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European Society of Cardiology

ESC statement on the Proposal for a revision of the Medical Device Regulation

The **European Society of Cardiology (ESC)** welcomes the European Commission's proposal to revise the **Medical Device Regulation (EU 745/2017)**.

The **Medical Device Regulation (MDR)** was adopted with the aim of improving patient safety, strengthening clinical evidence, and supporting innovation. However, implementation has revealed **significant structural challenges**, including reduced device availability, excessive regulatory burden, incoherent evidence requirements diverging national practices, and insufficient integration of clinical expertise. This has inadvertently **reduced access to innovative devices** for European patients, and caused migration of clinical research to other jurisdictions. While the ESC **welcomes** this initiative to simplify the current system, we recall that simplification should come through **stronger scientific coordination** at EU level, earlier and improved **structured dialogue** with manufacturers, better **coordination** with stakeholders greater **consistency** in the interpretation of evidence requirements across notified bodies (NBs), and further **operationalisation** of the role of **expert panels** and of the role of **EMA** in coordinating and supporting the regulatory framework.

The revision therefore represents an important and timely opportunity to **achieve a well-balanced EU medical-device ecosystem** – one that improves **patient access to meaningful innovation**, while upholding **high standards of safety and quality**. It also provides a chance to enhance the **generation and integration of appropriate clinical evidence** throughout the regulatory lifecycle, and to reinforce **EU-level governance and coordination**, which are essential to ensuring a coherent, predictable and effective system, with positive beneficial effects for clinical practice and patients.

The ESC strongly supports this initiative and offers the following comments and recommendations.

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I. Simplification and Proportionality

1. Time-unlimited certificates & triggers for corrective measures

The ESC recognizes the value of reducing unnecessary administrative burden**,** and the removal of the automatic five-year renewal requirement goes in that direction. Yet the introduction of **time-unlimited certificates**, especially if paired with the **elimination of contractual access requirements for demonstrating equivalence**, raises substantial concerns about the robustness of the clinical evidence underpinning devices on the EU market. In practice, this change risks lowering evidence thresholds.

These concerns are amplified by the fact that **no clear evidence-based framework** is proposed to determine limitations to the duration and /or validity of the certificate. Routine audits largely focus on **quality management systems**, rather than on clinical performance or emerging safety issues. Meanwhile, the proposal allows NBs to establish limitations to the length of certificates only in **"exceptional cases"**, that, if not clarified further may lead to differing interpretation by NBs. This gap is even more concerning because many device-related risks only become apparent **years after commercialization**: across implanted cardiovascular technologies, such as structural heart implants, pacemakers, defibrillators, stents and prosthetic valves, clinically significant performance issues may only become apparent after several years of real-world use.

Consequently, without clear triggers for regulatory action grounded in clinical evidence, the combination of unlimited certificate duration and relaxed equivalence rules risk undermining the very objective of ensuring long-term patient safety.

Recommendations

- Define **mandatory evidence-based external triggers** for field corrective safety actions, suspension or withdrawal of certificates, such as safety signals from clinical trials or registries, or discrepancies between expected and real-world performance at the time of issuance of the certificate, and as part of the "appropriate surveillance activities" conducted by NBs. For example, clear triggers should be defined in case low performance or adverse events are identified in national pacemakers and ICD registries. Seamless interaction of the

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revised MDR with the European Health Data Space (EHDS) and any national or local frameworks will be fundamental to ensure the medium- and long-term safety of devices, especially in case of Breakthrough and Orphan devices.

- The revision facilitates the possibility for **devices** to enter the market with a limited level of **evidence**, which makes the role of patient and healthcare professional organizations even more important Consequently, there is a need to achieve the level of data **granularity** and **quality** to support the development, uptake, and long-term maintenance of safe and innovative medical devices (especially in the case of orphan and breakthrough devices), while ensuring a high degree of transparency and trust in the system. To **safeguard patient safety** as routine on-site audits are reduced, the shift to risk-based oversight must be underpinned by robust real-world evidence. **Coordinated EU actions** to support an extensive increase of clinical registries is **essential** to generate the "for-cause" signals that enable NBs to trigger targeted and, where necessary, unannounced audits. In parallel, healthcare-professional organizations should be empowered to feed timely clinical intelligence in a structured way into the post-market surveillance and vigilance cycle, ensuring that real-world performance continuously informs regulatory decisions across the device lifecycle.

