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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
Subject:	COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE EVALUATION on the Targeted evaluation of Regulation (EU)2017/745 on Medical Devices and Regulation (EU)2017/746 on In vitro Diagnostic Medical Devices *Accompanying the document* Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I

Delegations will find attached document SWD(2025) 1052 final.

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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE EVALUATION

on the Targeted evaluation of Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In vitro Diagnostic Medical Devices

Accompanying the document

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and *in vitro* diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I

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1. Context

Medical devices and *in vitro* diagnostic medical devices (IVDs) are crucial for healthcare, providing essential solutions to help diagnose, prevent, and treat diseases. In Europe, there are over 2 million medical technologies, including X-ray machines and pacemakers and IVDs such as HIV and pregnancy tests, play a key role in clinical decision making. In 2025, the European medical device market is estimated at approximately 170 bn EUR, making it the second largest in the world. Since the 1990s, EU rules have existed to ensure safe and performant devices are available to patients. In 2017, two EU Regulations replaced three Directives under which safety crises arose, to create a strengthened and more sustainable framework, protecting patient health whilst supporting innovation.

Challenges in transitioning to these Regulations led to extended transition periods for devices moving from the Directives to the Regulations to mitigate the risk of shortages and implementation delays, exacerbated by the COVID-19 pandemic.

2. The Targeted Evaluation

While an evaluation is legally required by May 2027, in light of the above, the Commission initiated a targeted evaluation of the Regulations in 2024, covering the period between their adoption on 5 April 2017 and 31 December 2024. Whilst implementation is still on-going, it has assessed how the EU Regulations on medical devices are performing to date and in particular the impacts on device availability, innovation, costs and administrative burdens, especially for SMEs. The analysis covers whether the Regulations are so far effective in meeting their objectives, cost-efficient, coherent to other EU legislation and fit for purpose whilst bringing EU added value. The findings are based on a broad evidence base but are subject to limitations on data availability and a cost-benefit quantification.

3. Key findings

The evaluation found that while the EU Regulatory framework **benefits from a more robust infrastructure for safe and performant medical devices,** it is **not always effective** in achieving its objectives. Furthermore, implementation delays, increased administrative burdens, and inconsistent application of requirements have revealed shortcomings and **structural inefficiencies** leading to unpredictability, reduced device availability and impacting competitiveness.

Whilst the Regulations have brought **benefits for patients**, through stronger safety requirements and oversight mechanisms, compliance **costs are disproportionate and unevenly distributed**, particularly affecting SMEs and niche device manufacturers. Streamlining procedures, reducing administrative complexity, along with more flexible regulatory pathways would help balance regulatory burdens against public health gains.

Whilst the MDR and IVDR are generally coherent with one another, stakeholders highlighted the need to avoid contradictory requirements or overlaps in their **coherence** with other EU digital, environmental and health legislations. The Regulations offer **EU added value** by providing a unified framework over individual national laws, preferred by stakeholders for

improved consistency and potential cost-efficiency. Finally, while the **Regulations remain relevant** to their objectives of ensuring patient safety, public health protection, and market functioning, challenges in innovation, technological development, and competitiveness indicate the need for **targeted adjustments** to better align with evolving market realities.