MedTech Europe
from diagnosis to cure

MedTech Monthly

June 2025

Dear readers,

The transatlantic trade tensions that have unfolded over recent months show no signs of abating, and unfortunately, their impacts on our sector concern us deeply. In the second package of proposed EU tariffs, medical technologies are once again caught in the crossfire, despite repeated calls to exempt health-critical solutions from such measures.

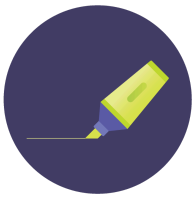
More than 800 trade codes relevant to our industry appear on the current list. This is a troubling development, for business and innovation, and for patients, healthcare professionals, and public health systems. Tariffs on medical technology solutions threaten supply chains, delay access to essential care, and undermine Europe's health resilience.

We will submit a formal response to the consultation launched by the European Commission ahead of the 10 June 2025 deadline. This response is part of our continued, first-line commitment to contributing constructively to finding a viable, long-term solution. Our position remains firm: medical technologies must not be used as instruments in trade retaliation.

We call on policymakers to eliminate existing tariffs and to refrain from introducing new ones. It is time to work towards a zero-for-zero agreement which includes medical technologies and their components, because health should never be collateral in trade disputes.

Warm regards,

- Miriam D'Ambrosio, Senior Manager Communications



Highlights of the month

MedTech Europe recommendations to the upcoming Danish Presidency of the Council of the European Union

Jessica Imbert
Director External Affairs

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As Denmark prepares to assume the Presidency of the Council of the European Union in the second half of 2025, Europe stands at a critical crossroads. With rising geopolitical tensions and increased global competition, the EU must act now to safeguard its position as a global leader in health innovation.

The life sciences sector—anchored by medical technologies—is a key pillar of Europe's resilience and growth. MedTech Europe urges the Danish Presidency to prioritise timely, equitable access to medical technologies, strengthen regulatory and digital infrastructure, and integrate environmental and economic goals.

Our recommendations to the Danish Presidency focus on five strategic pillars:

- Enhancing competitiveness: align legal frameworks to accelerate innovation
- Modernising regulation: fix structural challenges in MDR/IVDR
- Driving digital transformation: ensure swift, harmonised rollout of European Health Data Space and Artificial Intelligence Act
- Supporting joint decarbonisation and competitiveness planning: integrate environmental and economic goals
- Ensuring a level playing field: enable fair competition globally and within the EU

The Danish Presidency offers a timely opportunity to advance a strong, comprehensive EU Life Sciences Strategy. MedTech Europe stands ready to collaborate and contribute to this shared ambition, for patients, for healthcare systems, and for a resilient Europe.

MedTech Europe calls for urgent fixes to keep Medical Devices Regulation and *In Vitro* Medical Devices Regulation on track

Merlin Rietschel
Senior Manager Medical Devices

DISCOVER OUR LEAFLET

Last week, 26 May 2025, we marked eight years after the EU's regulatory framework for Medical Devices Regulations (MDR) and *In Vitro* Diagnostic Medical Devices Regulation (IVDR) came into force. As the system approaches a critical juncture, ongoing challenges related to capacity, predictability, and efficiency continue to affect the timely availability of medical devices and diagnostics across Europe.

MedTech Europe has published a concise leaflet identifying four practical areas where improvements could enhance the system's performance and sustainability in the near term.

The four proposed measures aim to:

- Make initial product approval faster, more efficient, predictable and less costly.
- Make change notification processes faster, more efficient, predictable and less costly.
- Introduce a dedicated and accelerated pathway for breakthrough innovations.
- Shift to lifetime risk-based certification to reduce duplication and lower burden.

The leaflet is intended to contribute to ongoing discussions about the future of regulation in Europe.

Blogs & podcasts

Europe's population is ageing, and this trend brings a higher burden of age-related diseases. The medical technology industry is stepping up to meet these challenges by innovating to produce less invasive and more personalised medical interventions.

