Industry reinstates its call for solutions to ensure a workable transition to the new regulatory frameworks for medical devices and *in vitro* diagnostics

Barely seven months remain until the 26 May 2021 (re-)certification deadline for medical devices, and 19 months until the 26 May 2022 deadline for *in vitro* diagnostics (IVDs). The medical technology industry continues to urge EU-level action to solve the ongoing implementation challenges, to enable a successful transition to the new rules, and to safeguard the continuity of patient care, particularly in the COVID-19 pandemic.

MedTech Europe, the trade association representing the European medical technology industry, is concerned by statements made at a TOPRA Symposium last week regarding the EU's transition to the new Medical Devices Regulation (MDR) and *in vitro* Diagnostic Medical Device Regulation (IVDR).

Since Day 1, MedTech Europe and its members have welcomed the goal of strengthened regulation of medical devices and IVDs in Europe.

For MDR, our industry remains fully committed to complying with the new requirements of the MDR by its implementation deadline, despite Europe's very slow progress in making available the needed regulatory infrastructure. The medical devices industry is not requesting further delays to the MDR deadline.

The situation with the IVD Regulation, however, is very different and extremely alarming. Today, merely 4 Notified Bodies are designated to the IVDR to certify – for the very first time – some ~45.000 IVDs before the 26 May 2022 deadline. Moreover, critically needed IVDR infrastructure, such as EU reference laboratories, is yet to be put in place. Key guidance, on topics like clinical evidence and the new risk classification criteria, remains unpublished. And the list of concerns goes on.

"*Given how COVID-19 has brought the EU's IVDR implementation progress to a halt, compounding on the challenges that already existed, the remaining IVDR transition time is not tenable and urgently requires attention and solutions*," said Serge Bernasconi, CEO of MedTech Europe.

The ongoing pandemic has shown the critical role that *in vitro* diagnostics play each day in the seamless delivery of care to millions of patients and healthcare systems across Europe.

MedTech Europe is therefore reinstating its urgent call on the EU institutions to engage all stakeholders in dialogue, to solve the above public health challenges heightened by the ongoing COVID-19 pandemic.

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.

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