- Whereas NBs determine the issue of a **conditional certificate**, such conditions shall include clear **expectations** on the additional actions required -such as Post market clinical follow up (PMCF) activities, randomized controlled trials, or targeted registry analyses- to ensure that remaining evidence gaps are systematically and transparently addressed. To ensure predictability, the **Medical Device Coordination Group** shall be tasked with adopting guidance documents dedicated to the **assessment of High-risk devices** after appropriate consultation of stakeholders, issuing guidance dedicated to specific types of devices should the need arise. Type-specific guidance would also allow to further clarify conditionality of the certificates by reference to specific parameters such as a percentage increase in reported adverse events from registries. The generic reference to "exceptional cases" shall be clarified by **referring to the role of**

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expert panels in the assessment of risk and consequent determination related to the issue of conditional certificates, as provided for in Annex IX section 5.1 (g).

- In order to retain a balance between the reduction of red tape for manufacturers and the level of confidence of patients, **implant cards** should be maintained also for well-established technologies.

2. Clinical evidence, equivalence & transparency

Clinical data definition and equivalence

The ESC warns that expanding acceptable "clinical data" and re-introducing **equivalence without contractual access to data** may significantly weaken safety assurance.

Problems historically associated with an equivalence pathway for approval based on generic "similarity" include high numbers of **EU recalls**, proliferation of **valve and structural heart devices** with limited evidence, frequent **"medical reversals"** when rigorous trials contradict earlier assumptions[1]. A CORE-MD publication found that only a minority of the studies used to support approval of high-risk devices were randomized trials (19% in cardiology, 9% in orthopaedics, and 29% in diabetes). Moreover, just 9%, 0%, and 18% of those studies, respectively, were published at the time of approval.[2]

Recommendations

- For Class III and IIb implantables, "credible demonstration" of **equivalence** may be insufficient without access to the original clinical data of the reference Device. Hence, it is necessary to provide for a **risk-based** approach to equivalence recognition, ensuring that class IIb implantable devices and above

[1] Hwang, T. J., Sokolov, E., Franklin, J. M., & Kesselheim, A. S. (2016). Comparison of rates of safety issues and reporting of trial outcomes for medical devices approved in the European Union and United States: cohort study. *BMJ*, *353*, i3323. https://doi.org/10.1136/bmj.i3323

[2] Fraser, A. G., Buccheri, S., Byrne, R. A., Kjaersgaard-Andersen, P., James, S., Jüni, P., Bally, L., Bulbulia, R., Koletzko, B. V., Landray, M. J., Louati, C., Lübbeke, A., De Mheen, P. J. M., McCulloch, P., Patro-Golab, B., Rademakers, F. E., Schnell-Inderst, P., Siontis, G. C., Torre, M., . . . Ziskoven, C. (2025). Recommended methodologies for clinical investigations of high-risk medical devices—Conclusions from the European Union CORE–MD Project. *The Lancet Regional Health - Europe*, *58*, 101460. https://doi.org/10.1016/j.lanepe.2025.101460

demonstrate robust similarity and access to clinical data of the reference device, as appropriate according to the novelty and risk classification of the device.

- Require **mandatory** regulatory action (as appropriate review/generation of evidence/restriction/suspension/withdrawal) of any device CE-marked on equivalence when the referenced device becomes subject to recall/field safety corrective actions or comparable serious safety signals.

3. Summaries of Safety and Clinical Performance

Under the MDR, manufacturers of all **implantable** devices and all **Class III** devices must prepare a Summary of Safety and Clinical Performance (SSCP), validated by the notified body (NB) and made publicly available via Eudamed. The SSCP must be clear for the intended user and, where relevant, for the patient, and include a summary of the clinical evaluation and PMCF, among other elements. In practice, however, many SSCPs have **been hard to find and difficult to interpret** for both clinicians and lay readers.

The Commission's **revision** narrows Article 32 to only **those higher-risk** devices for which the NB conducts a technical-documentation assessment (in practice, Class IIb implantables and Class III), with custom-made, investigational, and well-established-technology devices out of scope.

Clinicians and patients need **publicly accessible and comprehensible evidence for high-risk devices and device evidence** available to health-care professionals should be no less transparent than for medicinal products[3]. Since SSCPs are the principal instrument ensuring public visibility of pre- and post-market clinical evidence for high-risk devices, any narrowing of scope or weakening of readability obligations risks diluting their value unless counterbalanced by stronger requirements on clarity and accessibility.

[3] Fraser, A. G., Butchart, E. G., Szymański, P., Caiani, E. G., Crosby, S., Kearney, P., & Van De Werf, F. (2018). The need for transparency of clinical evidence for medical devices in Europe. The Lancet, 392(10146), 521–530. https://doi.org/10.1016/s0140-6736(18)31270-4

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Recommendations

- Maintain SSCP obligations for all Class IIb and Class III devices (not only implantables) to safeguard transparency.
- Require SSCPs to follow a uniform, plain-language structure, with reasonable length, minimum formatting and terminology rules, in addition to ensuring that they are easily discoverable and accessible.