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Sarah Falkland assumed that because she was healthy, her pregnancy would be smooth sailing. But then she was diagnosed with pre-eclampsia, a condition that's potentially life-threatening for both mother and baby. Below, she shares her story to help educate people about pre-eclampsia.

READ SARAH'S STORY

In short

Just released: MedTech Europe practical guide for the required use of the European Medical Device Nomenclature

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

To support consistent and compliant application, MedTech Europe released a practical guide for the required use of the European Medical Device Nomenclature for manufacturers operating under the (EU) 2017/745 Medical Device Regulation (MDR) and (EU) 2017/746 *In Vitro* Diagnostic Regulation (IVDR).

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Joint industry letter to Executive Vice-President Ribera on Draft Article 102 of the Treaty on the Functioning of the European Union Guidelines

Mirella Kavadaki, Manager Legal & Compliance - Legal Counsel

MedTech Europe, together with a group of European and international industry and trade associations, has sent an open letter to Executive Vice-President Teresa Ribera urging the European Commission to revise and re-consult its Draft Guidelines on exclusionary abuses under Article 102 of the Treaty on the Functioning of the European Union (TFEU).

READ THE JOINT LETTER

EuroMedLab conference: MedTech Europe joins Symposium on green and sustainable medical laboratories

Sigrid Linher, Director Sustainability and Environment

European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) hosted a symposium on the environmental impact of laboratory medicine at EuroMedLab Conference. MedTech Europe was delighted to engage in the panel debate chaired by EFLM's Tomris Ozben and Professor Anetor (Nigeria) to present key sustainability trends, challenges and opportunities from the perspective of European medical technology.

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News from the World Health Organisation, and from the Global Diagnostics Alliance to the World Health Organisation Global Forum on Medical Devices

Diana Kanecka, Director International Affairs

On 21 May 2025, the Global Diagnostics Coalition was officially launched during a side event at the 78th World Health Assembly (WHA78). The Global Medical Technology Alliance (GMTA) welcomes this important milestone, marking a significant step forward in global collaboration to improve patient access to diagnostics and drive innovation. The Coalition will serve as a collaborative platform and convening body, bringing together stakeholders to provide strategic direction and coordinate efforts to strengthen diagnostics capacity worldwide.

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EU green lights restriction to EU public procurement for medical devices and companies from China

Diana Kanecka, Director International Affairs

Earlier this week, EU Member States approved the adoption of measures under the International Procurement Instrument (IPI), aimed at addressing imbalances in access to public procurement market for European medical devices in China. As a result, entities and medical devices originating from China will face new restrictions in access to EU public tenders.

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The MedTech Forum 2025: Bridging green goals and competitive edge in healthcare

Sigrid Linher, Director Sustainability and Environment

From 13 to 15 May 2025, Lisbon Conference Centre was set in MedTech Forum colours. On the occasion three dedicated sustainability sessions were held to discuss latest developments, best practices and how to bridge green goals and competitive edge in healthcare.

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7 years of General Data Protection Regulation : protecting privacy and strengthening patient trust

Mirella Kavadaki, Manager Legal & Compliance - Legal Counsel

As we mark seven years of the General Data Protection Regulation (GDPR), MedTech Europe highlights the importance of strong data protection in building and maintaining patient trust. Medical technologies increasingly rely on data, from connected devices to digital health tools, to support better care.

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Updated - Innovative Health Initiative draft topic texts for Call 11

Patrick Boisseau, Director General Strategic Initiatives

The Innovative Health Initiative (IHI) has updated the draft topic texts for call for proposals #11, which is estimated to launch this summer. The topics include subjects such as diabetes, brain disorders, heart disease and medicines safety among others.

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A look back at The MedTech Forum 2025

Claudia Peters, Events Manager

In May 2025, Lisbon hosted The MedTech Forum 2025, Europe's largest gathering for the medical technology industry. Over the course of three dynamic days - from 13 to 15 May 2025 - nearly 1,000 leaders and professionals from industry, healthcare, academia, and policy came together to explore the evolving landscape of medical technology and its role in shaping healthier societies.

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