



MedTech Monthly

September 2026

Dear readers,

Welcome back. September has made one thing clear: Europe is rethinking how it buys, regulates and adopts medical technology, and the details will decide whether patients benefit or wait longer.

Start with procurement. The European Commission has unveiled its long-awaited Public Procurement Regulation, a key development for our sector given that around 70% of medical technologies in Europe are purchased through public tenders. We welcome the shift away from lowest-price buying towards quality and value, but the proposed European preference provisions risk the opposite effect if origin rules are applied without nuance. Co-legislators need to narrow them before they undermine the reform's own ambition.

On the regulatory side, discussions on revising the Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) continue, and our ask hasn't changed: a simpler, more coherent framework, with AI Act requirements for AI-enabled devices built into the MDR and IVDR rather than bolted on beside them. Our new paper on MDR Article 17 takes a firm line on one part of that revision: reusability should not become the regulatory default for single-use devices. We're calling on co-legislators to drop the proposed justification requirement and keep intended use where it belongs, with the manufacturer.

From how Europe buys to how it certifies devices, the direction is right. What's missing is the detail to make it work.

Read on for more.

Highlights of the Month

Beyond Lowest Price: MedTech Europe's First Reaction to the EU Public Procurement Regulation

[Oliver Bisazza](#), Chief Executive Officer

MedTech Europe welcomes the EU's new Public Procurement Regulation, particularly the end of lowest-price buying. But optional provisions, thin-quality weightings, and origin rules risk fragmenting Europe's market instead of unifying it. This reform gets the direction right by moving away from lowest-price buying. Now Europe must make sure that promise reaches every patient the same way, in every hospital, in every Member State.

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MDR Article 17: Why Reusability Should Not Be the Default

[Nina Mavc](#), Senior Advisor - Regulatory Affairs

As discussions on the revision of the Medical Devices Regulation's (MDR) Article 17 continue, MedTech Europe's new paper explains why the reuse of single-use medical devices should not become the regulatory default. It sets out recommendations to remove the proposed justification requirement, maintain a high level of patient safety and ensure a clear, workable and science- and risk-based regulatory approach.

[READ OUR PAPER](#)

AI-Enabled Medical Devices Need One Regulatory Home

One Device. One Regulatory System. One National Authority.

AI Act: MedTech Europe Responds on High-Risk Classification

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

From 19 May to 23 July 2026, the European Commission launched a stakeholder consultation for its Draft Guidelines on the classification of high-risk AI systems under Article 6 of the AI Act. MedTech Europe submitted a response to the consultation, highlighting the need for further clarification and alignment with the AI Act's legislative framework to ensure legal certainty.

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Joint Paper: MDR/IVDR Transition, a Middle East and Africa Focus

[Alice Bova](#), Senior Officer International Affairs

The transition to the EU Medical Devices Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR) is affecting healthcare systems beyond Europe. In a new joint paper, MedTech Europe and Mecomed outline recommendations to support patient access and continuity of supply in the Middle East and Africa. Read the paper and explore our key recommendations.

[READ THE JOINT PAPER](#)

DIGICAP: Accelerating the Digital Transformation of EU Device Certification

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

MedTech Europe and 19 leading European partners launched DIGICAP on 2 September 2026, a Horizon Europe project that aims to modernise medical device and in vitro diagnostic certification across Europe. By advancing data-driven conformity assessment processes, the initiative seeks to support innovation and efficiency.

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Join Europe's First EU Screening Week

[Gabriel West](#), Officer Communication

From 28 September to 4 October 2026, the first-ever EU Screening Week will raise awareness of early diagnosis and timely intervention for major health conditions, including cardiovascular disease, diabetes and other chronic illnesses. Learn how to register your activity and join stakeholders across Europe in building a culture of prevention.

