MedTech Europe
from diagnosis to cure

MedTech Monthly

April 2025

Dear readers,

The recent trade measures announced by the United States, including new tariffs, have sparked global concern. While governments have a duty to protect economic interests, such policies must not compromise access to healthcare or, more importantly, patient care.

At MedTech Europe, we urge policymakers to exclude medical technologies and their essential components from any tariffs. These are not just goods: they are life-saving solutions relied upon by millions across Europe and beyond.

Imagine a patient in urgent need of surgery, but the critical device required is delayed, or its cost has surged due to trade barriers. Such disruptions could put lives at risk, strain healthcare systems, and drive up costs for hospitals and patients alike.

The medical technology industry depends on global supply chains to ensure fast, reliable, and affordable access to innovation. Tariffs would only add unnecessary burdens, increase production costs, slowing down research, limiting innovation, and making medical solutions harder to access.

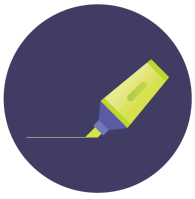
Europe is a global leader in medical technology. But if tariffs disrupt trade, they could harm our competitiveness and restrict the development of groundbreaking solutions for patients. The US is not just a trading partner. It is also a key supplier and a major export market for European medical technology. Retaliatory measures could escalate tensions, harming businesses and, most critically, patient care.

We recognise the complexity of trade policy, but healthcare is not just another industry: it is about people's lives. That is why we call on policymakers on both sides of the Atlantic to keep medical technologies free from trade barriers. When a patient's life is at stake, there is no room for delays or added costs.

Healthcare must remain accessible, innovative, and focused on what truly matters: saving lives.

Sincerely,

-Miriam D'Ambrosio - Senior Manager Communications



Highlights of the month

Meet the speakers shaping The MedTech Forum 2025

Claudia Peters
Events Manager

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The MedTech Forum 2025 is fast approaching, set to take place from 13 to 15 May in Lisbon. As Europe's premier event dedicated to healthcare innovation, policy, and regulation, this year's conference promises to bring together the brightest minds and most influential voices in the medical technology sector.

Explore the programme to discover more about our exceptional lineup of speakers. Among them is Rich Lesser, Global Chair of Boston Consulting Group (BCG). With a wealth of experience in strategic consulting, Lesser will provide insights into the evolving landscape of medical technology and its implications for global health systems.

A standout highlight of the #MTF2025 will be the CEO #nofilter session, which will bring together some of the most influential leaders in the medical technology industry for an open and unfiltered discussion on the challenges and opportunities shaping the sector.

Don't miss the chance to engage with thought leaders and visionaries driving the future of healthcare!

MedTech Europe responds to the European Commission's targeted evaluation of Medical Devices Regulation and *In Vitro* Diagnostic Medical Devices Regulation

Vaida Jukneviciute
Manager *In Vitro* Diagnostics

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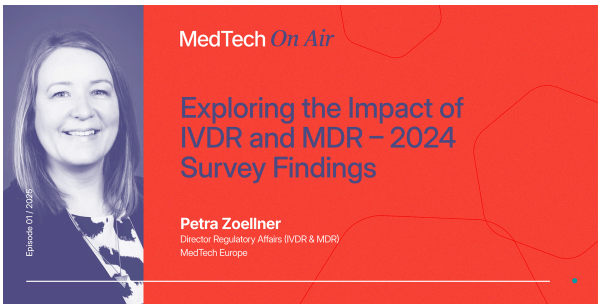
MedTech Europe has contributed to the European Commission's public consultations on EU rules on medical devices and *in vitro* diagnostics which closed on 21 March. This consultation marks an important milestone in moving towards a review and update of the Medical Devices Regulation (EU) 2017/745 (MDR) and the *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR).

The European Commission will be evaluating, among other, how effective, efficient and proportionate the two regulations are in achieving a robust, transparent, predictable and sustainable regulatory framework which ensures a high level of safety and health.

In response, MedTech Europe's Regulatory Affairs MDR/IVDR Working Groups prepared a comprehensive submission, aligning with the organisation's vision for the future of the regulatory system.

All MedTech Europe resources for targeted evaluation of IVDR and MDR can be accessed to our dedicated webpage: The Future of EU Medical Technology Regulatory System.

Blogs & podcasts



Exploring the impact of IVDR and MDR - 2024 Survey Findings

MedTech Europe 2024 Regulatory Survey reveals key challenges manufacturers face under the In Vitro Diagnostic Regulation and Medical Device Regulation. From conformity assessment timelines to the costs of compliance, the findings highlight important trends.

LISTEN TO THE PODCAST

The gift of walking

Born with clubfoot, Kirsty faced years of surgeries and pain before making a life-changing decision. Now, thanks to advanced prosthetics, she's back on her feet and competing in para-sports. Discover her inspiring journey.

