Urgent regulatory reform is required to ensure EU's competitivenss and patient access to medtech.

"MDR has resulted in a massive economic own goal. Reluctantly companies drop many time-proven products from their EU portfolios and move future R&D investment & new products to US leading to a marked standard of care deficit in EU compared to US."

John Power, CEO, Aerogen

For more information scan the QR code

Medtech in Ireland

There are more than 500,000 different types of medical technologies on the market ranging from glasses to pacemakers as well as combination products such as inhalers and insulin syringes.

The biopharma, medtech, and digital health sectors in Ireland are renowned for attracting international investment with 700+ companies operating across the country, employing 102,000 people directly, and making a global impact with exports in excess of €120 billion.

Specifically, there are 450 medtech companies with 9 of the world's top 10 medtech businesses having a base in Ireland as a gateway to Europe and beyond. This has helped to make us stand out in Europe as the greatest employer of medtech professionals, per capita, at 48,000 and the second largest exporter of medtech with €12.6 billion in global exports.

Nationally, the industry is a driver of regional investment and jobs growth with medtech companies operating in every constituency in Ireland and 60% of businesses are homegrown and 80% are startups or SMEs.

About Irish Medtech

Irish Medtech is the business association within Ibec representing the medical device, diagnostic, and digital health sectors. Irish Medtech works with more than 250 members, located throughout the island of Ireland. Irish Medtech is led by a Board of CEOs and Chief Representatives. It implements its strategy through working groups and taskforces.

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Medtech regulation needs to be reformed

Industry asks of Irish and European policymakers

irishmedtech.ie

How the EU medtech regulatory system works

To get into the health system, manufacturers must demonstrate that medical technologies meet EU-wide safety and performance requirements. These are assessed by Notified Bodies which are independent organisations designated by an EU country to grant approval for products which conform with the regulation and are awarded CE marks.

The new EU Medical Device Regulation (MDR), and In Vitro Diagnostics Regulation (IVDR), which came into effect 26 May 2021 and 26 May 2022 respectively, represents the greatest change for the regulatory system in over 20 years.

The new regulations impact not only device products but also drug-device products ('combination product') as there is no specific regulatory category for combination products. This has resulted in many pharmaceutical companies now being subject to MDR and IVDR.

Industry supports the goals of the MDR and IVDR legislation. However, industry is seriously concerned by the unintended consequences of its implementation which is now resulting in reduced access for patients to existing and innovative devices in Europe.

"Within the innovative Irish medtech start-up community, the majority of companies and their investors no longer see Europe as a viable initial go-to market because of the complex, costly and slow regulatory approval process."

John O'Dea, Serial Entrepreneur & CEO, Palliare

Our asks for Irish and European policymakers

Irish Medtech is calling on policymakers to prioritise reform of medtech regulation in the next European Commission and Parliament.

Reform must be comprehensive, structural and address efficiency, innovation, and governance, whilst maintaining the regulations' high level of device safety and performance.

Efficiency: The MDR/ IVDR system is proving unpredictable, slow, complex and costly.

Our asks include:

- Defined, predictable timelines for review and approval of products;
- Digital-labelling to support implementation and improve sustainability metrics;
- Structured dialogue with regulators to enable greater clarification of clinical and technical requirements; and
- Proportionate and predictable certification fees with greater support for SMEs.

Innovation: The MDR/IVDR system is not keeping pace with the innovation dynamics of medtech devices.

Our asks include:

- Dedicated, accelerated and clear regulatory pathways for innovative product certification;
- Recognition of regulatory decisions from other jurisdictions; and
- Specific regulatory pathways for orphan and paediatrics to keep and get these products to the market.

Governance: There is a lack of system-level governance.

Our asks include:

- An overarching structure to:
  - + manage the Notified Bodies (NB) across Member States;
  - + include development of clear system level guidance for NBs and manufacturers; and
  - + champion Europe's medtech industry and regulatory system internationally.

Did you know?

Almost **50%** of EU companies are deprioritising the EU market

Medtech Europe survey July 2022

Nearly **50%** of companies are putting EU innovation projects on hold

Medtech Europe survey July 2022

25% of medical device product portfolios either postponed or launched outside of the EU first.

Irish Medtech survey, November 2023

24% of medical device product portfolios reduced, cancelled or stopped.

Irish Medtech survey, November 2023

What clinicians say:

- Clinicians are already experiencing medical devices are no longer being available for use in clinical care.
- Devices for smaller patient populations, rare diseases and paediatric patients are particularly at risk.

EU losing out to US

The current EU system has resulted in US being the location of choice for product launches with many companies now choosing Asia as a second location.

In 2023, the FDA's Centre for Devices and Radiological Health (CDRH) approved the highest number of novel devices in the Centre's history, a five-fold increase since 2009.