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Urgent need to revise the medical devices regulation

European Parliament resolution of 23 October 2024 on the urgent need to revise the Medical Devices Regulation (2024/2849(RSP))

(C/2025/485)

The European Parliament,

— having regard to the Treaty on the Functioning of the European Union, and in particular Article 168 thereof,

— having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC ([1]) (MDR),

— having regard to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU ([2]) (IVDR),

— having regard to Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices ([3]),

— having regard to Regulation (EU) 2020/561 ([4]), Regulation (EU) 2022/112 ([5]), Regulation (EU) 2023/607 and Regulation (EU) 2024/1860 ([6]) extending the implementation periods of Regulation (EU) 2017/745 and Regulation (EU) 2017/746,

— having regard to the Commission's proposal for a regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices (COM(2023)0010),

— having regard to the European Medicines Agency's 2023 Annual Report and its review on market access and safety concerns for medical devices,

— having regard to Rule 136(2) and (4) of its Rules of Procedure,

A. whereas medical devices and *in vitro* diagnostic medical devices play a crucial role in high-quality healthcare, directly affecting the health, safety and well-being of millions of patients across the EU;

B. whereas approximately 500 000 different medical devices are available on the EU market, covering a broad range of technologies, from contact lenses to pacemakers, and serving different purposes, including diagnosis, prevention, treatment, rehabilitation and improving the quality of life of patients and the work of healthcare professionals and carers;

C. whereas disparities in access to medical devices persist across Member States, affecting patient care and leading to health inequalities; whereas such disparities underscore the need for improved availability and affordability of crucial devices;

([1]) OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj.
([2]) OJ L 117, 5.5.2017, p. 176, ELI: http://data.europa.eu/eli/reg/2017/746/oj.
([3]) OJ L 80, 20.3.2023, p. 24, ELI: http://data.europa.eu/eli/reg/2023/607/oj.
([4]) Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (OJ L 130, 24.4.2020, p. 18, ELI: http://data.europa.eu/eli/reg/2020/561/oj).
([5]) Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and the deferred application of conditions for in-house devices (OJ L 19, 28.1.2022, p. 3, ELI: http://data.europa.eu/eli/reg/2022/112/oj).
([6]) Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain *in vitro* diagnostic medical devices (OJ L, 2024/1860, 9.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1860/oj).

D. whereas the MDR and IVDR were adopted to strengthen the regulatory framework for medical devices and *in vitro* diagnostic medical devices, as a response to several high-profile scandals with unsafe medical equipment, with the purpose of ensuring higher standards of safety, transparency and clinical performance while also fostering innovation in the sector;

E. whereas the MDR and IVDR introduced more robust requirements for clinical evaluations, post-market surveillance and vigilance reporting, promoting transparency in the approval and monitoring processes;

F. whereas despite these aims, significant challenges have been encountered in implementing the MDR and the IVDR, not only leading to delays but also resulting in failures to achieve certification and approval of medical devices and *in vitro* diagnostic medical devices, particularly impacting small and medium-sized enterprises (SMEs), as well as resulting in shortages of medical devices and *in vitro* diagnostic medical devices, thus restricting patient access to innovative and life-saving therapeutic and diagnostic technologies;

G. whereas many stakeholders, in particular small and medium-sized manufacturers, notified bodies and healthcare providers, have reported difficulties in navigating the complex regulatory procedures under the current MDR and IVDR framework, with potential risks posed to the continuous availability of life-saving medical devices and critical *in vitro* diagnostic tests in the EU;

H. whereas the transitional periods for the implementation of the MDR and IVDR have been extended on numerous occasions to address issues including the capacity of notified bodies and to allow industry more time to adapt to new rules in order to prevent devices being withdrawn from the EU market;

I. whereas due to a lack of harmonised procedures across notified bodies in the EU, among other things, manufacturers can in some instances face unpredictable timelines for certification and market access, which creates unpredictability, alongside inconsistency in decisions and a lack of transparency in relation to the work of the notified bodies;

J. whereas there is a need for the regulatory frameworks to better accommodate innovative devices that address unmet medical needs and provide better prioritisation and fast-track pathways;

K. whereas the Commission initiated non-legislative actions to support the transition to the MDR and IVDR, focusing in particular on the availability of medical devices on the market, the preparedness of notified bodies, the development of orphan and paediatric devices, SME support and the waiving of fees for scientific advice in critical areas where, despite these measures, financial and administrative challenges persist, particularly in the orphan and paediatric sectors;

L. whereas the deadlines for implementing the MDR and IVDR have been extended multiple times to help the industry adapt to new regulations, to prevent market withdrawals and to ensure the continuous supply of devices; whereas these extensions were critical in maintaining public health protection during the COVID-19 pandemic;

