



Towards More Predictable Conformity Assessments in the EU:

Annex VII Implementing Act

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COCIR Statement on Annex VII Implementing Act

COCIR welcomes the adoption of [Commission Implementing Regulation \(EU\) 2026/977](#) (Annex VII on Notified Bodies' procedures) as a timely and necessary measure towards a **more predictable and harmonised EU medical devices system**. We appreciate the efforts of EU and national authorities in delivering this important outcome. The act introduces clear timelines and enhanced transparency for conformity assessment activities in Europe.

A more efficient system is essential to support timely certification processes and ensure patient access to safe medical devices faster, while maintaining the high safety standards under the Medical Device Regulation (EU) 2017/475 (MDR). Increased regulatory certainty also enables manufacturers to plan market access of innovative devices with greater confidence. This will **strengthen trust in the CE marking system and EU's competitiveness**.

We look forward to continued collaboration with notified bodies to ensure effective implementation of the act.

In parallel, the ongoing revision of the MDR provides a critical opportunity to build on this progress **towards a globally leading regulatory framework**. Key priorities should include reducing unnecessary administrative burden (removal of re-certification), achieving coherence among EU laws (sectoral approach for AI enabled medical devices under the AI Act), and make use of international best practices (recognition of MDSAP Certificates), while fully preserving the principles of the MDR that ensure high standards of safety and performance.

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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