MedTech Europe
from diagnosis to cure

MedTech Monthly

June 2026

Dear reader,

If there is a defining question for European healthcare this month, it is not where our medical technologies are made. It is how we buy them. As our CEO Oliver Bisazza notes, strategic procurement must reward quality and value, not the lowest bid.

In the digital landscape, MedTech Europe has responded to the provisional agreement on the Digital Omnibus on AI and to the proposed revision of the EU Cybersecurity Act.

The WHO's activation of its Emergency Use Listing for Ebola Bundibugyo virus diagnostics sends another urgent signal to industry. Manufacturers, especially those producing BDBV nucleic acid tests, are encouraged to engage.

The mandatory use of the first four modules of EUDAMED marks a significant step forward in strengthening the EU's medtech ecosystem.

Read on to discover more.

Highlights of the Month

The most pressing question in European healthcare procurement is not where our medical technologies are made. It is how we buy them. Price-only tenders undermine innovation, raise long-term costs and disadvantage European suppliers. Strategic procurement must reward quality and value, not the lowest bid.

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What Europe's diagnostics need: new MedTech Europe paper on the revision of the *In Vitro* Diagnostics Regulation

Vaida Jukneviciute, Manager *In Vitro* Diagnostics

Diagnostics inform most clinical decisions and are essential for modern healthcare. As discussions on the revision of the In Vitro Diagnostics Regulation progress, MedTech Europe's new paper outlines targeted changes to the Regulation aimed at improving patient access, enabling innovation, and strengthening Europe's diagnostics sector.

READ OUR PAPER

Ebola Outbreak - Urgent call to manufacturers: WHO launches the Emergency Use Listing for BDBV Diagnostics

Alice Bova, Senior Officer International Affairs

The WHO has activated its Emergency Use Listing pathway for Ebola Bundibugyo virus diagnostics, urging manufacturers, especially those producing BDBV nucleic acid tests, to engage promptly. Companies should submit the WHO product questionnaire and IFU to initiate pre-submission discussions to **diagnostics@who.int**. This process aims to accelerate access to high-quality, safe, and effective diagnostics in times of emergency.

MORE INFORMATION

MedTech Europe reaction to the provisional agreement on the Digital Omnibus on Artificial Intelligence

Leander Vranken,
Manager Digital Health AI

Following a first unsuccessful trilogue on 28 April 2026, EU institutions reached a provisional agreement on the AI Omnibus on 6 May 2026. While a sectoral approach was introduced for machinery products, medical technologies remain subject to both AI Act and the Medical Devices Regulation (MDR) and *In Vitro* Diagnostics Regulation (IVDR) requirements. MedTech Europe is therefore continuing its advocacy in the MDR/IVDR revision discussions.

MedTech Europe responds to public consultation on the proposed EU Cybersecurity Act revision

Nicole Campagnola,
Officer Cybersecurity and Digital Infrastructure

On 20 January 2026, the European Commission unveiled its proposed revision of the Cybersecurity Act, as part of the broader cybersecurity package. Following this proposal, a public consultation has opened to which MedTech Europe has submitted its response.