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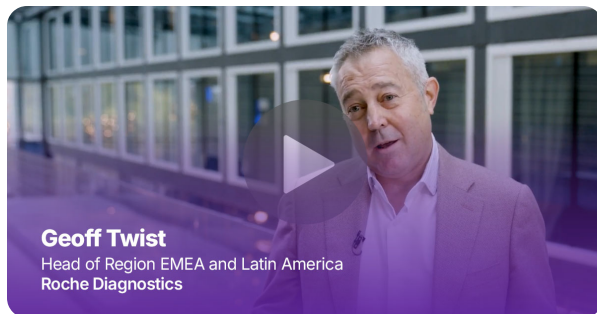
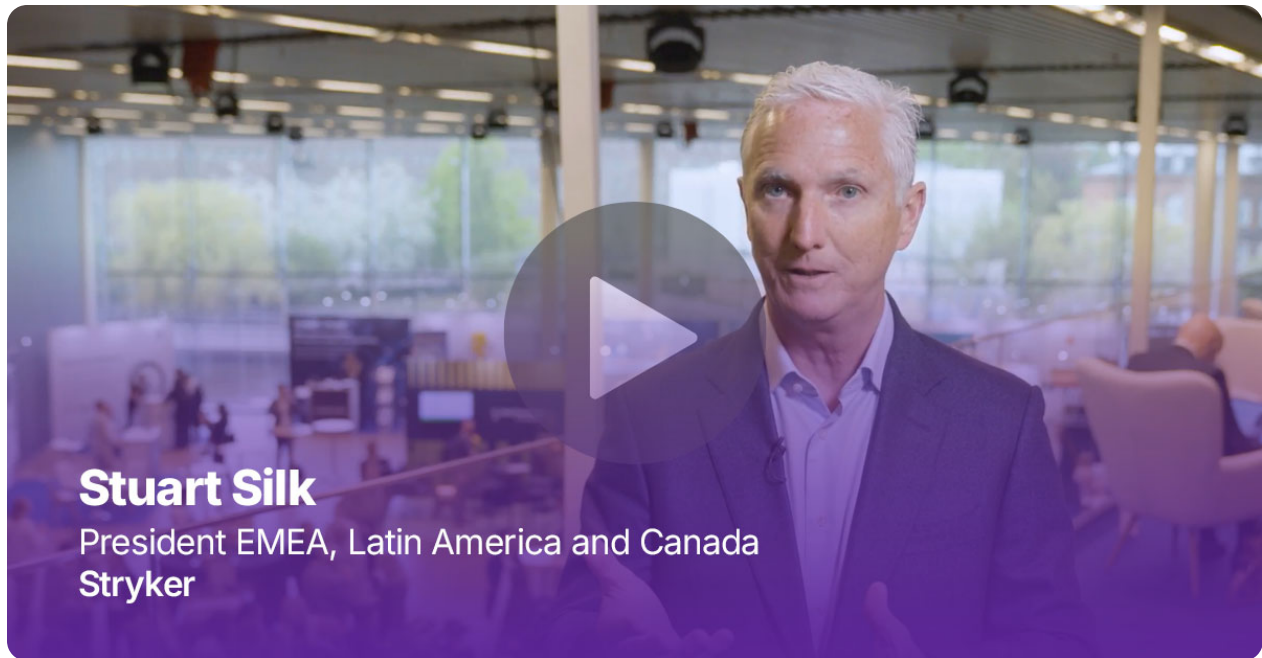
Beyond the test result: how the performance of diagnostic tests is continuously monitored

Vaida Jukneviute
Manager In Vitro Diagnostics – MedTech Europe

MedTech *Views*

MedTech Views

MedTech Leaders on Unlocking Europe's Potential



MedTech Europe in the Media

[Dominika Van Waesberghe](#), Manager Communications

- [POLITICO](#), 9 September 2026, It's Public Procurement Act day. The medtech lobby has a warning.
- [Business Monitor Online](#), 9 September 2026, United States Medical Devices Manufacturing
- [Euractiv](#), 8 September 2026, Surgical robots deliver – but who pays?
- [Medtech Insight](#), 7 September 2026, FDA Backs PFAS In Medical Devices As Europe Moves To Ban Them And Suppliers Offer Alternatives
- [Medtech Insight](#), 2 September 2026, EU project will digitize conformity assessment to free up manufacturer resources
- [MedTech Strategist](#), 16 August 2026, Europe's new Joint Clinical Assessments: Harmonization or just more hoops?
- [Medtech Insight](#), 12 August 2026, EU's AI Act climbdown raises stakes for MDR revisions
- [Medtech Insight](#), 13 July 2026, Tariffs meant to reshore medtech would send it offshore, industry tells USTR
- [Notiziario Chimico Farmaceutico](#), 8 July 2026, Digital Omnibus: A joint appeal by EFPIA, MedTech Europe, and other associations
- [POLITICO](#), 3 July 2026, MDR draft report gets broad thumbs up
- [POLITICO](#), 2 July 2026, It's timid optimism for medtech
- [Euractiv](#), 1 July 2026, Commission adds new medical device types to records

