MedTech Europe
from diagnosis to cure

Towards a Revised EU Regulatory Framework for Medical Technologies

Four urgent targeted measures to enhance rapid access to safe medical technology while safeguarding innovation

MAY 2025

The Future of Europe's Medical Technology Regulations

MedTech Europe's vision for an efficient, innovation-focused and well-governed regulatory framework

The EU has prioritised Europe's prosperity and competitiveness for the next four years. For the medical technology sector, achieving these goals depends on having a regulatory environment that is efficient, innovation-friendly, and well-governed. Improvements to this framework are urgently needed to ensure that safe and performing medical devices and diagnostic tests continue to reach patients. This will support innovative healthcare delivery across Europe and help maintain the EU's competitiveness across the SME-heavy industry.

Eight years after the publication of Europe's Medical Devices Regulation 2017/745 and *In Vitro* Diagnostic Medical Devices Regulation 2017/746, there is broad consensus that these regulatory frameworks are not living up to their objectives of achieving a *"robust, transparent, predictable and sustainable regulatory framework for [in vitro diagnostic] medical devices which ensures a high level of safety and health whilst supporting innovation."*

Manufacturers experience today's regulatory system as slow, costly, unpredictable and overly complex[1]. This undermines patient access, innovation, investment confidence and health system resilience. Europe is becoming less attractive as a region for launching innovation, which undermines its global competitiveness. Medical technology innovation is necessary for meeting the unmet needs of patients, effectively combating emerging health crises and responding to calls for more environmentally sustainable healthcare. It is also essential for providing digital healthcare solutions to empower patients and support care teams and the chronically overburdened health systems. Implementation alone cannot solve these challenges and a meaningful legislative reform of the regulatory system is now essential.

To address this, the European medical technology industry is asking for two key areas of action:

- **Legislative reforms of both regulations** governing medical devices and diagnostics. An evaluation being run by the European Commission until end 2025 should provide the proposed reforms. They should arrive by early 2026 and deliver regulatory systems that are efficient, innovation-friendly and well-governed.
- **Immediate four targeted actions** are needed until end 2025 at the latest, to protect access to devices and the future of the industry. They cannot wait for full reforms which will take years to get implemented.

The following four urgent targeted measures should be introduced with adequate legal strength:

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

The above-mentioned solutions will help patients get safe, innovative treatments faster and ensure Europe remains a global leader in medical technologies.

Discussions on legislative reforms must start now, while immediate targeted actions are implemented through existing tools like implementing acts, guidance and best practices.

1) For example, see Medtech Europe 2024 Regulatory Survey: key findings and insights

1. Make initial product approval faster, more efficient, predictable and less costly

State of Play

Under the EU Regulations for Medical Devices 2017/745 and *In Vitro* Diagnostic Medical Devices 2017/746, before companies can sell medical devices or diagnostics in Europe, they must go through an evaluation process called a 'conformity assessment'. This process ensures that products placed on the market are compliant with the regulatory rules and presents more benefits than risks. The level of oversight depends on the risk class of the product: the higher the risk, the stricter the checks. For example, devices like implants, heart monitors, or tests for serious conditions such as HIV must be reviewed by an independent auditing organisation called a 'Notified Body'.

Challenges

Europe has long been a leader in medical technology, giving patients timely access to safe and innovative devices. The EU Regulations for medical technologies were designed to ensure a smooth functioning of the EU internal market and a high protection for patients and users. Their implementation has created major obstacles, especially for small and medium-sized companies which make up 90% of the medtech sector. For instance, certification costs have more than doubled, even when the product itself has not changed. Documents that used to be 200 pages can now exceed 2,000 pages. Approval processes that once took a few months can now take double or triple the time. Additionally, the industry faces unclear and changing rules, heavy red tape and inconsistent decisions from different Notified Bodies across Europe.

As a result of high regulatory approval cost and a lack of predictability, over 50% of medical devices manufacturers stopped or are planning to stop production, manufacturing or supply of some devices[2]. Since entry into force of the EU Regulations for medical technologies, the choice of the EU as the first launch geography dropped among large medtech manufacturers by more than 30%[3]. The same surveys show that patients are already losing access to important medical solutions. At a time when we most need innovation to address our ageing population, chronic illnesses and overburdened healthcare systems, Europe risks falling behind.

2) European Commission study supporting the monitoring of availability of medical devices on the EU market
3) Medtech Europe 2024 Regulatory Survey: key findings and insights

Suggested Solutions

To ensure the latest medical technologies are available for patients and to keep Europe competitive, we need to restore predictability and legal certainty. Right now, approval processes are too unclear, too slow and too expensive. In the short term, the following measures need to be implemented through secondary legislation or other legally binding instruments. An implementing act is already planned by the European Commission.

