IDF Europe Response to the Targeted Revision of the Medical Devices Regulation (MDR) (EU) 2017/745 and In Vitro Diagnostic Medical Devices Regulation (IVDR) (EU) 2017/746

Executive Summary

- **IDF Europe welcomes efforts to improve regulatory efficiency, reduce bottlenecks and support innovation in the European Union (EU) medical devices framework**.
- **However, the proposed revision marks a concerning shift towards simplified pre-market procedures** and increased reliance on post-market oversight, **without fully addressing the safeguards required to ensure patient safety, transparency and system effectiveness**.
- **Increased flexibility in clinical evidence requirements**, including expanded equivalence approaches, as well as the replacement of recertification with periodic reviews **risks weakening pre-market scrutiny for medium- and high-risk devices**.
- **The proposal does not sufficiently ensure consistency of assessment across Member States (MS) and Notified Bodies (NBs),** meaning existing tools such as Common Specifications (CS) need to be implemented, where needed.
- **While the launch of EUDAMED is a positive step**, core clinical and performance data will remain largely inaccessible to patients and healthcare professionals. This constrains informed decision-making and trust in the system.
- **Key requirements such as human oversight and user understanding may not automatically apply to Artificial Intelligence (AI)-enabled medical devices** under the revised framework, despite their increasing role in real-time clinical decision-making.
- **Greater reliance on post-market surveillance is not matched with reinforced action to guarantee strong and efficient reporting** of performance and safety issues. Additionally, **the systematic involvement of people with lived experience in regulatory governance remains limited.**

To address these gaps, IDF Europe calls for the following priority actions:

- **Establish harmonised standards and CS:** develop EU-wide requirements for NBs and, in the absence of standards, proactively accelerate the development of CS to define minimum clinical, performance and study design requirements for relevant, established device areas, where EMA and expert panels are not currently envisaged to be involved.
- **Enhance transparency and access to data:** ensure public access to clinical and performance data, including for class IIb and higher-risk devices, in accessible and comparable formats through EUDAMED.
- **Embed AI safeguards within MDR/IVDR:** integrate requirements on human oversight and user understanding to ensure the safe use of AI-enabled devices such as CGMs and AID systems.
- **Strengthen post-market surveillance and lived experience involvement:** improve reporting systems, ensure coordination across MS and embed people with lived experience and patient organisations in regulatory processes and awareness efforts.

Background

The Medical Devices Regulation (MDR) (EU) 2017/745 and the In Vitro Diagnostic Devices Regulation (IVDR) (EU) 2017/746 govern the manufacturing, distribution and availability of medical devices in Europe, including essential devices used by people living with diabetes (PwD), such as blood glucose monitors, continuous glucose monitors (CGMs) and insulin pumps.

The proposed targeted revision of the MDR/IVDR framework seeks to address implementation challenges that have created bottlenecks, uncertainty and risks to the availability of essential devices in Europe by reducing unnecessary administrative burdens, increasing predictability of certification processes and supporting innovation and access, including for small and medium-sized enterprises (SMEs), while maintaining a high level of health protection. Any reform of the MDR must be evaluated against its capacity to guarantee both timely access and robust safeguards for end users of medical devices, particularly for medium- and high-risk devices.

Supporting innovation: positive steps towards greater regulatory efficiency

Fast-track procedures for breakthrough and orphan devices and the possibility of establishing regulatory sandboxes[1] are positive developments that can accelerate access to transformative technologies, provided that these pathways are accompanied by rigorous safety and performance requirements.

The proposed strengthening of European Union (EU)-level coordination and expertise is a positive step, with an enhanced role for the European Commission (EC), the European Medicines Agency (EMA) and expert panels **having the potential to improve consistency in classification, clinical evaluation, vigilance and market surveillance across Member States (MS)**. The reinforced coordination of notified bodies (NBs) through a formalised group reporting to the Medical Device Coordination Group (MDCG) could further support harmonisation and oversight.

We also welcome efforts to streamline the interaction between the Artificial Intelligence (AI) Act and the MDR/IVDR, including approaches that reduce regulatory overlap and improve coherence between frameworks.

