

MedTech Monthly

May 2026

Dear reader,

If there is a defining moment for European medtech, it is taking shape this May.

This month, we published **our position on the MDR and IVDR revision**, setting out concrete recommendations for a simpler, more predictable framework that puts patient safety, access, and European competitiveness at its centre. [Read it, share it, and use it.](#)

EU co-legislators have reached a deal on the **AI Act** this morning, and medical technologies will remain subject to its high-risk requirements. We fought for a single, coherent framework, and we did not get it. **The argument is not over; it moves to the MDR/IVDR revision**, and we intend to make it count.

Our CEO Oliver Bisazza reflects on MedTech Europe's participation in the first **European Health Industry Roundtable with Commissioner Várhelyi**, a milestone for our sector's standing in EU health policy dialogue. The Commission has also introduced new conformity assessment rules and launched a fast-track pilot for breakthrough cardiovascular technologies, both reflecting long-standing industry calls for action.

Progress on multiple fronts, with more still to secure. Next week, the conversation continues in person: join us in **Stockholm from 11 to 13 May** for the **MedTech Forum**. [Register here.](#)



WELCOME:
what the proposal gets right



STRENGTHEN:
targeted improvements needed



RETHINK:
reprocessing of single-use devices

Our position on the MDR/IVDR revision

Highlights of the Month



Working together for medtech: our conversation with Commissioner Várhelyi

[Oliver Bisazza](#), Chief Executive Officer

Last month, MedTech Europe joined the first European Health Industry Roundtable hosted by Commissioner Várhelyi, a significant moment for our sector's visibility at the highest level of EU health policy. In his latest blog, CEO Oliver Bisazza reflects on the key issues raised: regulatory modernisation, tariffs, health data and European competitiveness. Read on for his take on where progress is being made and where the work still lies ahead.

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Revision of the Medical Device and *In Vitro* Diagnostic Devices Regulations: MedTech Europe publishes its position

[Petra Zoellner](#), Director Regulatory Affairs (IVDR & MDR)

MedTech Europe has published its [position](#) on the [revision](#) of the Medical Devices Regulation ([MDR](#)) and *In Vitro* Diagnostics Regulation ([IVDR](#)), calling for a simpler, more predictable regulatory framework. The paper outlines key recommendations to address implementation challenges, improve patient access, and strengthen Europe's competitiveness in medical innovation.

[READ OUR POSITION PAPER](#)

AI Act deal lands: what it means for the medical technology sector?

[Leander Vranken](#), Manager Digital Health AI

EU legislators reached a deal on the AI Act in the early hours of this morning, confirming that medical technologies will remain subject to its high-risk requirements. MedTech Europe had advocated for a sector-specific approach. Our focus now shifts to the MDR/IVDR revision, where we will continue to press our case.

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New EU rules: more business predictability and transparency in medtech conformity assessment

[Merlin Rietschel](#), Associate Director Medical Devices

The European Commission has introduced a new [Implementing Regulation \(EU\) 2026/977 of 4 May 2026](#) to bring greater predictability, transparency and consistency to EU conformity assessment. MedTech Europe welcomes this step, which reflects long-standing industry calls for clearer timelines, reduced administrative burden, and stronger safeguards for manufacturers as a wider revision of the Medical Devices Regulation and *In Vitro* Diagnostics Regulation continues.

[READ OUR STATEMENT](#)



MedTech Views

Accelerating patient access to breakthrough medical technologies in Europe

Jana Russo
Senior Expert Medical Devices
MedTech Europe

On 28 April 2026, the EU launched a landmark pilot to fast-track breakthrough medical technologies, starting with cardiovascular innovations. The initiative aims to improve coordination, speed up approval processes and lay the foundation for a permanent EU pathway that accelerates patient access while strengthening Europe's innovation ecosystem.

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THE MEDTECH FORUM 2026

An event by  MedTech Europe
From diagnosis to cure

11 – 13 May
Stockholm

In Short

Europe's new Anti-Corruption Directive and the shift toward smarter integrity systems

[Marta Pacj](#), Senior Officer - Legal Counsel

The European Union has reached a decisive milestone in its anti-corruption agenda. On 21 April 2026, the Council of the European Union formally adopted a [Directive](#) establishing an EU-wide framework to prevent and combat corruption. This legislative development reflects a broader shift in global anticorruption thinking, identified in the [OECD Anti-Corruption and Integrity Outlook 2026](#).

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TEHDAS2 Stakeholder Forum: MedTech Europe contributes to the debate on EHDS and AI

[Verena Thaler](#), Senior Expert Digital Health

MedTech Europe took part in the third TEHDAS2 Stakeholder Forum (Second Joint Action Towards the European Health Data Space), representing industry views on the EHDS. The forum brought together stakeholders to discuss digital sovereignty and how to implement the EHDS to enable safe use of AI in healthcare.

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MedTech Europe participation at WHO governance meetings: WHA79 and EB159

[Clare Birmingham](#), Manager International Affairs

MedTech Europe will attend the WHO 79th World Health Assembly, 159th Executive Board and Global Diagnostic Coalition this May through the GMTA, engaging in discussions on diagnostics, digital health and AI and advocating for policies that support innovation, timely access to medical technologies and resilient health systems globally.

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MedTech Europe in the Media

[Dominika Suchonova](#), Manager Communications

- [POLITICO](#), 9 April 2026, **Medtech sector remains vigilant despite Middle East ceasefire**
- [MedTech Insight](#), 13 April 2026, **EU Data Act Brings Yet More Questions For Medtech**
- [Euractiv](#), 13 April 2026, **FIRST AID: health newsletter**
- [MedTech Insight](#), 28 April 2026, **RAPS 2026 Preview: EU Medtech Regulation At A Crossroads**
- [POLITICO](#), 28 April 2026, **AI omnibus crunch time. What's at stake for medtech?**
- [MedTech Insight](#), 29 April 2026, **MDR Breakthrough Medical Device Pilot Begins**

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Learn more about MedTech Europe's full position on the revision of the Medical Devices Regulation and In Vitro Diagnostics Regulation.



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