Joint Opinion of D-A-CH region industry associations

Strengthening the competitiveness of the MedTech sector through simplification

31th July 2025

Introduction

The Medical Device Regulation (MDR) and the In-Vitro diagnostics Regulation (IVDR) are the result of the need for *a fundamental revision* of the previous *Directives to establish* a robust, trans-parent, predictable and sustainable *regulatory framework for medical devices and IVDs which ensures a high level of safety and health whilst supporting innovation*[1]. It aims to *ensure the* smooth functioning of the internal market *as regards medical, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises*[2].

Eight years into implementation, the objectives of the regulations as outlined above have not been successfully attained as several aspects of the regulatory system remain dysfunctional, leading to device shortages, reduced innovation, SME closures, and manufacturers shifting their focus to other markets.
Medical devices and IVDs are essential to saving and improving the lives of millions of people each day. The largely SME driven sector is one of Europe's most innovative industries.
The signing associations are therefore encouraged, by the recent discussions acknowledging the challenges our sector is facing and welcome the many valuable suggestions provided by a variety of stakeholders, including CAMD and the European Parliament, on how to improve the regulatory system. We appreciate the steps already undertaken by the European Commission to gather the necessary evidence to implement legislative changes, as well as for the ongoing efforts to improve the regulatory system, reduce bureaucratic burden and ensure a smooth implementation.

The targeted Evaluation seeks to address some of the deeply rooted structural issues in key areas, such as governance. However, more decisive legal action is required to achieve a streamlined, innovation-friendly regulatory framework. We therefore call on the European Commission to initiate a legal proposal in 2025 to reduce bureaucratic burden within the medical device and IVD frameworks.

Administrative burden must be reduced and regulatory predictability improved, the initial product approval must be faster, more efficient, predictable and less costly.

[1] Recital (1) of Regulation (EU) 2017/745 (MDR)
[2] Recital (2) of Regulation (EU) 2017/745 (MDR)

With a focus on proportionality regulatory processes must be streamlined and reporting obligations must be reconsidered.

In order to achieve and implement these measures, we provide concrete examples of bureaucratic burden and suggest legal avenues for solutions, which are listed in the annex. They are based on the following principles:

1.
Reporting with purpose

Documentation and reporting efforts need to be reasonable and appropriate taking into account a high level of safety and availability of devices.

In addition to reducing individual requirements, such as high reporting frequencies and scope, the abolition of individual reporting obligations and the practice of reporting must be fundamentally reconsidered, in particular redundant reporting requirements and requirements without consequences and follow-up actions must be abolished.

2.
Streamlined regulatory processes

Regulatory processes and workflows need to be optimised to ensure efficiency and predictability especially by reducing redundancies in assessments and audits. They need to be thought through from start to finish.

The principle of good administration must be introduced and implemented to ensure that the CE certification system continues to operate in a fair, transparent and predictable manner under administrative accountability.
Clear timelines for procedural steps or the whole conformity assessment as well as procedures are needed also for breakthrough innovations.
The review of technical documentation must be comprehensive and complete. In further rounds, no completely new questions may be added to address issues and findings already raised.
To streamline time-critical processes, sequential procedures should be replaced by parallel procedures so that patients can access needed products more quickly.
The specific characteristics of well-established technologies must be taken into account to a considerable extend in order to maintain proven and safe products on the market.

3.
Increased focus on proportionality

The documentation effort needs to be appropriate and adequate for demonstrating that the objective pursued is achieved.

To demonstrate safety and performance of a device all obligations under a regulation and the associated effort should follow a least burdensome approach.
The MDR and IVDR contain obligations for Economic Operators, that do not result in any output or direct actions by notified bodies, competent authorities and therefore have no impact on devices or patient safety.

4.
Coherence to horizontal legislation

Where multiple regulatory frameworks apply, the specific requirements of the sectoral medical technology legislation must be taken into account in order to effectively manage overlaps, conflicting provisions and concurrent regulatory obligations.

Due to the principle of the new legislative framework[3] (NLF) multiple EU regulations can apply concurrently to one and the same product. At the same time there is no standard mechanism in NLF managing overlapping, conflicting and concurrent regulatory obligations. This leads to an overcomplexity of legal requirements and difficulties for any manufacturer to determine which requirements apply at which point in time.

5.
Legal Clarity

The legal provisions should be substantively clear, concise, structurally consistent, and linguistically unambiguous - without the need for supplementary interpretive guidance. Requirements containing vague or interpretation-dependent language should be revised, and overly specific provisions that go beyond what is necessary for effective oversight should be removed.

Legal clarity is essential to ensure that compliance with the regulations can take place as intended. It enables all actors to operate based on a shared understanding and helps reduce unnecessary bureaucratic compliance costs. Economic operators seeking to comply with the regulations currently need to be aware of over 150 endorsed MDCG –guidance documents, as well as harmonised standards, court decisions and national laws. This regulatory complexity is caused by non-intuitive, extremely specific or internally inconsistent provisions resulting in the need for guidance and should be amended at the source within the legal text, where possible.

In order to put these basic principles into practice, we have compiled a list of concrete improvement measures, which is attached to this position paper. This list is intended to be seen as a supplement to the administrative burden list of the undersigning provided by the signing associations in November 2024.

[3] https://single-market-economy.ec.europa.eu/single-market/goods/new-legislative-framework_en