A more integrated and efficient system has the potential to provide greater clarity for developers and regulators and to facilitate timely access to innovative technologies. Nevertheless, it is essential to ensure that this simplification does not result in gaps in the application of key safeguards for AI-enabled medical devices, such as CGMs and automated insulin delivery (AID) systems.

[1]Regulatory sandboxes generally refer to regulatory frameworks that provide a structure for healthcare innovation developers to test and experiment with new and innovative products, services, or approaches under the oversight of a regulator for a limited period of time. Modelling regulatory sandbox mechanisms and enabling their deployment to support breakthrough innovation | Horizon-europe.gouv.fr

Ensuring user safety, transparency and system effectiveness: gaps in the proposed revision

While we welcome the EC's clear intent to place user safety at the centre of the MDR revision, a number of aspects raise serious concerns. Taken together, these changes risk weakening pre-market safeguards, increasing the likelihood that sub-optimal or insufficiently evaluated devices could reach the market, and may leave gaps in protection for those relying on safe and reliable medical devices.

A shift towards post-market oversight without the safeguards to match

The revision clearly marks a shift towards simplifying pre-market procedures combined with an increased reliance on post-market oversight. For example, the proposal introduces increased flexibility in how equivalence can be established for certain high-risk (Class III) and implantable devices. This may allow manufacturers to rely on clinical data from comparable, but not exactly equivalent, devices as part of their conformity assessment, reducing the requirement to generate new clinical investigation data. **While intended to streamline procedures, this shift risks weakening pre-market clinical scrutiny for higher-risk devices which is essential for safeguarding user safety.**

One way in which the proposal seeks to improve pre-market assessments is the increased role of the EMA and expert panels in providing guidance upon request, in borderline or classification questions, or in the designation of a breakthrough or orphan device. **Despite the strengthening of the role of the EMA and the availability of external expertise** to manufacturers and NBs, **the revision does not call for the systematic involvement of expert panels; rather, these are only triggered in limited situations**. In most assessments, NBs can still rely solely on their own internal expertise, without any obligation to consult EU-level panels, and even when an expert opinion is requested, it is advisory rather than binding, although NBs must document the reasons for their decision. **The revision also introduces EU-level consultation fees for the use of expert panels and EMA scientific advice. Fees risk limiting uptake and undermining the effective use of EU-level scientific expertise**, especially for SMEs, which may already not have access to the broad level of expertise in their internal teams as larger manufacturers do. This is all the more concerning that the cost of certification was seen as a major impediment to innovation in the current framework.

In this context, **IDF Europe calls for a tiered approach to fees based on company size as well as a broader role for the EMA and expert panels, especially for new Class IIB and Class III devices**, as post-market surveillance cannot replace rigorous pre-market assessment.

Replacement of recertification: greater clarity required

The revision proposes replacing full recertification with proportionate periodic reviews and removing the current five-year maximum validity for certificates, a change that could streamline regulatory processes and reduce administrative bottlenecks. However, **this approach places greater reliance on effective and proportionate post-market surveillance**. For devices such as CGMs, which are used continuously and often integrated into complex management systems such as AIDs, systematic post-market clinical follow-up and robust vigilance processes are essential. **To safeguard user safety, greater clarity is needed on the scope, methodology and frequency of periodic reviews, and on how they will be applied across different device risk classes in practice**.

In consultation with the MDCG and the EMA/expert panels, the EC should, by implementing act, define a common methodology for periodic reviews, defining the minimum scope, evidence sources, risk-based frequency and triggers for more or less intensified review for each risk class. The act should ensure that higher-risk and continuously used devices are subject to more frequent and substantive review, including real-world performance and post-market clinical data.

Persistent structural weaknesses in the regulatory framework

The revision proposal does not sufficiently address a number of core structural weaknesses in the current regulatory framework, including the lack of uniform, EU-wide standards for NBs, frameworks and minimum requirements for assessing required clinical evaluation and investigation standards and the development of common study design approaches. **In the absence of clear, harmonised criteria at EU level, NBs are left to interpret general requirements in potentially divergent ways**, resulting in variability in conformity assessments and inconsistent levels of scrutiny across MS.

