MedTech Europe
from diagnosis to cure

MedTech Monthly

September 2025

Dear readers,

I hope you enjoyed a restful summer break. While many of us took some time to recharge, the medical technology world has certainly not stood still. Alongside the discussions on EU–US tariffs, which remain a concern for our sector, other important policy and industry developments have also kept us busy. You will find below a few updates from our side, and for those wishing to dive deeper into the tariff issue, we have included a dedicated news item further down.

Today, though, I'm especially pleased to share something that shines a positive light on our sector: the launch of Facts & Figures 2025. This annual publication is our most comprehensive overview of Europe's medical technology industry and highlights both its innovation and its impact on health and the economy across the continent.

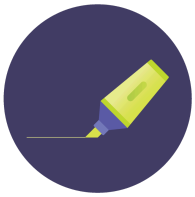
The figures are impressive. Just to give you a taste: over 930,000 people employed, more than the population of Amsterdam, each role creating significant value. More than 38,000 companies, the vast majority SMEs, driving progress across borders. And more than 15,700 patents filed in 2024, one every 30 minutes, showing medtech's position among Europe's most dynamic and inventive sectors.

But Facts & Figures is more than statistics. It paints a picture of how medical technology supports patients, strengthens healthcare systems, and helps Europe remain a leader in global innovation. It's designed as a practical tool for all of you, whether you are shaping policy, working in healthcare, investing in innovation, or simply curious about the sector.

I warmly invite you to explore the full report, and our interactive Data Hub. I trust you will find insightful and inspiring insights for the work ahead.

With best regards,

- Miriam D'Ambrosio, Senior Manager Communications



Highlights of the month

Simplification of EU digital legislation: MedTech Europe proposal to ensure coherent implementation

Benjamin Meany,
Senior Manager Digital, Software and AI Regulation

READ OUR POSITION PAPER

Digital health technologies like connected devices, diagnostic software, and AI tools are transforming healthcare delivery. At the same time, overlapping digital rules risk creating unnecessary complexity, slowing innovation, and increasing burdens for manufacturers, regulators, and the wider healthcare ecosystem.

MedTech Europe is calling on EU policymakers to ensure that horizontal digital legislation reflects the specific needs of the medical technology sector, avoids duplicative or conflicting obligations, and provides clarity for manufacturers and regulators alike.

In our recently published position paper, we advocate for an innovation-friendly, streamlined policy framework aligned with existing sectoral regulations, including the Medical Devices Regulation (MDR), the *In Vitro* Diagnostic Medical Devices Regulation (IVDR), and the European Health Data Space (EHDS) Regulation.

This shift towards clear, coherent rules is essential to ensure that digital health tools remain safe, effective, and accessible for patients and healthcare professionals.

MedTech Europe remains committed to working closely with EU institutions and national authorities to ensure digital legislation is fit for purpose, strengthen patient care, and support Europe's innovation ecosystem.

MedTech Europe's response to the EU–US joint statement

Diana Kanecka,
Director International Affairs

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On 21 August 2025, the European Commission issued the joint statement on a United States-European Union framework on an agreement on reciprocal, fair and balanced trade, which outlines the key terms of the political agreement reached on 27 July 2025.

On 28 August 2025, the European Commission further published two proposals to eliminate EU tariffs, paving the way for the implementation of the EU-US joint statement.

The European Union commits to eliminate tariffs on all US industrial goods. The US commits to apply the higher of either the US Most Favored Nation (MFN) tariff rate or a tariff rate of 15%, comprised of the MFN tariff and a reciprocal tariff, on originating goods of the European Union.

Alarmingly, the joint statement does not provide tariff relief for medical technologies and their essential inputs, which will be subjected to a 15% tariff rate.

In response, MedTech Europe has published a statement expressing its deep concerns over the imposition of tariffs by the United States and the lack of a negotiated EU-US agreement to eliminate tariffs for medical technologies and their essential inputs. These protectionist measures risk disrupting critical supply chains, with negative implications for patient care, healthcare resilience, and for one of Europe's most critical and innovative sectors.

