

# MedTech Europe Priorities for the Polish Presidency of the Council of the European Union

November 2024

As Poland prepares to lead the Council of the EU from January to June 2025, MedTech Europe welcomes the Presidency's announced priorities and is eager to contribute to advancing shared goals. MedTech Europe calls on the Presidency to prioritise health, innovation, and competitiveness to build a resilient and strong Europe. Ensuring the availability of and access to high-quality medical technology and care, advancing digitalisation in health, and supporting health system resilience and sustainability will contribute to increasing security in all dimensions.

To ensure Europe's continued global leadership in healthcare innovation, MedTech Europe encourages the Polish Presidency to align regulatory requirements across policy areas, reducing legal uncertainty and market fragmentation. Harmonising regulations and cutting administrative and reporting burdens will foster investor confidence and support more efficient and sustainable healthcare systems driving European industry's competitiveness. In this context, a predictable, consistent and well-governed regulatory framework is essential for medical technology innovation to thrive while ensuring safety, efficacy, and availability for patients. MedTech Europe calls on the Polish Presidency to address ongoing challenges in the implementation of the Medical Devices Regulation (MDR) and *In Vitro* Diagnostics Regulation (IVDR). Swift action to overcome these challenges, along with efforts to simplify processes and enhance regulatory coherence with digital health and sustainability goals are key to reducing legal complexity, fostering innovation, and enhancing access to cutting-edge care. We welcome the emphasis placed on building resilience of the environment and societies to climate change and promoting the fight against the causes and effects of climate change first and foremost through incentives and support.

In digital health, supporting patient access to state-of-the-art, safe, and cyber-secure digital health technologies should take priority. Strengthening the overall cyber-resilience of European health systems will be key to strengthening security. This includes increasing capacity and cyber-expertise in healthcare systems and addressing system vulnerabilities holistically. Additionally, in the harmonised implementation of the European Health Data Space (EHDS) should be prioritised, with the Presidency addressing open questions on scope, definitions, and the framework for electronic health record systems (EHR). In parallel, advancing the implementation of the AI Act, ensuring clarity, consistency, and alignment across existing and future regulations will further foster innovation while safeguarding safety and fairness in AI applications.

Medical technologies play a pivotal role at every step of the patient journey, from prevention and early diagnosis to treatment and recovery. By reducing disease burdens, empowering patients, and enhancing healthcare system efficiency, these technologies deliver long-term value and resilience to healthcare systems. In addition to policies that prioritise prevention, attention must be given to the full patient pathway to address health holistically and achieve the best outcome for patients and health systems in Europe.

MedTech Europe stands ready to collaborate with the Polish Presidency to advance these priorities during its upcoming mandate. Together, we can strengthen Europe's resilience, innovation, sustainable prosperity and competitiveness to build a healthier and more secure future for all.

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### **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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