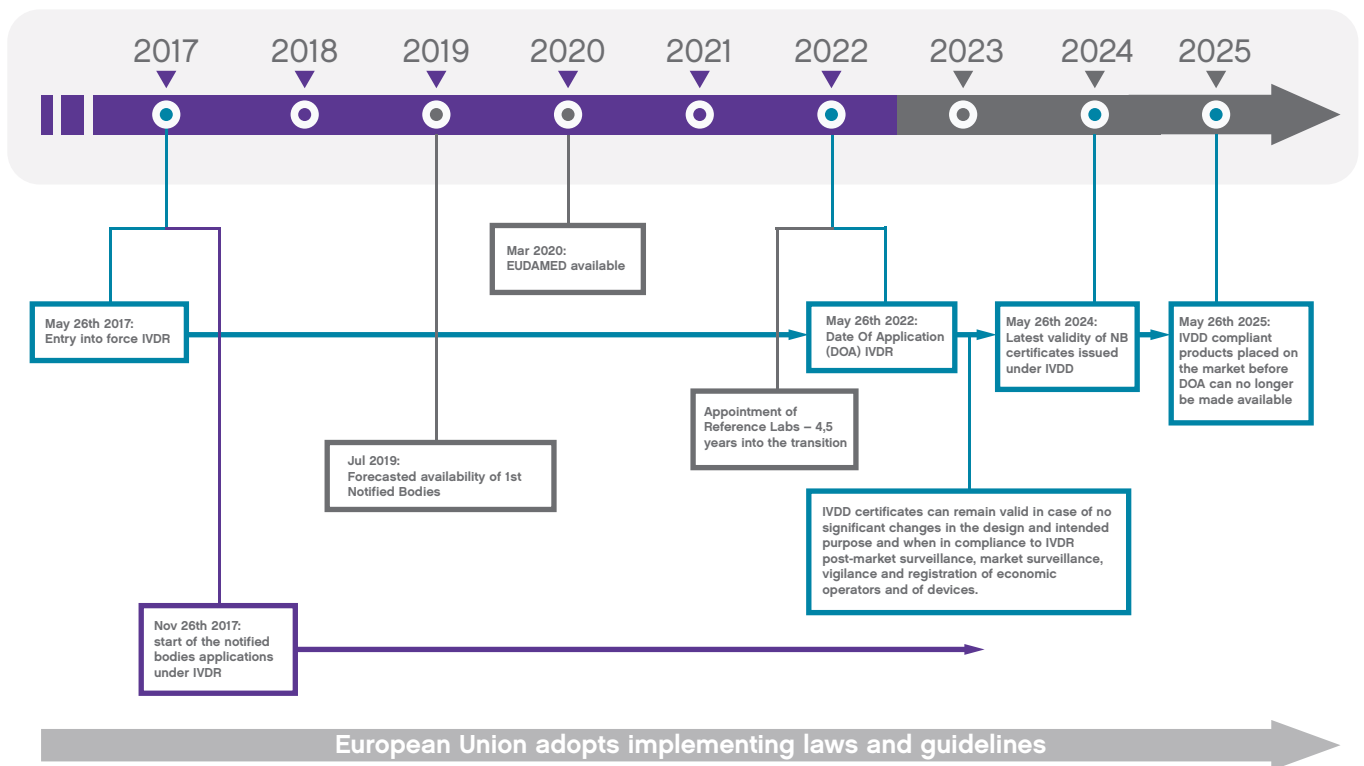
**During this transition period, which lasts until 26 May 2022, IVDs can be placed on the EU market following either the current Directive or the new IVD Regulation.** Also, products which have been certified by a Notified Body under the IVD Directive, may have (up to) an additional two years after 26 May 2022, during which they can continue to be placed on the market, i.e., up until 26 May 2024. IVDs that are not supervised by Notified Bodies under the Directive must comply with the new Regulation, from 26 May 2022 onwards, in order to be lawfully placed on the market.

**It is therefore both anticipated and in line with EU legislation for IVDs to continue having, until at least 26 May 2024, regulatory documentation issued under the current Directive,** including but not limited to:

- Declarations of Conformity (DoCs),
- Certificates issued by Notified Bodies,
- Labelling (instructions for use, product labels, etc.), and others
- etc.

This documentation, issued under the Directive, can be valid until May 2024, as can any related Free Sale Certificates issued by EU Member States.

This valid documentation may therefore remain in circulation, in parallel with new regulatory documentation issued under the new Regulation. Regulatory documents, issued under the new Regulation, may have additional content and different formatting, compared to similar documents issued under the current Directive. This is, again, acceptable and in line with EU legislation.



**Q. Why does it take so long to transition from the current Directive to the new Regulation? If it is the law, everyone must follow it, right?**

Yes, everyone must transition to the new Regulation. But in order to do so it must be possible to follow the law. The overall safety and performance requirements of the Regulation are consistent with those of the Directive, and both systems enable the CE marking of IVDs. However, the Regulation system adds some new requirements that are intended to be phased in over time.

Detailed secondary legislation, containing important implementation details, will be prepared and published by the European Commission over a number of years. This secondary legislation will address precisely how key provisions of the new Regulation will work. For example, further detailed information will be available regarding how the new European Database on Medical Devices (Eudamed) functions, and which reference laboratories may support the certification of certain high-risk IVDs.

A requirement for all key stakeholders in the process is education about and adaptation to the new Regulation, for example:

- EU Member State authorities will need to effectively monitor the new vigilance system, which relies on new tools yet to be available, such as the new Eudamed database.
- Notified Bodies will need to be assessed and designated under the new regulation, before they can then conduct audits of manufacturers and of IVDs.
- Manufacturers must classify their products appropriately and ensure that all product documentation and evidence of compliance is made available and conforms with the new Regulation.

The above changes will require considerable time and effort. Everyone involved has a lot of work to do before they can comply with the new Regulation.

**Q. Are IVDs CE marked under the Directive still fit for market circulation?**

Yes, all validly CE marked IVDs can continue to be placed on the EU market during the transition and until the related certificate (for IVDs under Notified Body supervision) expires. It is important to note that there will be a period of up to approximately 7 years, during which time certain IVDs CE marked under the Directive, and those CE marked under the new Regulation, will both simultaneously (and lawfully) be in circulation.

Simply because an IVD is CE marked under the current Directive does not mean it is exempt from the requirement to be fit for purpose and reliably provide information to be used for diagnostic purposes. In addition, IVDs CE marked under the current Directive will still be subject to an extensive vigilance process to ensure that any problems which may arise are rapidly identified and corrected.

Simply because an IVD is on the market under the current Directive does not mean that it is inferior to an IVD that has been CE marked under the new Regulation before May 2024.

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