- [Euractiv](#), 1 July 2026, Medtech chiefs press for MDR overhaul
- [Euractiv](#), 25 June 2026, Medtech groups back MDR overhaul

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Health innovation is a team sport: Niklas Blomberg on the future of Europe's medtech

Niklas Blomberg
Executive Director – Innovative Health Initiative (IHI)

MedTech *On Air*

Meanwhile in the world

EU-US transatlantic trade relationship: state of play

[Clare Birmingham](#), Manager International Affairs

Following the EU's adoption of measures implementing its tariff commitments towards the US, based on the framework outlined under the [2025 EU-US joint statement](#), remaining EU tariffs on industrial goods, among other measures, have been eliminated. This includes relevant trade codes for medtech, especially under chapter 90. The tariff outlook for EU medical technologies is still evolving with a few US trade investigations still ongoing.

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Singapore Calls: MedTech Europe at APACMed's MedTech Forum

[Clare Birmingham](#), Manager International Affairs

MedTech Europe will join industry leaders, policymakers and innovators in Singapore on 29–30 September for [APACMed's MedTech Forum](#). Under the theme "Scaling Healthcare Innovation: From Breakthroughs to Better Outcomes," discussions will explore how AI, digital health and new care models can deliver meaningful patient impact across Asia Pacific at scale.

IMDRF's 30th Management Committee Session

[Alice Bova](#), Senior Officer International Affairs

Ahead of the 30th International Medical Device Regulators Forum (IMDRF) Management Committee meeting, taking place in Singapore from 16 to 18 September 2026, MedTech Europe, together with APACMed, Mecomed, MTAA and CBLD, will organise a second Deep-Dive Session on the EU MDR/IVDR for non-EU authorities and its impact on international registrations for medical devices on 11 September 2026.



The hidden economic burden of wounds: why Europe cannot afford to ignore wound care

Luella Trickett
Executive Director, Medical Devices, Value and Access – ABHI

MedTech *Views*

Webinars

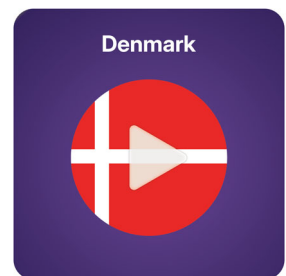
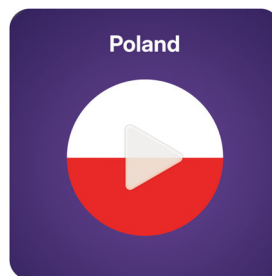
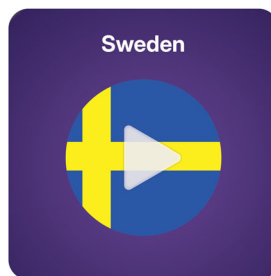
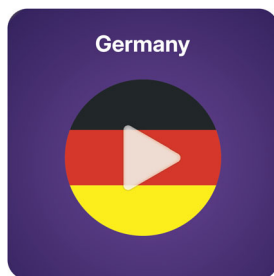
CVS and e4ethics: A Quick Refresher

[Dhana Ong](#), CVS Compliance Officer

Whether you're new to the Conference Vetting System (CVS) and e4ethics, an experienced submitter, or just checking on event status, join our webinar on **13 October 2026, 14.00–16.00 CET**, for practical, hands-on guidance.

[REGISTER HERE](#)

Discover how SMEs can navigate Europe's healthcare systems and the evolving market access landscape for medical technologies



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