It is crucial that it (or other instruments) addresses all of the following:

- **Establish clear, consistent and binding timelines for reviews:** predictable and maximum time limits should be set for product and quality system approvals, including rules for when the process can pause and restart, so that all actors can plan with confidence.
- **Enhance a (structured) dialogue between companies and Notified Bodies:** allow for an ongoing communication (also at early stage of the process) that will help clarify expectations, especially on the level of clinical data required.
- **Increase transparency:** Notified Bodies should publish clear reports on how long product and quality system approvals take as well as the cost incurred per device type.
- **Improved efficiency**: ensure the product approval process itself is lean, effective and efficient without the current overly complex review. Unnecessary steps and paperwork must be removed.

2. Make change notification processes faster, more efficient, predictable and less costly

State of Play

In Europe, companies must get pre-approval from their independent auditing organisation, known as a 'Notified Body', when making important changes to a medical device or diagnostic test, for example, in how it is designed, made or used. This process is known as 'change notification'. When a manufacturer makes an important change to a product or its quality system, it must notify its Notified Body, which assesses whether the change affects the original approval. This process is intended to ensure continued alignment with the regulatory requirements under the EU Regulations for Medical Devices 2017/745 and *In Vitro* Diagnostic Medical Devices 2017/746.

Challenges

Europe has long been a leader in medical technology, giving patients timely access to needed devices. The rules are clear: only important changes should be assessed. In practice however, many Notified Bodies are asking for all kinds of changes to be notified, even some which are not required by the EU Regulations. This creates barriers and delays patient access to improved devices. The review of changes can take several months, which may lead to delays and uncertainty in the system. Demand to notify all kinds of changes – even less important ones – is creating backlogs that block continuous improvement, leaving European patients with outdated versions of medical devices while the rest of the world moves forward.

Overall, the way in which the system is being implemented today, is too slow and rigid to support the kind of continuous development which is common in the medical technologies sector. As a result, some products are withdrawn or no longer updated, not due to safety concerns but because the process has become too complex and unpredictable. Where changes can be approved faster outside of the EU, this may lead to availability of different versions of the same product in different regions. This puts Europe's role as a medical technology leader at risk and limits patients' access to better care.

Suggested Solutions

The system should provide faster, more predictable approvals by focussing on assessing important changes in an efficient manner. Companies need predictable rules, reasonable timelines and cost control to plan updates and bring best-in-class devices to market. It is essential to swiftly adopt and implement these solutions through secondary legislation or other legally binding instruments.

The process should focus on what truly matters:

- **Categorise changes by complexity with fixed timelines for each category.**
- **Implement what is required by EU law:** only important changes should be notified and reviewed by the Notified Body including changes affecting safety, performance, usability and the risk-benefit balance and changes to the device range covered.
- **No notification should be required for all other changes** which either are minor, fall within agreed limits or are managed by predefined controls, allowing routine improvements to proceed efficiently and without delays.

Making the change notification process more efficient and predictable would reduce unnecessary delays, ease the burden on both companies and Notified Bodies and ensure patients gain faster access to best-in-class medical technologies.

3. Introduce a dedicated and accelerated pathway for breakthrough innovations

State of Play

The stated aims of the EU Regulations for Medical Devices 2017/745 and *In Vitro* Diagnostic Medical Devices 2017/746 are to protect patient health and safety while ensuring timely access to safe and innovative solutions. They also aim at supporting the competitiveness of Europe's medical technology sector in particular its small and medium-sized companies. To achieve these goals, the regulatory system must enable continuous innovation. While innovation can take many forms, breakthrough innovations, which bring entirely new solutions for serious or life-threatening conditions, have the potential to transform patient care.

Challenges

Today, Europe has no dedicated regulatory pathway for breakthrough innovations. Unlike the fast-track EU systems in place for medicines and advanced therapies, no equivalent exists for medical technologies while other regions such as the US, Japan and Australia have already introduced fast-track pathways for breakthrough technologies. Under the current EU system, requirements for breakthrough innovations often are unclear, particularly regarding the evidence needed before and after their approval. Timelines for approval are also often unclear. This leads to unpredictability, higher costs, reluctant investors and slower market access.

Suggested Solutions

To accelerate the development of breakthrough innovations, a dedicated and fast CE-marking pathway should be established.

While some may worry that speeding up approvals could compromise safety, a dedicated pathway should be designed to allow for earlier expert involvement, clearer guidance and ongoing monitoring after approval. This would ensure a high level of safety and efficiency and enable Europe to become competitive at a global level again.

A dedicated pathway for breakthrough innovations should:

- Include a maximum 120-day end-to-end review timeline for breakthrough medical devices and *in vitro* diagnostics.
- Be built on clear eligibility criteria based on clinical benefit and the potential to address unmet medical needs. Early dialogue between manufacturers, Notified Bodies (independant auditing organisations) and Expert Panels would help clarify requirements, align expectations and prevent delays.
- Make use of conditional approval models with the support of Real-World Evidence.
- Be sustainable and accessible for any size of manufacturer.

Altogether, this approach must speed up access to life-saving technologies, reduce pressure on the overall system and uphold high safety and performance standards.

To establish a pathway for breakthrough innovation, a two-step approach is needed:

1. Immediate action: The European Commission should launch a pilot in 2025 to test out a breakthrough innovation pathway, supported by guidance.
2. Include as part of the legislative reform of IVDR and MDR: establish the pathway based on the pilot's results.

