

Implementing the new IVD and Medical Devices Regulations - Transition Periods -

MedTech Europe calls on the European Commission and Member States to ensure the support for consistent interpretation and respect for the transition periods of the new In Vitro Diagnostic (IVD) Medical Device and the new Medical Device (MD) Regulations. For all the actors, like EU and non-EU hospitals, clinical laboratories, authorities and payers, and all other relevant stakeholders, there is a demonstrable need for clarity and consistent application of the various transitional arrangements foreseen within the three-year (for medical devices) and five-year (for IVDs) transition periods.

This time is needed to establish the new regulatory system and to allow the issuing of CE-marking certificates under the new Regulations. Furthermore, markets from both within and outside the EU should continue to accept products complying with the current Directives until the new Regulations become fully applicable in May 2020 for MDs and in May 2022 for IVDs.

The transition periods are long, but they are essential for proper implementation of the system.

The medical technologies industry is concerned that there is currently a lack of clarity between authorities, notified bodies and industry regarding the complex transitional provisions and timelines of each of the new Regulations. The new Regulations provide all actors with several years to transition from the Directives to the Regulations. This time is needed for all players to fully apply the new system, e.g. for designating notified bodies; harmonising standards to the Regulations; and setting up the EU database (Eudamed), to name a few. These changes will require considerable time. Everyone involved has a lot of work to do before they can comply with the new Regulations. Only if that work is completed can manufacturers plan and implement (re-)certification of their existing and new product portfolios.

Most diagnostics and devices cannot comply yet with the new Regulations. Secondary legislation, containing important implementation details, still needs to be prepared, agreed upon and then published by the European Commission. This secondary legislation is needed to specify how key provisions of the new EU Regulations will work, such as how the new Eudamed will function. Moreover, new governance and oversight structures need to be set up, such as the Medical Devices Coordination Group, notified bodies, expert panels and reference laboratories that will support certification of certain high-risk devices, etc.

For some years, the current IVD and Medical Devices Directives will remain valid EU laws.

It is important to stress that until the end of the transition periods, namely 26 May 2020 for MDs and 26 May 2022 for IVDs, the EU medical devices directives will remain valid and fully applicable. This means that products can be placed on the market, following the rules of the current Directives.

Additionally, in certain cases, the certificates issued under the Directives can continue to be valid beyond those transition periods:

- **Medical devices** may continue to be placed on the market up until 26 May 2022 or 26 May 2024, subject to conditions and depending on the type of certificate issued (note: Class I MDs without certificates only have until 26 May 2020), and
- **IVDs** may continue to be placed on the market up until 26 May 2024, again subject to conditions (note: this provision is applicable only to a small percentage of higher risk and self-tests IVDs).

The industry therefore needs a strong explanation and communication effort from the Commission and Member States, to ensure that all relevant stakeholders understand and accept the transition periods and the continued validity of CE-marking certificates under the current Directives.

About MedTech Europe

MedTech Europe is the European trade association representing the medical technology industries, from diagnosis to cure. Our members are multinational companies and national medical technology associations operating in Europe and worldwide

There are more than 500,000 products, services and solutions currently made available by the medical technology industry. These range from bandages, blood tests and hearing aids to cancer screening tests, pacemakers and glucose monitors. Our sector employs more than 650,000 people. There are more than 26,000 medical technology companies in Europe, of which 95% are SMEs.

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