MedTech Europe
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# The transition to a new regulatory framework for medical devices in the European Union

**This document provides an overview of the transition period from the Medical Devices Directives to the Medical Devices Regulation (EU) 2017/745. It explains the impact for medical devices being placed on the market during the transition period.**


**Summary:**

- From May 2017 to May 2020, Medical Devices will start to transition from being CE marked under the two current (and separate) Medical Devices Directives - Directive 93/42/EEC and Directive 90/385/EEC to being CE marked under the new Medical Devices Regulation (EU) 2017/745.
- However the transition may last until at least May 2024 for those devices that are certified by a Notified Body under the current Directives. No new certifications under the current Directives can take place after 26 May 2020.
- EU Member State authorities and Notified Bodies will continue to oversee the EU market, ensuring that all medical devices are safe and perform as intended, regardless of whether they are CE marked under the current Directives or the new Regulation.
- A medical device is not inferior simply because it is CE marked under one of the current Directives instead of under the new Regulation
- Regulatory documentation - such as Declarations of Conformity, certificates, labels and instructions for use – issued under the current Directives, 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 medical devices

Since the 1990s, Directive 90/385/EEC (for active implants) and Directive 93/42/EEC (for other medical devices) have regulated medical devices that are placed on the European Union (EU) market. This legislation, which aims to ensure that medical devices are safe and perform as intended by the manufacturer, is currently being replaced by one single new EU Medical Devices Regulation: Regulation (EU) 2017/745.

The system for ensuring that medical devices 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 Directives 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.

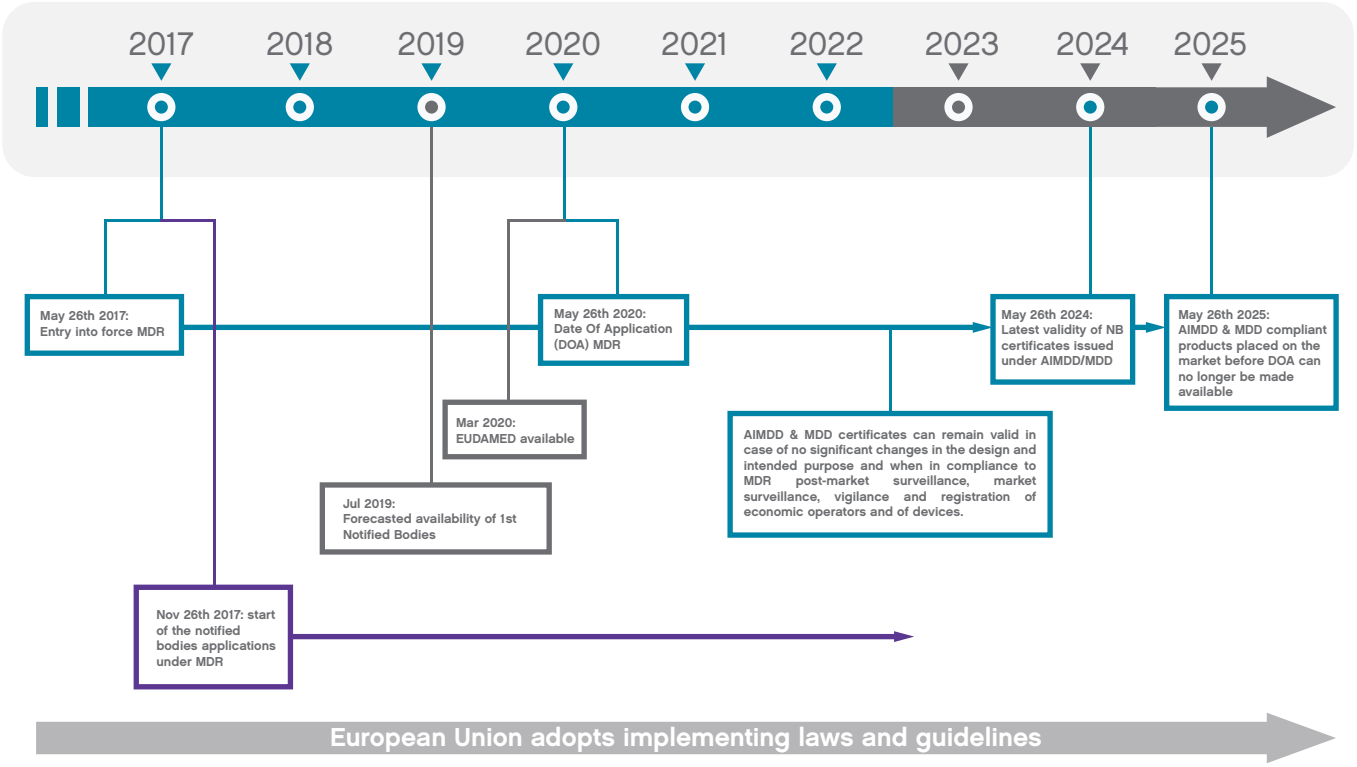
**During the transition period, which lasts until 26 May 2020, medical devices can be placed on the EU market following either the current Directives or the new Regulation**. Also, medical devices which have been certified by a Notified Body under one of the old Directives may have (up to) an additional two or four years after 26 May 2020, during which they can continue to be placed on the market, i.e., up until 26 May 2022 or 26 May 2024 (depending on the type of certificate the Notified Body granted under the Directives). Class I devices that are not supervised by Notified Bodies under the Directives must comply with the new Regulation, from 26 May 2020 onwards, in order to be lawfully placed on the market.

**It is therefore both anticipated and in line with EU legislation for medical devices to continue having, until at least 26 May 2024, regulatory documentation issued under the current Directives**, 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 Directives, 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 Directives. This is, again, acceptable and in line with EU legislation.**




**Q. Why does it take so long to transition from the current Directives 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 Directives, and both systems enable the CE marking of medical devices. 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 expert panels may support the certification of certain high-risk medical devices.

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 made 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 medical devices.
- 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 Regulations.

**Q: Are medical devices CE marked under the Directives still fit for market circulation?**

**Yes, all validly CE marked medical devices can continue to be placed on the EU market during the transition and until the related certificate (for products 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 devices CE marked under the Directives, and those CE marked under the new Regulation, will both simultaneously (and lawfully) be in circulation.**

Simply because a medical device is CE marked under one of the current Directives does not mean it is exempt from the requirements to be safe and to perform as intended. In addition, medical devices CE marked under the current Directives will still be subject to an extensive vigilance process to ensure that any problems which may arise are rapidly identified and corrected.

**Simply because a medical device is on the market under one of the current Directives does not mean that it is inferior to a device that has been CE marked under the new Regulation before May 2024.**

For more information please contact MedTech Europe: regulatory@medtecheurope.org