M. whereas since the adoption of the MDR and IVDR, the Commission has also introduced new provisions regarding the European Database on Medical Devices (EUDAMED) and a notification system for market interruptions or supply discontinuation;

N. whereas it is important to ensure that patients and healthcare professionals have access to all relevant documents and decisions taken by the notified bodies;

O. whereas the innovative regulatory framework referring to substance-based medical devices, which was introduced by the MDR, is intended to encourage the development of therapies that act through non-pharmacological, non-immunological and non-metabolic means; whereas guidelines and decisions issued by national authorities set limits that classify products falling within the scope of the MDR under other regulatory categories, which goes against the EU legislator's aim of fostering therapeutic innovation;

P. whereas e-health applications of which the purpose corresponds to the definition of medical devices are not currently certified, and therefore potentially endanger users' health data;

1. Calls on the Commission to propose, by the end of Q1 2025, delegated and implementing acts to the MDR and the IVDR to address the most pressing challenges and bottlenecks in the implementation of the legislative frameworks and to propose the systematic revision of all relevant articles of these regulations, accompanied by an impact assessment, to be conducted as soon as possible;

2. Calls on the Commission to make full use of legislative and non-legislative tools to resolve issues of divergent interpretation and of practical application to streamline the regulatory process, improve transparency, and eliminate unnecessary administrative work for notified bodies and manufacturers, particularly SMEs, without compromising patient safety;

3. Deplores the risk of shortages of medical devices and the lack of access to certain medical devices and *in vitro* diagnostics in parts of the EU; stresses that access to and quality of healthcare, including medical devices and *in vitro* diagnostics, should not depend on where in the EU a patient is located;
4. Encourages the notified bodies to ensure that there are sufficient resources to meet the market demand in a timely manner; in this regard, calls on the Commission and the Member States to enhance support and cooperation to ensure that the notified bodies have the optimal capacities and capabilities to fully implement the regulatory framework;
5. Advocates the creation of transparent and binding timelines, including clock stops for procedural steps in conformity assessment by notified bodies, thus creating predictability and certainty for manufacturers regarding the market access procedure and its duration within the EU;
6. Calls for transparency in notified bodies' fees and fee structures, to allow economic operators to compare notified bodies and make informed choices, ensuring that fees remain a fair compensation for the public service provided;
7. Stresses the need to eliminate the unnecessary re-certification of products, and underlines that certain product updates or adjustments should not necessarily lead to an entire re-certification of the product; stresses the need to harmonise such provisions and ensure consistency across the EU; calls for cooperation between the competent authorities and advisory bodies responsible for other regulatory frameworks, and stresses the need for products to be classified correctly and consistently;
8. Strongly calls on the Commission to consider fast-track and prioritisation pathways for the approval of innovative technologies in areas of unmet medical need and for devices linked to health emergencies;
9. Stresses the need to protect health data collected by e-health applications by expressly including these applications in the scope of the revised MDR and by laying down appropriate provisions on them;
10. Highlights the need to establish a clear working definition of 'orphan device', as determined by the Medical Device Coordination Group in the MDR and IVDR, to facilitate the adoption of harmonised measures across the EU; additionally calls for a robust system to prevent misuse through artificial 'orphanisation';
11. Calls for the introduction of adapted rules for orphan and paediatric medical devices, without compromising patient safety, and emphasises the need for more efficient conformity assessment procedures tailored to medical devices and *in vitro* diagnostics serving relatively small markets, such as products for the treatment of children or rare diseases;
12. Calls on the Commission to facilitate the collection of clinical data from existing national registries for small patient groups treated or diagnosed with orphan and paediatric devices, in compliance with the protection of personal data; recognises the challenges faced by various SMEs in adapting to the legal frameworks; invites the Member States and the Commission to develop specific measures to support SMEs, including the provision of model application documents and forms, regulatory guidance and other assistance to reduce the costs and complexity of the regulatory frameworks;
13. Calls on the Commission to continuously monitor the availability of devices, particularly the last remaining devices of particular types, and to take appropriate action to keep them available in the EU market; in this regard, calls for an urgent full implementation of EUDAMED, which will enable information about medical devices and manufacturers to be processed to enhance transparency, provide better access to information for the public and healthcare professionals, and enhance coordination between Member States;
14. Emphasises that any new rules or changes to existing rules must come with an appropriate transition period to allow all stakeholders sufficient time to adjust to the changes;
15. Instructs its President to forward this resolution to the Council, the Commission and the governments and parliaments of the Member States.