4. Reprocessing

The ESC welcomes the proposal to **harmonize** the currently fragmented r**eprocessing landscape** across the EU by introducing a **unified framework** applicable to all Member States. Such alignment has the potential to improve safety, predictability, and sustainability.

However, we caution that the revised approach may inadvertently **allow manufacturers to unilaterally designate devices as single-use**, without any form of independent **clinical or technical validation**. If these designations are not subject to appropriate oversight, refurbishing may become the only available pathway for such devices – yet in practice, this option is likely to be difficult to implement, resource-intensive, and unsuitable for most hospital settings. This could **limit the ability of clinicians** and healthcare institutions to **assess**, based on their expertise and real-world experience, whether reprocessing could be performed safely and responsibly.

For this reason, we stress the need for an **objective, expert-driven mechanism to evaluate single-use claims** and to ensure that reprocessing remains a viable option, where safe and clinically justified.

ESC recommendations

- Require **independent expert review of** single-use claims by notified bodies. In addition, the assessment of single-use claims should take into account the state of the art, considering well-established practices of devices reprocessing, and the status of the device in other jurisdictions.
- Ensure that the **Common Specifications** on "*general requirements regarding reprocessing of devices or fully refurbishing of single-use devices*" include clear,

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evidence-based criteria for **the correct classification of the single-use status** developed through consultation with expert panels, and Healthcare Professionals' organizations.

- As part of the "information about the appropriate reprocessing process" to be provided in the instructions for use, manufacturers should make available to reprocessors or healthcare institutions the **information necessary to assess whether reprocessing is technically possible**, safe, and practically feasible in light of available infrastructure, expertise and resources. This should include relevant **construction features and material**, chemical, physical and biological properties of devices.
- **Take-back and material-reuse programmes** for the reprocessing and refurbishing of medical devices should be encouraged to improve sustainability of health systems.

5. Stand-alone software

ESC welcomes the **clarification of requirements for AI medical devices**. however, it recommends **targeted measures** for **AI-based standalone software** to be implemented through Common Specifications.

In particular, standalone software, often deployed as centrally hosted or cloud-based solutions and subject to frequent updates, raises specific challenges that are not fully addressed by device-centric regulatory frameworks. ESC therefore **supports the development of Common Specifications** clarifying proportionate pre-market evidence expectations for such software, including the demonstration of clinically meaningful performance and impact in the intended clinical context, as well as lifecycle obligations. These should include clear **principles for managing software changes and updates**, with predefined criteria to determine when re-assessment or re-validation is required, ensuring that safety and performance are maintained over time without undermining innovation or access.

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II. Priority Pathways and Innovation

ESC strongly supports the introduction of **dedicated pathways for orphan and breakthrough devices**, drawing on successful models such as the FDA Breakthrough Devices Program and EMA's PRIME scheme. These mechanisms can meaningfully **accelerate access to high-impact technologies**. However, certain aspects of the current definitions would benefit from further refinement to ensure they are both clinically **meaningful and consistently applicable**.

For **orphan** devices, reliance on **epidemiological** thresholds remains challenging, as prevalence and incidence data are often **incomplete or unavailable** in several cardiology sub-specialties, including pediatric and congenital conditions.

Similarly, the proposed definition **of breakthrough devices,** while centered appropriately on clinical novelty and unmet medical need, may not sufficiently capture other dimensions of innovation that are highly relevant in cardiovascular care. **Breakthrough designation should also consider the real-world impact of a disease** and the device's potential to reduce **procedure-related adverse events**, recovery time, invasiveness, or recurrent hospitalizations. Meaningful improvements in these areas may offer **important clinical benefit** even without major technological novelty. It should also take into account **system-level/procedural efficiencies**, recognizing that devices which make established interventions safer, more efficient, or scalable may yield important societal benefits, especially in high public-health need settings.

ESC recommendations

- In the definition of **breakthrough devices**, improvements in real-world clinical outcomes, reductions in procedure complexity or system burden should be taken into account.
- As further outlined in the paragraph dedicated to the role of expert panels, it is critical to ensure the i**nvolvement of stakeholders in early and regular dialogues between expert panels and manufacturers**, particularly in ensuring that the evaluation of the state of the art reflects real-world clinical practice and current evidence.

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- Ensure that **fast-tracked procedures** are achieved by prioritization and adequate deployment of resources, without compromising the assessment of the clinical evidence underpinning the evaluation of Medical Devices by excessively forcing the evaluation process.

III. Clinical Expertise

The ESC welcomes the expanded remit of **expert panels**, their earlier involvement in clinical development strategies, and particularly the requirement for them to consider input from clinicians and patients.

