MedTech Europe
from diagnosis to cure

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# MedTech Europe urges the European Commission to prioritise the competitiveness of the medical technology industry for the benefit of patients in Europe

On behalf of the medical technology industry, MedTech Europe congratulates President Ursula Von der Leyen who was re-elected today to serve a second term at the head of the European Commission. The medical technology sector applauds the President's call for a major European competitiveness boost, as well as her commitment to make business easier and faster. The medical technology industry stands ready to support the European Commission and EU co-legislators in delivering on this political agenda for 2024-2029.

Europe is attractive for its innovative medical technology research ecosystem, its efficient and accessible healthcare systems, and its growing efforts towards value-based healthcare. However, Europe's current political, legislative, and regulatory trajectory gives investors cause for hesitation. We support policymakers and stakeholders to work collaboratively and proactively together to keep Europe's innovation and investment landscape attractive and globally competitive.

It is imperative to ensure that healthcare across Europe is patient-centric and resilient and that healthcare systems are digitally advanced and sustainable. This is a crucial time for the European Commission to champion policies that support patients and healthcare systems. Such policies need to ensure equitable access to top-tier healthcare for all patients in Europe, foster a unified digital health ecosystem across Europe, build resilient healthcare systems capable of withstanding future crises, and establish healthcare systems that are financially and environmentally sustainable. We cannot lose sight of these goals over other priorities. The Commission should now work with the Council, the European Parliament and stakeholders to build a healthier Europe.

There is a crucial need to ensure access to medical technologies for patients across the EU. To achieve this, reforming the regulatory system for medical technologies should be centre stage when implementing the Commission's agenda. Seven years after their publication, the Medical Devices (MDR) and In Vitro Diagnostic Medical Devices (IVDR) Regulations[1] continue to hamper access to life-saving and life-sustaining medical technologies as they are plagued by inefficient and unpredictable processes, skyrocketing cost of compliance, insufficient support for innovation, and a lack of accountable governance.

The time has come to deliver urgent and effective reform and ensure that the regulations deliver for patients. We appreciate the call from several policymakers for swift and meaningful reform, including recent suggestions to amend the MDR which represent a significant contribution to the discussion. We urge the re-elected Commission President to make an early and comprehensive reform of both the MDR and the IVDR central to her health and competitiveness agenda, taking into account input from their targeted evaluation.

Providing over 500,000 medical technologies and employing more than 880,000 people across the member states, the medical technology sector offers multiple solutions to existing health, societal, and economic

[1] *In Vitro* Diagnostic Medical Devices Regulation 2017/746/EU (IVDR) and Medical Devices Regulation 2017/745/EU (MDR).

challenges. An important prerequisite for this will be a European market that invites investment, fosters innovation, and provides a regulatory framework that is lean and efficient.

## 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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