

BRUSSELS, 7 MAY 2026

# AI omnibus: DIGITALEUROPE welcomes machinery breakthrough but warns medtech left behind

Last night's trilogue agreement on the AI omnibus delivers a major win for Europe's manufacturers, but a missed opportunity for its medtech innovators.

Manufacturers across Europe will no longer face double conformity assessment under both the AI Act and their existing safety framework.<sup>1</sup> For a typical SME, this eliminates up to €600,000 in duplicative Year 1 compliance costs.<sup>2</sup> Machinery moved from Section A to Section B of Annex I.

**Medical devices, however, were left out.** Europe's medtech companies, 95% of them SMEs and innovative scale-ups, still face overlapping obligations under the Medical Device Regulation and the AI Act, despite the Commission's own December proposal to fix this. The EU is already no longer a first-launch market for medical devices; adding AI Act duplication will widen that gap.

**Cecilia Bonefeld-Dahl, Director General of DIGITALEUROPE, said:**

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**“***Draghi 1, Red Tape 0 – European Parliament champions simplification...the simplification game continues. This is what happens when legislators listen to industry: European manufacturers just got a regulation that allows them to innovate with AI. Europe can lead on AI safety without adding additional burden to its companies. Unfortunately, the co-legislators dropped the ball for our medtech innovators and connectivity champions.*

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The deal also includes a mechanism to limit duplicative requirements through delegated acts. There are also clarifications that could reduce uncertainty for connected device makers under the Radio Equipment Directive. These improvements must now be delivered with genuine industry input and support to European companies who are champions of connectivity.

Europe accounts for less than 10% of global AI investment<sup>3</sup>, whilst its major opportunity to win the AI race lies in these industrial sectors. Yet overlapping regulation risks making innovation

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<sup>1</sup> European Commission press release, 'Commission welcomes political agreement on new rules to ensure the safety of machinery and robots,' 15 December 2022, available at [https://ec.europa.eu/commission/presscorner/api/files/document/print/en/ip\\_22\\_7741/IP\\_22\\_7741\\_EN.pdf](https://ec.europa.eu/commission/presscorner/api/files/document/print/en/ip_22_7741/IP_22_7741_EN.pdf).

<sup>2</sup> Based on R. Kilian, L. Jäck & D. Ebel, *European AI Standards: Technical Standardization and Implementation Challenges under the EU AI Act*, German AI Association / General Catalyst Institute, March 2025.

<sup>3</sup> Stanford University, *Artificial Intelligence Index Report 2025*, available at <https://hai.stanford.edu/ai-index/2025-ai-index-report/economy>.





and AI adoption significantly harder. A near-20% reduction in AI investment had previously been projected from implementing the AI Act.<sup>4</sup>

Moving machinery to section B reflects one of key proposals put forward by industry in recent weeks, including the joint industry letter led by DIGITALEUROPE and signed by over 50 EU and national associations, representing hundreds of thousands of companies.

DIGITALEUROPE congratulates the European Parliament, Council and Commission for finding common ground, and remains committed to working together on the technical finalisation and on further simplification.

FOR MORE INFORMATION, PLEASE CONTACT:

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### About DIGITALEUROPE

DIGITALEUROPE is the leading trade association representing digitally transforming industries in Europe. We stand for a regulatory and investment environment that enables European digitalising businesses across multiple sectors and citizens to prosper from digital technologies. We wish for Europe to grow, attract and sustain the world's best digital talents, investment and technology companies. Together with our members, we shape industry positions on all relevant policy matters, and contribute to their development and implementation. Our membership represents over 56,000 businesses who operate and invest in Europe. It includes 120 corporations which are global leaders in their field of activity, as well as 43 national trade associations from across Europe.

<sup>4</sup> Center for Data Innovation, *How much will the Artificial Intelligence Act cost Europe?*, July 2021, available at <https://www2.datainnovation.org/2021-aia-costs.pdf>.

