# MedTech Europe reaction to the European Parliament's Joint Motion for a Resolution on the urgent need to revise the Medical Devices Regulation

23 October 2024

MedTech Europe welcomes today's resolution from the European Parliament calling for measures to address the most pressing challenges and bottlenecks in the implementation of the Medical Devices Regulation (MDR) and *In Vitro* Diagnostic Medical Devices Regulation (IVDR) by early 2025. We call on the European Commission to do their utmost to resolve such challenges and bottlenecks via any means that carry sufficient legal weight.

In the immediate term, the European medical technologies industry believes that the European Commission should focus on reversing the trend that many devices on the market today as well as future medical technologies are not reaching patients in Europe as they should.

Thus, MedTech Europe proposes immediate action to address the most pressing challenges and reduce bottlenecks: reducing and making predictable initial assessment timelines and costs, making assessments of changes to medical technologies more efficient, building an accelerated pathway for breakthrough innovation, and adapting certification timelines to follow a life-cycle approach. All these measures are needed to ensure availability of devices for patients – including availability of first in class and best in class medical technologies as well as maintaining existing devices for Europe's patients and health systems.

MedTech Europe also supports the Parliament's call on the Commission to propose the systematic revision of all relevant articles of these regulations, accompanied by an impact assessment, to be conducted as soon as possible. In this context, we welcome the swift publication of a clear revision timeline and an identification of areas for intervention by the European Commission. This should accompany the Targeted Evaluation and result in a full legislative proposal immediately following that assessment.

MedTech Europe welcomes the specific areas for attention which are called out in the Resolution, including its focus on bringing predictability, support for innovative and life-saving medical technologies, the support of SMEs and eliminating unnecessary administrative burdens. In addition to these items, it is critical that a systematic revision of these regulations also include establishing a single, dedicated governance structure to oversee the regulatory system and ensure that it remains sustainable, efficient and delivers for patients.

MedTech Europe remains committed to working closely with the European Commission, European Parliament and Member States to ensure that the MDR and IVDR meet their objectives and foster a regulatory environment that supports innovation, protects public health and maintains the availability of life-saving medical devices across Europe.

## 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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