

MedTech Europe urges EU authorities to make IVD Regulation implementation workable

Brussels, 09 July 2020 - MedTech Europe, the trade association representing the medical technology industry, is raising the alarm on the halted progress in implementing the EU's *In vitro* Diagnostic Medical Device Regulation (IVDR).

The new IVD Regulation will enter into legal application on 26 May 2022 and will introduce significant changes in the regulatory infrastructure of the IVD sector. The industry continues to welcome the new IVD Regulation and remains committed to making it succeed in order to continue serving patients and healthcare systems with high-quality tests.

The industry remains concerned, however, that many critical building blocks needed in the infrastructure do not exist until now.

Elements of this infrastructure include guidance documents, EU reference laboratories, and common specifications. At the same time, notified bodies must be re-designated against considerably strengthened requirements. Without this infrastructure being made fully available, the certification of tests cannot be completed.

The COVID-19 pandemic posed even more challenges in the implementation work as it shifted the focus of Member State authorities, laboratories, health institutions and the IVD manufacturers away from IVDR implementation.

Serge Bernasconi, CEO of MedTech Europe, states that the *“diagnostics industry continues to be committed to helping Europe combat COVID-19 and works towards recovery from the crisis. However, the pandemic impact on the IVDR implementation has been considerable, and this must be neither underestimated nor ignored.”*

In vitro diagnostics remains an extremely critical element of the healthcare sector – in particular around the screening, diagnosis, prediction and monitoring of medical conditions in Europe. The vital role of diagnostics has been proven in the COVID-19 pandemic, where tests represent an indispensable part in managing the acute crisis and in supporting effective exit strategies.

MedTech Europe has published a [position paper](#) today outlining the growing concerns of the sector. The association encourages immediate dialogue with stakeholders to ensure continued actions to address the current public health challenge and appropriately adjust IVDR implementation activities.

Serge Bernasconi further states that *“MedTech Europe and the diagnostics industry are ready to fully engage in discussions with authorities and stakeholders to find workable solutions and make the implementation of the new IVD framework successful.”*

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, visit www.medtecheurope.org.

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