CGMs illustrate the practical consequences of this gap. **As devices that are used continuously and directly inform clinical and self-management decisions** many times per day, **CGMs require a high and predictable level of accuracy, reliability and clinical performance**. However, the absence of harmonised, CGM-specific assessment criteria and minimum performance thresholds has already allowed sub-optimal devices to enter the market, in some cases leading to serious issues. This experience demonstrates how the lack of EU-wide standards, combined with the lack of device-specific guidance and full transparency of clinical evidence, can translate directly into patient risk, even under a strengthened regulatory framework.

These concerns are further amplified by the proposal's move towards greater flexibility in acceptable clinical evidence, including increased reliance on non-clinical data, in silico testing and expanded equivalence approaches. While innovative methodologies can complement traditional clinical evidence, loosening pre-market requirements in the absence of robust, EU-wide and device-specific standards risks lowering the evidence bar for devices with a direct and continuous impact on user safety. For such devices, such as CGMs, minimum clinical and performance requirements should be clearly defined and reinforced rather than diluted.

The EC must make full use of the existing tools within the regulatory framework to address these gaps and ensure that devices requiring additional guidance receive it in a timely manner. **Common Specifications (CS) should be developed for established technologies** such as CGMs, which have repeatedly shown variability in performance, defining minimum clinical and performance requirements, as well as, importantly, appropriate study design approaches. This is even more crucial with the proposal of greater flexibility in clinical evidence. The EC, in collaboration with the MDCG and expert panels, should act without delay to develop a CS that is fit for purpose for the EU market.

Beyond CGMs, medical devices across all class groups vary significantly in their use, complexity and impact on user safety, and the MDR framework must be able to account for these differences. Where horizontal requirements are insufficient, and EMA and expert panels are not systematically involved, the EC should proactively identify device areas that require additional guidance and develop CS to ensure consistent and appropriate levels of scrutiny across the EU. Without this, the potential for sub-optimal CGMs to reach the market remains high.

The proposal also falls short of addressing known resource gaps, including funding and training needs for NBs, which are essential to ensure that they can handle the volume and complexity of evaluations required under the MDR.

Insufficient transparency of clinical and performance data

EUDAMED has the potential to significantly enhance transparency of the regulatory system. However, the current proposal falls short in proposing mechanisms that truly ensure trust and enable patients and healthcare professionals (HCPs) to make informed decisions. Under the current framework and the proposed revision, the public version of EUDAMED will allow the general public, end users, HCPs and other stakeholders to identify a device (name, model), see who manufactures and places it on the market, and, for certain higher-risk devices (class III and implantable devices), consult a Summary of Safety and Clinical Performance (SSCP) that explains the main clinical evidence, benefits and risks in lay language. They will also be able to find basic information on registered clinical investigations and some official safety communications, such as field safety notices and certain regulatory warnings.

However, this level of transparency is both limited and insufficient. Core post-market documents and data, including the detailed clinical evaluation, the full clinical and performance study files, periodic safety update reports (PSURs) and most of the real-world performance data collected through manufacturers' post-market surveillance systems, will be shared only with NBs and competent authorities (CAs) and not made routinely accessible to the public. This means that the proposed revision still does not call for any systematic obligation to make clinical and performance data (especially for class IIb and higher-risk devices) publicly available in accessible formats, nor to publish real-world surveillance data in a timely and user-friendly way. As a result, **even once EUDAMED is fully operational, end users, HCPs and other stakeholders will have only a partial, high-level view of safety and performance, even for higher risk devices such as class IIb and class III devices**, which are widely used in clinical decision-making and have a direct and continuous impact on patient care.

In addition to greater accessibility of information, there is also a need for more structured and comparable reporting of clinical evidence. A key issue, regardless of whether it is pre- or post-market clinical evidence, is whether their results are reported in a consistent and transparent manner that allows for meaningful comparison across devices within the same therapeutic area. In well-established domains such as diabetes care, clearer expectations regarding the content and structure of clinical reporting, including the information presented in the SSCP could strengthen trust in the regulatory system and improve the ability of clinicians and end users to understand device performance.