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MedTech Europe in the Media

Dominika Suchonova, Manager Communications

- **POLITICO**, 5 May 2026, MDR/IVDR revision a 'good starting point'
- **Euractiv**, 5 May 2026, Medtech group calls to change EU single-use device rules
- **Medtech Insight**, 6 May 2026, Could Do Better: MedTech Europe Supports MDR/IVDR Revision Plan But Wants More
- **Medtech Insight**, 7 May 2026, Medtech AI Act Simplification Push Fails At Last Hurdle
- **POLITICO**, 7 May 2026, Europe's medtech loses push to swerve AI Act rules
- **Medical Product Outsourcing**, 8 May 2026, What U.S. Manufacturers Need to Know About EU's Medical Device Rules Fix
- **Euractiv**, 12 May 2026, MedTech Forum opens in Nobel banquet hall, setting tone for ambition
- **Euractiv**, 13 May 2026, Sweden warns on Europe's medtech future
- **Medtech Insight**, 15 May 2026, 'Seize The Global Initiative,' MedTech Forum 2026 Tells European Leaders
- **Euractiv**, 15 May 2026, Stuck in Limbo: How the EU is straining medtech entrepreneurs
- **Medical Buyer**, 15 May 2026, Stockholm: Where medtech found its pulse
- **Medtech Insight**, 21 May 2026, The Call At MedTech Forum 2026: Bring The Medtech Innovation Launch Pad Back To Europe
- **Medical Device Network**, 22 May 2026, The 2026 MedTech Forum: Europe's crisis preparedness takes the fore
- **Euractiv**, 28 May 2026, Buying European is not enough: Europe must buy better

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In Short

EUDAMED reaches a major milestone: mandatory use of the first four modules begins

Katalin Mate, Senior Expert Regulatory Affairs (IVDR & MDR)

28 May 2026 marks a major step forward in the EU's regulatory framework for medical devices and in vitro diagnostic medical devices. The first four modules of EUDAMED, the European Database on Medical Devices, become mandatory for use.

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Key IHI support and upcoming opportunities

Jeroen Schuermans, Director Strategic Initiatives

IHI has released a new Field Manual to help scale innovations from public–private partnerships, offering practical guidance on value creation and scale up pathways. In addition, upcoming highlights include the IHI Call Days for Call 13 in June 2026 and the October 2026 IHI Forum in Brussels focused on translating research into impact. Register now to get involved.

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Where to Find us in June

- **Brussels, 3-4 June 2026** — EU Green week — Sigrid Linher, Director Sustainability & Environment, Roumiana Santos, Senior Expert Chemicals, Alina Rachiteanu, Senior Officer Sustainability & Environment, Lorenzo Foglietti, Officer Sustainability & Environment, Hanna Saarinen, Intern Sustainability & Environment
- **Brussels, 4 June (online) 2026** — CVS training to PCOs — Pablo Rojas Abad, Associate Director Legal & Compliance – Senior Legal Counsel, Marta Paci, Senior Officer - Legal Counsel, Dhana Ong, CVS Compliance Officer, Sara Abanto, Assistant Compliance Officer
- **London, 9 June 2026** — Liability Frameworks in the Life Sciences sector and Implications for the EU Single Market Event — Pablo Rojas Abad, Associate Director Legal & Compliance – Senior Legal Counsel
- **Brussels, 9 June 2026**— Arnold & Porter EU/UK Medical Device & IVD Bootcamp — Flavia Pirovano, Manager Regulatory Affairs
- **Brussels, 9 June 2026** — Driving the Uptake of Medical Technologies in Cancer Care: Bridging Innovation and Access — Christopher Breyel, Director General European & Global Member Services, Alexander Olbrechts, Director Digital Health & Medtech Value
- **Bern, 10 June 2026** — Swiss Medtech Day 2026 – Oliver Bisazza, CEO
- **Stockholm, 11–14 June 2026** — EHA 2026 Congress – Jesús Rueda Rodríguez, Director General Industrial Affairs & Strategies
- **Oslo, 16 June (remotely) 2026** — BioMed Alliance Spring Meeting 2026 – Oliver Bisazza, CEO
- **Kyoto, 16-17 June 2026** — MDSAP Forum – Diana Kanecka, Director International Affairs
- **Brussels, 23 June 2026** — Europe's Choice: The value of investing in innovation — Clara Romero, Director Public Affairs
- **London, 23–25 June 2026** — CleanMed Europe 2026 — Oliver Bisazza, CEO
- **Brussels, 30 June 2026** — CEO Summit — Oliver Bisazza, CEO

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MedTech Europe is the European trade association representing the medical technology industries, from diagnosis to cure.

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