



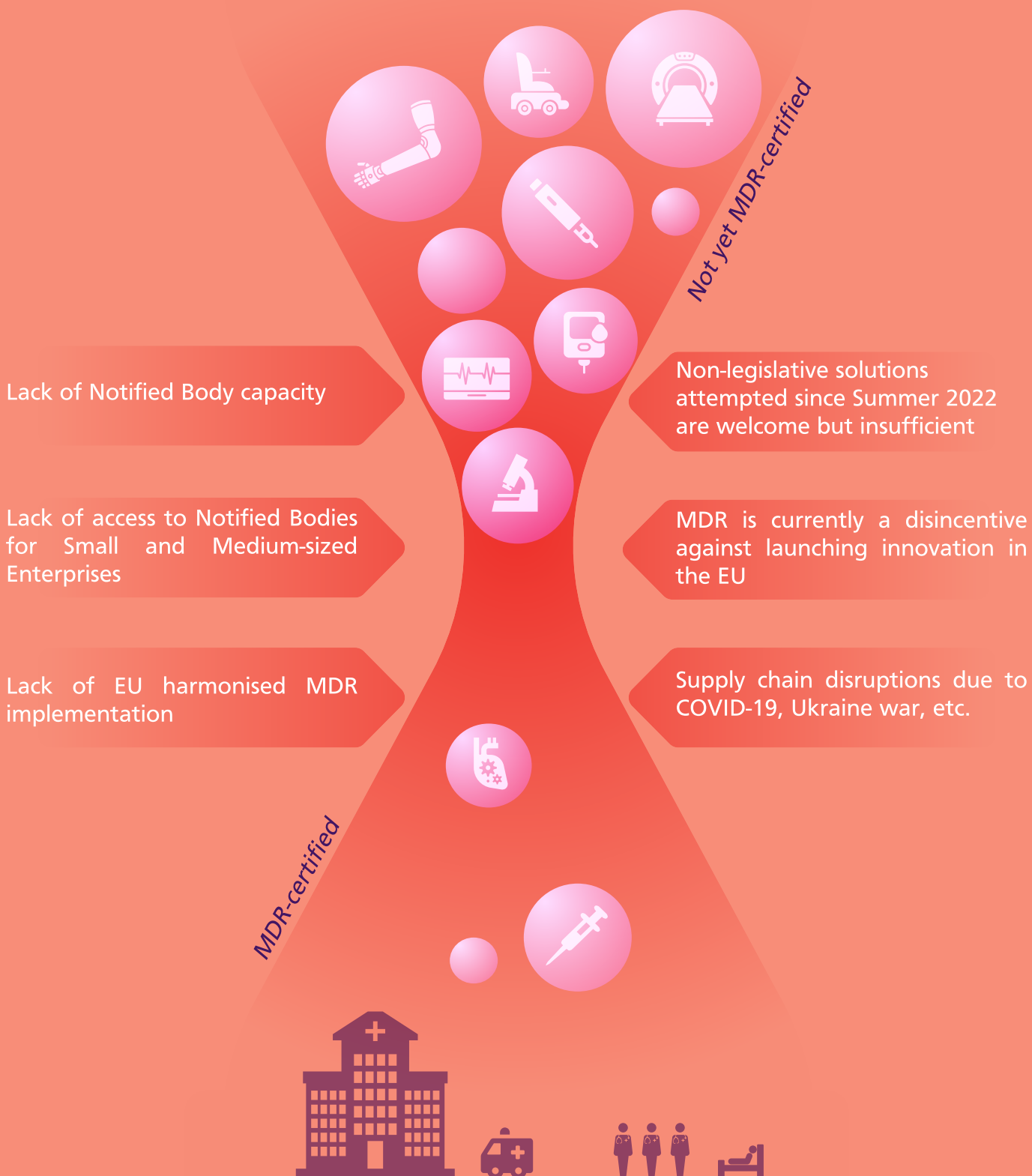
Making the EU Medical Devices Regulation more Workable

Europe is facing the imminent threat of shortages of medical devices needed by hospitals and physicians to care for patients. This situation is critical and affects both new and existing devices.

Immediate and urgent action by the EU institutions is needed.

Medical devices are crucial for patients, care teams and health systems across Europe

The Medical Devices Regulation (MDR) implementation is creating massive product certification bottlenecks...



... threatening the availability of lifesaving medical devices in Europe

The situation is critical, threatening the lives of patients across Europe. In order to ensure access to medical devices, the EU urgently needs...

New legally binding solutions

Extend the validity of expiring Directive certificates

Allow conditional and temporary MDR certifications

Abolish the 'warehousing' deadline

Further work and clarity on existing measures

Leverage and reuse evidence from previous assessments

Adopt more pragmatic clinical evidence expectations

Grant manufacturers early dialogue opportunities with Notified Bodies

As a last resort, make EU-wide derogations more workable

Urgent call for action




MedTech Europe urgently calls on legislators to support the adoption of bold EU-level legislative solutions that help ensure patients and health systems have access to all categories of medical devices

Medical technology provides lifesaving support

The MDR came into full application on 26 May 2021. The medical technology industry has always supported the MDR goals and made substantial progress in implementing the new rules. However, despite intensive efforts of all stakeholders, the new system itself is still not functioning in a way that is predictable and sustainable for all.

Without immediate legislative action, the continued availability of much-needed medical devices is threatened, which endangers healthcare delivery to patients both in Europe and around the world.

Did you know?

-  Due to certification bottlenecks before the 26 May 2024 end of transition time, to date only a small fraction of the ~25,000 former Directives certifications have transitioned to MDR.
-  Time-to-certification has doubled to 13-18 months on average under the MDR across all device categories.
-  There are already 19 non-legislative solutions to the issues arising out of the MDR, which the industry supports, but none of these have been sufficient so far to address the structural capacity issues and the growing emergency of expiring certifications.

If action is not taken, there will be significant consequences...

For the EU as a whole

- Higher market volatility and loss of European competitiveness against other global constituencies.

For patients & healthcare providers

- High risk of delay or discontinuation of access to existing and new medical technology products.
- Device disappearances are impacting all product categories

For manufacturers

- Difficulty in obtaining CE marking due to lack of available Notified Bodies
- Increased vulnerability for SMEs
- Lack of business predictability

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 who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

www.medtecheurope.org

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