To enhance transparency, trust and clinical decision making, end users and HCPs must be able to easily access SSPCs and clinical evidence for all devices in which a clinical investigation is performed. Given that clinical evidence is generated through patient participation and exposure to risk, ensuring that this information is meaningfully accessible is not only good practice, but an ethical imperative.

Critical gaps: AI literacy and human oversight

While the approach to aligning the AI Act and MDR/IVDR has clear benefits in terms of efficiency and legal clarity, certain AI-specific requirements, such as those relating to human oversight[2] and literacy[3] are not reflected within the proposal, and therefore may not automatically apply to medical devices.

[2] meaning that a human can monitor, question, and intervene in how the AI system operates
[3] meaning that people using or affected by an AI system have enough understanding to use it safely and appropriately

In diabetes care, technologies such as CGMs and AID systems rely on algorithm-driven functionalities to generate insights and, in most cases, support or automate treatment decisions in real time. As these systems play a direct role in day-to-day disease management, ensuring their safety and reliability is essential. Within this context, for these AI-enabled devices, people with lived experience and HCPs must be able to understand how systems operate, recognise their limitations and intervene where necessary. This is especially relevant for devices such as AID systems, where algorithm-driven outputs can directly influence insulin delivery.

To address this gap, the revised MDR/IVDR should explicitly incorporate equivalent requirements for human oversight and AI literacy, ensuring these critical safeguards automatically apply to medical AI devices through conformity assessment.

Improving regulation through patient empowerment and inclusion

With greater reliance on post-market oversight, the regulation of devices will also depend more heavily on end users of devices to report problems and incidents. End users, HCPs and other stakeholders must be encouraged, and have simple, well-understood pathways to report problems and incidents. For this to work in practice, people with lived experience and HCPs need targeted education and training on when, how and to whom to report device problems. Associations of people with lived experience and HCPs can play a key role not only as dissemination channels, but also as partners in the co-creation of awareness campaigns, training materials and reporting guidance and need to be involved in a structured and systematic manner. Authorities must also have the capacity and tools to analyse these problems rapidly and act decisively when needed, including collaboratively with other competent authorities across the Union. Without strong, transparent, user-friendly and clear surveillance systems, increased reliance on post-market controls risks creating gaps in protection rather than enhancing it.

Finally, the meaningful and systematic involvement of people with lived experience in device assessment and regulatory governance structures, including expert panels, is largely absent. While the regulation does indicate that people with lived experience can be consulted by expert panels, this inclusion is not mandatory. Embedding users' voices within these structures is required to strengthen the quality, relevance and legitimacy of regulatory decision-making.

Key recommendations

To align the revision fully with the safety of those using these devices, the following priority actions are essential:

- **Harmonise NB standards**: establish EU-wide requirements, including training of NBs, clinical evaluation frameworks and study design expectations, to eliminate variability in conformity assessments, especially for medium to high-risk devices.
- **Make full use of the available instruments under the MDR/IVDR**: adopt implementing acts for CS to set measurable minimum thresholds for accuracy, reliability and clinical performance for established devices where no guidance exists, building on international best practices, ensuring all meet baseline quality before market entry.
- **Strengthen post-market surveillance and transparency**: provide accessible, user-friendly reporting pathways for people with lived experience, HCPs and other relevant stakeholders; and mandate full disclosure of clinical/performance data for class IIb and above devices on the publicly accessible version of EUDAMED.
- **Ensure full AI safeguards are applied under MDR/IVDR**: embed safeguards for AI-enabled devices, including human oversight and literacy, so people living with specific conditions and HCPs can interpret system outputs, recognise limitations, and intervene when necessary.
- **Embed people with lived experience in governance structure and processes**: integrate the perspectives of end users in assessments, expert panels and governance structures to strengthen the relevance and legitimacy of regulatory decisions.

By integrating these safeguards with simplification measures, the MDR revision can deliver an efficient, protective framework, ensuring timely access to innovative devices while guaranteeing safe, high-performing medical devices for all people across Europe.