European Commission DG SANTE
Unit D3 - Medical devices
Head of Unit
Flora Giorgio

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via e-Mail to ***flora.giorgio@ec.europa.eu***

Urgent need for action: Legal short-term measures to facilitate MDR/IVDR implementation in Q1 2025

Dear Flora,

Recital (1) of Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR) states that the objective is "to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation". Furthermore, according to recital (2), the MDR and IVDR aim to ensure the smooth functioning of the internal market for medical devices, with a high level of health protection for patients and users, taking into account the small- and medium-sized enterprises active in the sector.

However, after more than six years of implementing these regulations, the availability of both long-standing and new modern medical devices in Europe has declined, negatively impacting patient care. The unpredictability, complexity and lack of harmonization, as well as the administrative burden of the regulations have led to high and unproportionate costs, product discontinuations and migration of innovation.

While the undersigned associations welcome a targeted evaluation in 2025 to further explore root causes and simplification, urgent legal measures are required now, to restore trust in the system and among all stakeholders, to protect patient care with both proven and modern medical devices, and to maintain the EU as a competitive center of innovation.

In line with the European Parliament's resolution of 23 October 2024 on the urgent need to revise the Medical Device Regulations (2024/2849(RSP)), we support a prioritized approach, beginning with short-term solutions that can be implemented through implementing acts. These measures also support EU Commission President von der Leyen's agenda to reduce bureaucracy.

Specifically, we propose the following deliverables for Q1 2025:

1. **Implementing Act regarding Annex VII**

Article 36 (3) MDR/ article 32 (3) IVDR allows the Commission to establish implementing acts in regard to the application of Annex VII. *„In order to ensure the uniform application of the requirements set out in Annex VII, the Commission may adopt an implementing act, to the extent necessary to resolve issues of divergent interpretation and of practical application."* Topics of major importance that could be addressed here are related but not limited to e.g. establishing a common understanding of the steps and timelines for conformity assessment in order to enhance predictability, efficient change notification and management, structured dialog, content of a written agreement ensuring a level playing field, templates for certificates, Notified Body contract, and technical documentation structure and format. More details regarding possible measures within this legal act are highlighted in yellow in the attached list.

2. **Implementing Act regarding clinical evidence**

To *"ensure the uniform application of Annex XIV, the Commission may, having due regard to technical and scientific progress, adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application"* (see article 61 (13) MDR/ article 56 (7) IVDR). Also, in order to achieve a *"uniform application of the requirements regarding the clinical evidence or data needed to demonstrate compliance with the general safety and performance requirements set out in Annex I"* the Commission may establish implementing acts (see article 81 (g) MDR/ article 77 (g) IVDR). Other specific provisions also allow for implementing and delegated acts (e.g. article 32 (3), article 52 (5) MDR/ article 29 (3), article 48 (13) IVDR). Questions in regard to the summary of safety and clinical performance (SSCP), the concept of well-established technologies and to making use of the possibility outlined in article 61 (10) MDR can thus be addressed. Possible measures are marked in green.

3. **Adapt certification to follow a life cycle approach**

Today, recertification for medical technologies is required every 5 years, which represents a high bureaucratic effort and re-investment burden without resulting in additional safety benefits. This is because the Notified Bodies are already required to continually assess devices and quality systems after their certification on an annual and ongoing basis. Therefore, there is an immediate need for aligning certification with the life-cycle approach introduced by the regulations in order to avoid unnecessary bureaucracy, costs and potential bottlenecks. Proposals to do so are outlined in blue.

4. **Implementing Act in regard to the digitalization of processes and documents/eIFU**

Results of multiple surveys show that the current framework for the very limited use of electronic instructions for use is outdated. A broad application of electronic instructions for use will help reduce

bureaucracy and protect the environment. Improvements in regard to e-labelling and digitization of processes are also needed. Proposed solutions are highlighted in purple.

5. **Implementing act regarding Classification rules as well as pathways for orphan devices and breakthrough innovations**

Article 51 MDR/ article 47 IVDR allows for the Commission to decide by means of implementing acts on issues that refer to the application of Annex VIII, that is classification and/or reclassification of a given device or category or group of devices. There are a number of proposals in this regard that are outlined in red.

In summary, the compilation of these solutions would immediately reduce administrative and financial burden for manufacturers and Notified Bodies, without compromising the safety or performance of medical devices or patient well-being. Swift implementation would also enhance the EU's innovative strength and global competitiveness.

Following this, a supplementary amendment to the regulations should be enacted within 2025. Additional proposals that should be considered for this amendment as well as ongoing short term specific measures to improve the implementation of the regulations are also provided (without colour) in the following table.

For the benefit of patients, the national healthcare economy, industry, and the EU as a vital business and innovation hub, the original objectives of the MDR/IVDR can only be achieved by addressing all steps mentioned above.

We would be pleased to provide a more detailed explanation of the points outlined. Please don´t hesitate to contact us in case of questions.

Best regards,

Corinna Mutter on behalf of the above listed associations
Attorney at law / In-house Council
Director Regulatory and EU-Affairs SPECTARIS