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NOTE

From:	General Secretariat of the Council
To:	Council
Subject:	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 *- General approach* *- Statements*

Germany, France and Denmark have requested that the following statement be entered in the Council minutes:

Statement by Germany, France and Denmark

On the 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 (COM/2025/1023 final)

The revision of the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR), is an important opportunity to substantially simplify the EU regulatory framework, improve the security of supply and the competitiveness of the medical devices and in vitro diagnostic medical devices industry in the European Union, while maintaining a high level of patient safety.

Germany, France and Denmark are fully committed in delivering on these objectives and appreciate the efforts made by the Presidency to work in this direction. Nevertheless, the current compromise text falls short of the necessary reform objectives. In particular, it lacks effective measures to strengthen the competitiveness of the European medical technology sector, as urged in the Draghi and Letta reports.

Germany, France and Denmark therefore reiterate two key demands that were also raised during the negotiations:

1. Complete removal of mandatory recertification

We call for the complete removal of the five-year recertification requirement for all devices, as introduced by the Commission in its legislative proposal. According to estimates by the European Commission, this would generate annual savings of approximately EUR 227 million.
Patient safety is ensured through the regular monitoring of Notified Bodies, vigilance activities and regulatory market surveillance. Compulsory recertification will result in unnecessarily high costs for patients and public health systems without strengthening patient safety. The capacities freed up at Notified Bodies as a result could be redirected towards the certification of innovative medical devices.

2. Creating a level playing field for European manufacturers

The compromise text facilitates access to the European market but fails to provide sufficient incentives to ensure that medical devices continue to be researched, developed and manufactured in the EU. It is important that the simplification agenda also ensures a level playing field for medical devices developed and produced in Europe.

There must not be incentives in the MDR/IVDR that expose European based manufacturers, particularly SMEs, to greater regulatory oversight than manufacturers of similar products in third countries. This will ultimately undermine the intended reduction of regulatory burden for European industry.

Germany, France and Denmark therefore call for targeted reduction of regulatory burden for manufacturers based in the European Union using a risk-based approach that recognises that European manufacturers often are subject to direct supervision by national authorities whilst manufacturers in third countries are not exposed to comparable regulatory oversight.

Europe must not merely serve as a sales market for medical devices; it must also remain a leading location for research, development and manufacturing. This is a matter of competitiveness, technological sovereignty and security of supply.

Germany, France and Denmark will therefore continue to work to overcome these shortcomings in the legislative process in Council and will advocate for substantial improvements throughout the trilogue negotiations.

Italy has requested that the following statement be entered in the Council minutes:

Statement by Italy

on the PROPOSAL AMENDING
THE MEDICAL DEVICES REGULATION AND THE IN VITRO DIAGNOSTIC REGULATION
ST 15342/26

Italy welcomes the Presidency compromise proposal for a Council General Approach on the targeted revision of the Medical Devices (MDR) and In Vitro Diagnostic Medical Devices (IVDR) Regulations.

We view the current draft as a pragmatic and well-balanced outcome. It effectively addresses structural bottlenecks, streamlines administrative burdens and enhances regulatory predictability for manufacturers, while safeguarding public health and maintaining high standards of patient safety. For these reasons, Italy supports the adoption of the General Approach.

In particular, the compromise introduces important operational flexibilities for Notified Bodies and prioritised pathways for breakthrough and orphan devices, while ensuring continued patient access to critical health technologies. Furthermore, it establishes objective and predictable safeguards for strategic sectors, ensuring that compliance verifications remain strictly product-specific and evidence-driven.

Italy welcomes the balanced solutions reached on governance and product qualification. The text appropriately preserves the primary responsibility of national competent authorities, while defining clear administrative boundaries for Union agencies.

Nevertheless, on this point, Italy would have preferred the principle enshrined in Recital 11 — requiring specific and substantiated evidence before raising doubts about products already covered by a valid certificate — to be reflected more directly in the operative provisions (Article 4 MDR and Article 3 IVDR), we consider its inclusion an essential interpretative cornerstone for ensuring legal certainty.

At the same time, we understand that this text represents a delicate and carefully negotiated balance, reflecting a mature consensus achieved through intensive work, and maintaining its stability is paramount.

For these reasons and in a spirit of compromise, Italy supports the compromise text proposed by the Presidency.