

MedTech Europe's reaction to the President of the European Commission's State of the Union Address

Brussels, 17 September 2026 – President von der Leyen told Parliament that kickstarting Europe's economy is her number one priority. Europe's medical technology industry agrees, with one condition the speech left largely unspoken: none of it works without health. Where there is no health, there is no wealth.

Health was present in the address: a European Care Deal, AI-supported medtech as the example of what industrial AI can do for society. Health named among five priority sectors for the initiatives due in November. That is welcome recognition of health as a competitiveness asset rather than a cost line. The test is delivery.

"The President has placed health inside Europe's competitiveness agenda. Now the words have to reach the hospital ward. Two files will show whether they do: a public procurement regulation that ends buying on price alone, and a device regulation that lets innovation certified in Europe reach patients in Europe first," said Oliver Bisazza, Chief Executive Officer of MedTech Europe.

Simplification must reach the hospital ward

The twelve omnibus proposals are cutting around 17 billion euros a year in administrative burden, and the President is right that simplification cannot be a one-way street. **Her call for a pact against gold-plating should start where patients feel it.**

Nearly a decade into the Medical Devices Regulation and the In Vitro Diagnostics Regulation, the sector still faces slow and unpredictable conformity assessment, disproportionate administrative burden and inconsistent national interpretation. Hospitals and laboratories have reported device availability problems since the MDR and IVDR entered into force, and companies are moving performance studies to the United States to escape European delays. The result is that European patients wait longer for innovations developed on their own continent. Divergent interpretation of one EU law across twenty-seven markets is gold-plating in all but name. Make medtech the pact's first test case.

Our asks are already on the table: open-validity certificates with risk-based review, clearer change control, risk-based sampling, broader recognition of clinical evidence and full digitalisation. None of that is a shortcut on patient safety. It is the condition for it.

Buying European is not enough. Europe must buy better

The speech did not mention public procurement. It should have. Public procurement is worth more than 2.6 trillion euros a year, roughly 15 per cent of EU GDP, and in healthcare it decides which technologies reach patients. Today 61.8 per cent of medtech tenders are awarded on price alone, against 51.8 per cent across all sectors. That is a self-inflicted barrier to competitiveness.

The Public Procurement Regulation tabled on 9 September 2026 is a real step forward, and ending price-only buying is the single most important improvement available to European healthcare. Four points still need fixing: a minimum quality weighting of 30 per cent still lets price decide the award; derogations are too broad; market consultation stays optional; and bid deadlines are shortened without forward visibility. Fix them and Europe gets one predictable market instead of twenty-seven.

On European preference, we welcome that it remains voluntary and trade-compliant. Health should be exempted, or preference confined to categories where competition is sufficient and supply is secure. Origin rules built on final assembly overlook the research, design and certification delivered in Europe.

The President's line that AI must empower doctors, not replace them, is the right one. Delivery depends on coherence. The Digital Omnibus on AI rightly postponed AI Act obligations for embedded high-risk systems to August 2028, but it did not resolve the overlap with the MDR and IVDR. **November's health initiative must simplify rather than duplicate, implementing AI requirements through the sectoral device framework.** The prize is large: analysis published by MedTech Europe has estimated that digital health could save around 400,000 lives a year, 200 billion euros in system costs and 1.8 billion working hours. And if doctors are to have instant access to the data behind the best decision, the European Health Data Space must work in practice, with proportionate procedures, realistic timelines, protected intellectual property and consistent application.

One coherent framework for AI in health

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Secure supply depends on open trade

A medical technology crosses borders many times before it reaches a patient. Resilience for our sector rests on two things: diversified supply, and a robust, competitive medical technology industry based in Europe. On the first, health-critical inputs belong inside Europe's new supply security architecture. The President said the European Corporation on Critical Raw Materials will stockpile what Europe needs for electric cars, chips, batteries, clean tech, defence 'and so much more'. The materials hospitals depend on must be part of that. On the second, trade matters. The United States is among the sector's most important trading partners, and a 15 per cent tariff on European medical technologies, with further measures added since, takes revenue out of companies that research, manufacture and employ in Europe. Every euro lost that way is a euro not invested in European capacity. Medical technologies should be exempt from tariffs on both sides of the Atlantic

"Resilience for medical technology means diversified supply and open markets, not a choice between them. Patients cannot be the collateral damage of trade tensions," Bisazza added.

The Care Deal needs a budget line

A Care Deal that helps people age at home is only as good as the diagnostics, remote monitoring and interoperable data that make independent living possible. Europe faces a shortage of around 1.2 million health workers, and almost 130 million citizens will be 65 or older by 2050. Technology is part of how that gap closes. Yet health is still not a strategic pillar of the next Multiannual Financial Framework. Together with more than 50 partners in the EU Health Coalition, we ask for health and life sciences to be a cross-cutting priority, with ring-fenced funding for research, digital transformation and clinical trials.

Europe's medical technology sector files a patent every thirty minutes. Too often, that innovation reaches patients elsewhere before it reaches patients in Europe. The President has promised to complete the overhaul of the Single Market by the end of next year. For our sector, that means two things: a procurement system that rewards value rather than the lowest price, and a device regulation that certifies innovation once, predictably, for all twenty-seven Member States. The measure of this State of the Union is simple: whether European patients get faster access to the technologies Europe already develops.

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About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations that research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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