Nevertheless, some **further clarity on their role** in the regulatory system should be expected, especially with reference to the current framework: it is unclear to what extent the **opinion** of the expert panel is reflected in the Conformity Assessment process.

This suggests possible **misalignments** between independent clinical review and the final decisions made by Notified Bodies, with lacking systematic feedback and **transparency** on **how recommendations are used**. This has been partly addressed by the proposed revision, which mandates NBs to provide a "substantiated justification" if it did not take into consideration Expert Panels' recommendation. Furthermore, we note that the proposed revision appears to reduce the **role of panels in the evaluation of Class IIb** devices, which constitute a large share of high-impact technologies in daily cardiology practice.

At the present moment, the MDR framework lacks an effective mechanism to ensure that **clinical evidence-based judgement prevails over procedural considerations**. Unless the ongoing revision bridges this gap appropriately, the essential purpose of expert review - to safeguard patients by keeping clinical performance and emerging real world safety risks at the centre of conformity assessment outcomes- cannot be fully realized.

In this respect, it is essential that expert panel deliberations are systematically informed by robust real world evidence on **benefits, implementation and risks**, including data generated through clinical registries, and that a structured channel exists for expert

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panels to engage with the healthcare professional organisations that manage these registries at national and European level.

Recommendations

- While the proposal mandates stakeholder consultation by expert panels, it is essential to make this operational through **a structured, transparent, and consistently applied procedure for engaging healthcare-professional organizations** across all stages of panel activity, from early dialogues to the formulation of scientific opinions and their support to regulatory decision-making. This would ensure that expert-panel outputs take into account the collective expertise and clinical consensus of the broader professional community, rather than the views of individual experts.
- Allow expert panels to engage in further dialogue with the NB in the case of diverging opinions by establishing an operational feedback loop allowing further alignment and collaboration, enhancing the effectiveness of the system over time.

IV. Governance

ESC strongly **supports** the proposed **expansion of the European Medicines Agency**'s role within the medical-device regulatory system. Strengthening the EMA's mandate as the secretariat for expert panels and as the coordinating hub for borderline and classification issues, vigilance activities, and market-surveillance actions represents an important step toward **greater consistency** and coherence across the Union.

Likewise, entrusting the Agency with the management of EU-level **regulatory sandboxes and** with dedicated **support** for small and medium-sized enterprises can significantly enhance early **dialogue**, foster innovation, and reduce fragmentation between Member States. Together, these extensions signal a welcome move toward a more integrated and strategically aligned EU governance architecture for medical devices.

Recommendations

- Ensure that HCP organizations can meaningfully contribute to EMA activities under the revised system by bringing their expertise across the regulatory cycle,

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drawing on the collaborative dialogue long established in medicines regulation (e.g., via the HCPWP).

- Strengthen alignment between **MDCG** and **EMA**, avoiding duplication or conflicting approaches, in the direction of improving centralization and efficiency of regulatory processes for both Medical Devices and Medicines.

V. Availability & Shortages

ESC particularly welcomes the Commission's effort to address the growing problem of **medical device shortages,** an issue that has become increasingly acute across cardiology and is especially burdensome in pediatric and orphan indications. Yet several elements of the proposal leave important gaps unaddressed.

First, the requirement for manufacturers to provide **six-month advance notification** of withdrawals offers only **limited practical benefit** in the absence of a clear, EU-level response mechanism capable of acting on this information. Without a structured process to **evaluate the clinical consequences** of a withdrawal and to coordinate timely regulatory action, notification risks becoming a formality rather than an effective safeguard.

Second, the proposed system continues to place **manufacturers at the center** of shortage detection, whereas clinicians and hospitals, those who **experience shortages first-hand** and understand their clinical impact, remain largely **under-used as sources of real-time intelligence**. Their contributions could meaningfully strengthen early identification of risks and provide essential context on patient harm and service disruption.

Finally, existing **derogation procedures** remain slow, fragmented, and unpredictable, limiting their usefulness in addressing urgent supply gaps. In practice, these mechanisms are **cumbersome to activate** and do not provide the level of coordinated EU action needed to ensure continuity of care when critical devices become unavailable.

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Recommendations

- Ensure that the **Union List of Critical Devices** is developed with meaningful and systematic input from healthcare professionals, and that clinicians are promptly informed of any emerging or confirmed shortages. The assessment of alternative clinical solutions in shortage situations should likewise be conducted in close collaboration with healthcare-professional organizations, which must be adequately supported to contribute effectively to this process.
- Establish a **coordinated EU-wide derogation process**, integrating HCP and patient organizations in the assessment of clinical impact.
- Create a **clinically-led rapid-response mechanism** for essential devices at risk of withdrawal.
- Ensure shortage-reporting IT systems allowing **hospital-level reporting** and harmonize data with EUDAMED and national vigilance systems.

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