MedTech Europe keeps calling on both the EU and the US to eliminate tariffs on medical technologies and their essential inputs to protect patients, secure supply chains, and ensure the competitiveness of the medical technology sector.

Blogs & podcasts

After a seizure led to a Magnetic Resonance Imaging (MRI), Charlie Broadhurst discovered he had a brain tumour that had been missed years earlier. His journey through surgery, treatment, and recovery highlights the life-saving role of medical technologies like MRI.

READ CHARLIE'S STORY

Cybersecurity is now one of the biggest priorities in european healthcare. In this new MedTech ON AIR episode, Benjamin Meany shares how our sector is tackling cyber risks, from ransomware to patient data protection, and what it takes to strengthen digital resilience across health systems.

LISTEN TO THE PODCAST

In short

MedTech Europe calls for technical documentation sampling of *In Vitro* diagnostics to become more risk-based

Vaida Jukneviciute, Manager *In Vitro* Diagnostics

Current European guidelines on technical documentation sampling for *In Vitro* diagnostics (IVD) under the *In Vitro* Diagnostic Medical Devices Regulation 2017/746/EU (IVDR) place a disproportionate administrative burden on mid- to lower-risk class devices.

MedTech Europe calls on the Medical Device Coordination Group to adopt a more-risk based approach, focusing reviews on the highest-risk tests where patient safety is most critical, avoiding unnecessary duplicate assessments, and reducing costs and paperwork for smaller businesses.

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MedTech Europe joins in EU Health Coalition call for strategic Multiannual Financial Framework investment in future health

Melanie Wahl, Senior Policy Adviser

MedTech Europe, as a member of the EU Health Coalition, has contributed to the Coalition's latest response on the European Commission's proposed Multiannual Financial Framework (MFF) for 2028–2034.

The Coalition urges EU policymakers to elevate health to a strategic priority, ensure clear, ring-fenced funding for research and innovation, and provide robust investment in resilient and inclusive health systems.

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Carbon Border Adjustment Mechanism: MedTech Europe responds to the European Commission public consultation

Sigrid Linher, Director Sustainability and Environment

This summer, the European Commission consulted stakeholders on the upcoming review of the Carbon Border Adjustment Mechanism (CBAM) regulation considering its extension to downstream products, anti-circumvention measures and rules for the electricity sector.

In its response, MedTech Europe outlines the sector specificities to be taken into account in the further proceedings.

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Register now for the Healthcare Ethics & Compliance Conference "HETHICO 2025"

Marta Paci, Junior Legal Counsel

We are pleased to announce that registration for HETHICO is officially open and spots are filling up fast.
Join us on 7 – 8 October 2025 at The Hotel, Brussels, for two days packed with engaging sessions, networking opportunities and valuable takeaways.

Secure your place today by visiting HETHICO website.

REGISTER

Build your future collaborations: IHI Brokerage Event in Brussels

Jeroen Schuermans, Director Strategic Initiatives

The Innovative Health Initiative (IHI) Brokerage Event is the ideal place to network and start building your consortia, whatever your type of organisation.

This public, in-person event will take place in Brussels, Belgium, on 4 – 5 November 2025.

It will focus on IHI's next single-stage call for proposals and will offer a variety of sessions and opportunities to connect and collaborate with potential partners.

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Registration open: APACMed MedTech Forum 2025

Diana Kanecka, Director International Affairs

We are delighted to announce that registration for the APACMed MedTech Forum 2025 is now open.

This event will take place on 16 - 17 September 2025 at ITC Maurya Hotel, New Delhi, India.

Across two dynamic days, we will dive deep into the most critical topics shaping the healthcare industry in India: Health Resilience, Access, Innovation, Patient-Centered Care and discuss opportunities for growth

This landmark forum will bring together global medical technology leaders, government officials, policymakers, healthcare providers, regulators, and innovators — all with one goal of, "Swasth Bharat- A Healthier India Together"

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

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