4. Shift to lifetime risk-based certification

State of Play

Under the EU Regulations for Medical Devices 2017/745 (MDR) and *In Vitro* Diagnostic Medical Devices 2017/746 (IVDR), certificates are valid for five years. To renew them, manufacturers must submit a re-certification dossier, even if the product and manufacturing process have not significantly changed. Without a valid certificate, medical technologies cannot be placed on the market.

Challenges

Re-certification duplicates initial certification and post-market scrutiny, creating unnecessary administrative burden without improving safety. Devices are already subject to strict ongoing oversight, including annual audits, safety reporting, clinical evaluations and post-market surveillance. Notified Bodies (independent auditing organisations) continuously monitor safety and performance of devices and are able to suspend or withdraw certificates at any time based on evidence. Other regions like the US, do not require fixed renewal cycles but will act if the device poses a risk on the market.

The IVDR and MDR implementation deadlines have already been extended four times due to bottlenecks in the transition process. From 2026 to 2029, among other activities, Notified Bodies will need to conduct re-certifications while also certifying new devices and the many thousands of existing devices still transitioning to the EU Regulations. This is expected to create yet another bottleneck in the transition[4].

The system is also unfair: early MDR and IVDR adopters need to re-certify sooner than those using the extended transitional periods. Re-certification procedures are very costly, which especially impacts smaller companies (SMEs), making it harder for them to sustain product availability and remain competitive in the EU market. Many companies are forced to withdraw products or miss tender opportunities due to certificates not renewed on time. Valuable resources are wasted on redundant reviews instead of being invested in innovation.

4) See published European Commission data giving the status of applications and the rate in which they are being converted to certifications (Study supporting the monitoring of availability of medical devices on the EU market - https://health.ec.europa.eu/study-supporting-monitoring-availability-medical-devices-eu-market_en

Suggested Solutions

The current system already provides strong oversight over the full life-time of a device. The need for a renewal of the certificate should be based on an actual risk posed by the device post-market, including safety concerns or changes which are substantial enough to trigger a new conformity assessment of the product or the quality management system.

Such an approach would maintain safety while eliminating inefficiencies and supporting innovation.

To improve safety, efficiency, and patient access, the following two reforms are needed:

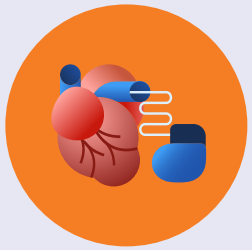
- **Immediate action:** automatically extend the validity of certificates issued before 26 May 2024 under MDR and IVDR from 5 to 10 years. This would avoid bottlenecks in the transitional periods, free up Notified Body capacity for critical tasks and prevent disruption of supply, all without compromising safety.
- **Include as part of the legislative reform of IVDR and MDR:** eliminate the limited validity of the certificates and replace re-certification with a risk-based model, taking into account the novelty of the technology. Devices should be reassessed only, when necessary, for example, due to safety concerns, changes which transform a device into a new product, or incident trends. Since strong ongoing checks are already in place, re-certifications should be phased out.

What is medical technology

Medical technologies are products, services or solutions used to **save and improve people's lives**. In their many forms, they are with you from prevention to diagnosis and cure. There are three main categories of medical technologies:

There are more than **2,000,000** medical technologies, categorized into more than 7,000 generic devices groups*, available in hospitals, community care settings and at home.

* WTO, Medical Device Overview (accessed on 08/05/2024)



Medical Devices (MDs)

Are products, services or solutions that prevent, diagnose, monitor, treat and care for people.

In vitro diagnostics (IVDs)

Are non-invasive tests used on biological samples (for example, blood, urine or tissues) to determine the status of a person's health.

Digital health

Are tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring and management of a person's health and lifestyle.

About MedTech Europe

MedTech Europe is the European trade association representing the medical technology industries, from diagnosis to cure. We represent diagnostics, digital health and medical devices manufacturers operating in Europe.

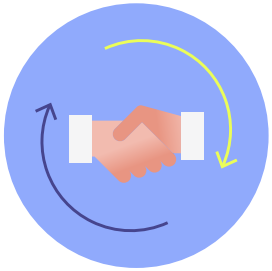
MedTech Europe's mission is to make innovative medical technology available to more people while helping healthcare systems move towards a sustainable path. MedTech Europe encourages policies that help the medical technology industry meet Europe's growing healthcare needs and expectations. It also promotes medical technology's value for Europe focusing on innovation and stakeholder relations, using economic research and data, communications, industry events and training sessions.

Our association aims to represent all the relevant actors in the medical technology field including: national associations, corporate members including SMEs. The latter are the drivers of grassroot innovation and bottom-up solutions, vital maintain and improve European competitiveness in the medical technologies field.

37,000
Medical technology companies in Europe
90% are SMEs

One patent every 30 minutes
Is filed with the European Patent Office in the field of medical technology

880,000+
People employed directly by the medical technology industry



€11 billion
of Europe's trade surplus in 2023

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Scan the QR code to explore MedTech Europe's complete vision for the future of the regulatory system.