

MedTech Monthly

April 2026

Dear readers,

April is rarely quiet in Brussels, and in the current global climate, that is an understatement.

Trade tensions, shifting alliances and growing questions about strategic dependencies are reshaping the policy landscape at speed. For the medtech and in vitro diagnostics sector, our CEO Oliver Bisazza argues: *medical sovereignty is not a slogan; it is a strategic imperative*. This edition examines what that means in practice, from **our position on the Digital Omnibus** to the **EU-Australia Free Trade Agreement** and the evolving dynamics of **EU-US relations**.

Inside, you will also find key details on [IHI call 12](#) and more on our [webinars](#) on EUDAMED readiness.

And if you have not yet registered for the [MedTech Forum 2026](#) in Stockholm (11-13 May), do not wait. [Secure your spot now](#).

Highlights of the Month



MedTech Views

Medical sovereignty is not a slogan

Oliver Bisazza
CEO, MedTech Europe

The graphic features a portrait of Oliver Bisazza on the left, smiling. The background is a gradient from light blue to yellow. The text is in a clean, sans-serif font.

Europe's medtech strength is not in question. Its policy environment is. Without resilient supply chains, open trade and a fit-for-purpose regulatory framework, medical sovereignty is rhetoric. A Europe that cannot attract and retain

medtech investment is not a sovereign healthcare market. It is a dependent one.

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A strategic milestone: EU-Australia Free Trade Agreement finalised

[Alice Bova](#)

Senior Officer International Affairs

The EU and Australia recently concluded negotiations on the [EU-Australia Free Trade Agreement \(FTA\)](#) in March 2026, bringing to a close almost nine years of negotiations. The agreement will eliminate over 99% of tariffs on EU exports to Australia, enhance access to critical raw materials, and strengthen the EU's strategic ties with the Indo-Pacific region.

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EUDAMED onboarding webinars

[Katalin Mate](#)

Senior Expert Regulatory Affairs (IVDR & MDR)

The central medical device database, EUDAMED – a key EU medical device regulatory infrastructure – will become mandatory from 28 May 2026. Preparing for EUDAMED readiness requires a cross-functional transformation, involving teams across regulatory affairs, quality, R&D, labelling, product data management and commercial functions.

[WATCH THE WEBINARS](#)



MedTech Views

Smarter regulation, not deregulation: why the Parliament's position on AI in medtech points in the right direction

Alexander Olbrecht

Director Digital Health & Medtech Value,
MedTech Europe

Digital Omnibus and Digital Fitness Check: MedTech Europe's response to the public consultation

[Alexander Olbrecht](#)

Director Digital Health & Medtech Value

MedTech Europe welcomes the opportunity to comment on the EU's Digital Simplification Package, stressing the need for clearer, more coherent digital rules that support innovation while maintaining high safety standards. With digital technologies transforming care, aligning horizontal legislation with medical device frameworks is essential to ensure patients benefit from safe, effective and trusted solutions.

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Innovative Health Initiative: Turn ideas into impactful collaborations with call 12

[Jeroen Schuermans](#), Director Strategic Initiatives

The [Innovative Health Initiative](#) (IHI) is advancing collaborative health research across Europe. [IHI call 12](#) is now open until 21 April 2026, and the first insights from call 9 are now available, with more projects preparing to launch soon.

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In Short

A step forward for the EU-Mercosur Trade Agreement

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

The EU-Mercosur interim Trade Agreement is set to apply provisionally as of **1 May 2026**, applying between the EU and Mercosur countries that have completed their ratification process. At present, Argentina, Brazil, and Uruguay have submitted their notifications; Paraguay has ratified the agreement and is expected to notify shortly.

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CE marking in the UK: MHRA consults on indefinite recognition of EU-certified devices

[Clare Birmingham](#), Manager International Affairs

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has launched a consultation on the future **recognition of CE-marked** medical devices and in vitro diagnostic devices in Great Britain. The outcome will shape the UK's long-term regulatory approach, with implications for market access, regulatory alignment and the availability of medical technologies.

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U.S. Section 301 investigations: implications for medical technology and transatlantic trade

[Clare Birmingham](#), Manager International Affairs

The United States has launched two Section 301 investigations, including one on manufacturing capacity and forced labour. While not sector-specific, the outcomes may have implications for medical technologies and European suppliers to the US market.

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European Parliament vote advances EU-US tariff implementation

[Clare Birmingham](#), Manager International Affairs

The European Parliament has approved measures to implement the EU-US trade deal, including tariff reductions on industrial goods. The vote marks an important step forward, with implications for the medical technology sector.

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THE MEDTECH FORUM 2026

An event by  MedTech Europe
from diagnosis to cure

11 – 13 May
Stockholm

In the Media

[Dominika Suchonova](#), Manager Communications

- [MedTech Insight](#), 4 March 2026, “We Can’t Wait Years” For MDR/IVDR Change: Industry Urges EU Co-Legislators To Move At Pace.
- [Euractiv](#), 12 March 2026, The Digital Omnibus: Europe's chance to lead, not just legislate
- [MedTech Insight](#), 26 Mars 2026, AI Act Amendments Bring Relief Not Resolution

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



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