READ KIRSTY'S STORY

In short

MedTech Europe and industry partners call for stronger future governance of medical technologies

Jana Russo, Manager Medical Devices

MedTech Europe, in collaboration with key EU trade associations AESGP, COCIR, EEAR, EUROM, and FIDE, has published a joint discussion paper advocating for a reform of the European regulatory system for medical devices and *in vitro* diagnostic medical devices. The paper builds on MedTech Europe's 2023 position paper on the Future of the regulatory system from 2023.

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MedTech Europe response to the European Commission public consultation on potential countermeasures against US tariffs

Diana Kanecka, Director International Affairs I **Dario Belluomini**, Manager International Affairs

Following the United States' imposition of tariffs of up to 25% on imports of steel, aluminium, and certain products containing steel and aluminium from the European Union (EU), the EU has announced a step-wise approach to protecting EU interests, including a package of new countermeasures on US exports that has undergone a public stakeholder consultation.

MedTech Europe has responded to this public consultation highlighting high concerns to see several codes for finished medical devices, along with nearly a hundred codes related to inputs for medical technologies

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Joint statement on the crucial need to effectively fund health research and innovation in the upcoming European Framework Programme

Estefanía Cordero, Manager External Affairs

MedTech Europe, together with leading health stakeholders, has released a joint statement emphasising the need to effectively fund health research and innovation in the upcoming European Framework Programme (FP10). The statement outlines recommendations on priority areas and advances six recommendations to bolster the effectiveness and impact of the FP10 and strengthen the world-class EU (health) research and innovation ecosystem.

READ THE FULL STAMENT HERE

MedTech Europe at the European Parliament EAMBES event on Strategic Autonomy and Competitiveness of Medical Technologies

Sigrid Linher, Director Sustainability and Environment

On 25 March 2025, Members of the European Parliament Castillo, Kulja and Gonzalez Casares hosted an EAMBES session on "Strategic Autonomy and Competitiveness of EU Medical Technologies Industry" at the European Parliament. MedTech Europe had the opportunity to present its views on the role of biomedical engineering in strengthening medical technology innovation, sustainability and competitiveness.

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The Innovative Health Initiative calls for proposals 9 and 10 have launched

Patrick Boisseau, Director General Strategic Initiatives

The Innovative Health Initiative's (IHI) latest calls for proposal are open, with the deadlines approaching soon. Call 9, is an applicant driven approach aligned with the IHI's key objectives; Call 10 covers diverse topics, including

digital labelling for medical technologies. Find the full details, deadlines, and supporting resources here.

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Ensuring an efficient implementation and use of the EUDAMED Clinical Investigation and Performance Studies module

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

As part of MedTech Europe's advocacy on EUDAMED, a Clinical Investigation and Performance Studies module (CIPS) specific position paper has been published. Compliance activities for the EUDAMED CIPS module are foreseen to be resource-intensive for Sponsors. The central database offers solely manual filling of all CIPS forms.

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MedTech Europe reached 50 000 followers on LinkedIn

Gabriel West, Officer Communications

MedTech Europe has surpassed 50,000 followers on LinkedIn, marking a significant milestone for the medical technology community. This achievement reflects the growing engagement of professionals, policymakers, and stakeholders dedicated to advancing innovation, improving patient care, and supporting more sustainable healthcare systems across Europe.

The increasing number of followers underscores the importance of collaboration and knowledge-sharing in the sector. Through LinkedIn, MedTech Europe continues to provide regular updates on regulatory developments, industry insights, and key discussions shaping the future of medical technology.

Not following us yet? Join the conversation, follow MedTech Europe on LinkedIn to stay informed and engaged!

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The Medical Device Coordination Group *in vitro* Diagnostic Medical Devices Classification Guidance revises SARS-CoV-2

Iana Slobodeaniuc, Senior Manager *In Vitro* Diagnostics

The MDCG 2020-16 Guidance has been updated with key changes to the classification of SARS-CoV-2 tests. These tests are, in general, no longer considered as the highest risk class D. Self-tests are now Class C, while other tests are Class B. The revision also includes editorial amendments for improved clarity.

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News from Japan: high-level updates from the International Medical Device Regulators Forum

Diana Kanecka, Director International Affairs

The 27th International Medical Device Regulators Forum (IMDRF) Management Committee Meeting was recently held in Tokyo, Japan, on 10-14 March 2025. It was chaired by Japan and hosted by the Japanese Pharmaceuticals and Medical Devices Agency (PMDA).

The 28th IMDRF Management Committee Meeting will be held in Sapporo, Japan, during the week of 15 September 2025.

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New ECIPE study highlights the rise of mass litigation in the EU and its economic impact

Pablo Rojas Abad, Legal & Compliance Senior Manager – Senior Legal Counsel

The European Centre for International Political Economy (ECIPE) recently published a comprehensive analysis of the growing shift toward private enforcement of regulatory requirements in the EU. The study explores the macro-economic consequences, key drivers behind this trend, and potential solutions to ensure a balanced legal framework.

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CONTACT US

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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