MedTech Europe welcomes the Medical Device Regulation's entry into full application and urges continued work to deploy the new regulatory system

26 May 2021, Brussels - Today's date of application of the Medical Device Regulation (MDR) marks an important milestone for the medical devices sector. Since the MDR's inception more than a decade ago, the medical technology industry has fully supported its goals and has heavily invested resources to comply with its strengthened requirements, geared towards protecting patients even further and increasing trust in the EU's legal framework.

The new regulatory regime for medical devices provides additional benefits including a strengthened notified body system, a new database enabling more transparency, a unique device identification system facilitating supply chain traceability, stricter clinical evidence requirements and more.

"Medical technologies save lives, improve health and contribute to sustainable healthcare. The new Regulations are welcomed by our industry as these will strengthen patient safety and the existing robust approval system of our sector", says Serge Bernasconi, CEO of MedTech Europe.

While the first "implementation" chapter closes today, the medical device industry and other stakeholders are now entering another second major chapter of the MDR story. While some positive progress was achieved in preparing the new infrastructure over the past four years, some key pillars of that infrastructure are still not fully operational or even in place.

The challenges industry currently faces include:

- Non-harmonised interpretation and application of MDR rules across the EU,
- Limited capacity among Notified Bodies, especially for certification of new and innovative devices,
- Uncertainties with regards to pending discussions on the rules and agreements between the EU and other countries, especially Switzerland, a key supplier of medical devices to the European Union, and
- Unpredictable recognition of MDR certifications at international level *vis-à-vis* regulatory approvals from other jurisdictions.

Until these challenges are resolved, roadblocks will continue to limit the sector's ability to seamlessly supply certified devices under the new rules. This is especially true for many small and medium enterprises (SMEs), who contribute a significant portion of Europe's medical device innovations.

Such challenges need ongoing attention and work by the EU Commission and Member States, if Europe is to ensure a workable system in the long-term.

Last but not least, a major overhaul of the diagnostics sector, with the *In Vitro* Diagnostic Regulation (IVDR), will apply in 12 months. As with the MDR, the medical technology industry fully supports the new regulatory

regime for IVDs but due to many factors, the system is not yet ready to support its implementation. Urgent solutions are needed here as well, and lessons learned from the MDR implementation should be taken into account.

"Due to the complexity of the Medical Device Regulation and the delay in the new system's full readiness, European patients are losing their previous opportunities to be the first to benefit from critical medical technology innovation. Solutions envisaged for MDR and IVDR should avoid unnecessary bureaucracy and most importantly ensure legal certainty, predictability and space for innovation to bloom in the EU," adds Serge Bernasconi.

MedTech Europe will continue to work with the EU institutions and stakeholders to rapidly propose solutions to avoid disruptions in the supply of life-saving medical devices and diagnostics.

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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