COCIR response to the publication of the Proposal for a Targeted Revision of the Medical Device Regulation (MDR)

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The medical devices sector is a strategic industry for the European Union. It enhances the resilience of healthcare systems, playing a critical role in advancing the diagnosis and treatment of diseases. It also fuels innovation across the life sciences ecosystem.

COCIR welcomes the publication of the legislative proposal for a targeted revision of the Medical Devices Regulation (MDR). We **thank the European Commission for its efforts to address the challenges** observed with the implementation of the current framework over the past eight years.

This revision is a cornerstone for the European Commission to deliver on its political guidelines to increase the competitiveness and attractiveness of Europe. COCIR fully supports the overall simplification objective while maintaining a high level of patient safety.

As political negotiations begin, we encourage EU co-legislators to reach an agreement on a legal text that ensures:

- predictable, proportionate and efficient certification process,
- system centralization with Notified Bodies' oversight,
- harmonised application and interpretation across EU Member States,
- ambitious approach to fast-track pathways for innovation,
- alignment of MDR with other relevant EU legislation, including the integration of AI requirements in Medical Devices Regulation,
- promotion of international reliance,
- faster adoption of harmonised standards.

"The MDR revision represents a critical opportunity to establish a globally leading regulatory framework that reduces bureaucracy and legal uncertainty while safeguarding patient safety.

COCIR remains fully committed to work with all stakeholders to advance possible solutions. We look forward to continuing a constructive dialogue with policymakers over the coming months, which will be crucial to **boost the competitiveness** of the European market, while **safeguarding continued access to safe and innovative** medical devices.", highlighted COCIR Secretary General Klaus-Dieter Axt.

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About COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. We provide a wide range of services on regulatory, technical, market intelligence, environmental, standardisation, international and legal affairs. COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (globalditta.org). www.cocir.org