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COVER NOTE

From:	European Economic and Social Committee
date of receipt:	19 May 2026
To:	General Secretariat of the Council
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I *- Opinion of the European Economic and Social Committee (EESC)*

Delegations will find attached opinion adopted by the European Economic and Social Committee on the above-mentioned proposal.

Other language versions can be found in the following website: Proposal for a Regulation - Targeted revision of the EU rules for medical devices and in vitro diagnostics | EESC

European Economic and Social Committee

OPINION

European Economic and Social Committee

Medical devices and in vitro diagnostics/Simplification

Proposal of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex

(COM(2025) 1023 final – 2025/0404 (COD))

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Advisor	Ana SOLDO (to the rapporteur)
Legislative procedure	EU Law Tracker
Referral	European Parliament, 2/2/2026 Council of the European Union, 24/3/2026
Legal basis	Articles 114 and 168(4) of the Treaty on the Functioning of the European Union
European Commission document	COM(2025) 1023 final – 2025/0404 (COD)
Relevant Sustainable Development Goals (SDGs)	SDG 8 – Decent work and economic growth SDG 9 – Industry, innovation and infrastructure SDG 12 – Responsible consumption and production SDG 13 Climate action
Section responsible	Single Market, Production and Consumption
Adopted in section	15/4/2026
Adopted at plenary session	29/4/2026
Plenary session No	605
Outcome of vote (for/against/abstentions)	191/0/4

1. RECOMMENDATIONS

The European Economic and Social Committee (EESC):

1.1 **welcomes** the Commission's proposal to simplify and streamline the regulatory framework for medical devices and in vitro diagnostic medical devices (IVDs), recognising the need to address persistent implementation challenges under the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) while fully safeguarding a high level of patient safety, public health protection and trust in the regulatory system;

1.2 **stresses** that simplification must result in greater predictability of certification timelines and outcomes, and must not lead to new divergences in the practices of notified bodies across Member States;

1.3 **stresses** that the removal of time-limited certificate validity and the shift towards periodic, risk-based reviews must be accompanied by clear, transparent and harmonised EU-level rules in order to avoid legal uncertainty for manufacturers, particularly SMEs and micro-enterprises;

1.4 **points out** that the decentralised regulatory system established under the New Legislative Framework, based on conformity assessment and CE certification issued by notified bodies, remains a cornerstone of the EU framework for medical devices and in vitro diagnostic medical devices;

1.5 **emphasises** that digitalisation of documentation, conformity assessment procedures and audits (including increased use of remote audits) must not result in higher adaptation costs, especially for small and micro-enterprises, nor create parallel or duplicate administrative requirements;

1.6 **calls** for digitalisation measures to be accompanied by adequate guidance, training and technical support in order to prevent additional workload for workers and healthcare staff and ensure effective and safe implementation in practice;

1.7 **insists** that the reduction of regulatory obligations must not be neutralised by increased fees charged by notified bodies, and calls for transparency, proportionality and SME-sensitive fee structures to ensure that simplification leads to tangible economic relief;

1.8 **supports** the introduction of dedicated regulatory pathways for breakthrough and orphan devices, recognising their potential to stimulate innovation and address unmet medical needs, provided that these mechanisms are fast, transparent and clearly oriented towards the public interest, rather than solely towards market speed;

1.9 **stresses** that simplification of conformity assessment procedures, reduced audit scope and increased reliance on remote assessments must not weaken oversight of manufacturing conditions, occupational health and safety, or quality management systems;

1.10 **stresses** that changes in clinical and non-clinical evidence requirements must not increase pressure on healthcare professionals by exposing them to insufficiently tested products or unclear responsibilities in real clinical settings;

1.11 **emphasises** that the reduction of administrative requirements must not undermine transparency regarding the safety and performance of medical devices and IVDs, and that patients must continue to have access to clear, reliable and understandable information, including through the effective and coherent use of the European database on medical devices (EUDAMED);

1.12 **calls** for particular attention to be paid to digital inclusion, ensuring that electronic instructions for use and other digital information tools do not exclude vulnerable patient groups or create inequality in access to safe use of devices;

1.13 **believes** that the concept of reprocessing of medical devices should be carefully defined and should not introduce unnecessary regulatory burdens for manufacturers, particularly SMEs and micro-enterprises; the designation of a device as single-use should remain based on the characteristics of the device and the clinical context in which it is used;

1.14 **underlines** that increased flexibility for in-house devices must not lead to uneven levels of safety and quality between healthcare institutions, and calls for appropriate safeguards and oversight to ensure consistent standards across the EU;

1.15 **stresses** that strong and effective post-market surveillance, vigilance and market surveillance systems are a key compensatory measure for increased flexibility in pre-market requirements, and are essential to protect patients, support healthcare professionals and maintain confidence in the regulatory framework;

1.16 **welcomes** the role of expert panels, supported by the European Medicines Agency (EMA), in promoting evidence-based, consistent and coordinated implementation across Member States;

1.17 **calls** for the systematic involvement of the social partners, healthcare professionals, patient organisations and other civil society actors in monitoring and evaluating the implementation and real-world impact of the revised regulatory framework, including its effects on employment, working conditions, patient safety and quality of care.

2. EXPLANATORY NOTES

Arguments in support of recommendation 1.1

2.1 Experience of the implementation of the Medical Devices Regulation and the In Vitro Diagnostic Medical Devices Regulation has shown that, while their objectives remain fully valid, structural shortcomings such as regulatory complexity, limited notified body capacity and unpredictable procedures have negatively affected device availability, innovation and market access, particularly for SMEs and producers of niche or low-volume products. Targeted simplification is therefore necessary to restore proportionality and ensure the smooth functioning of the internal market.

2.2 At the same time, there is broad agreement that simplification must not undermine patient safety, public health protection or trust in the regulatory system. A more proportionate and predictable framework, focused on actual risk and consistently applied across the EU, can reinforce compliance, support innovation and ensure continued access to safe and high-quality medical devices and IVDs.

Arguments in support of recommendation 1.2

2.3 Divergent interpretations and practices among notified bodies have resulted in inconsistent certification timelines and outcomes across Member States, creating legal uncertainty for manufacturers and undermining a level playing field within the internal market. Simplification must therefore be accompanied by measures that enhance harmonisation and predictability.

2.4 If not carefully designed and implemented, simplification risks replacing formal regulatory requirements with informal divergences in practice, which would further increase uncertainty instead of reducing it. Predictable and transparent certification processes are essential for investment planning, innovation and the timely availability of medical devices and IVDs, particularly for SMEs.

Arguments in support of recommendation 1.3

2.5 The removal of fixed certificate validity periods can reduce unnecessary administrative repetition, but without clear EU-level criteria and procedures for periodic, risk-based reviews it may generate legal uncertainty for manufacturers. Harmonised rules are essential to ensure consistent expectations, planning security and equal treatment across notified bodies.

2.6 Legal uncertainty disproportionately affects SMEs and micro-enterprises, which have limited regulatory and financial capacity to manage unclear or changing requirements. Transparent and predictable review rules are therefore crucial to prevent market withdrawal of products, support innovation and maintain device availability.

Arguments in support of recommendation 1.4

2.7 The New Legislative Framework underpins the MDR and the IVDR by ensuring free movement of products and a high level of public health protection while remaining adaptable to technological progress; it should therefore be preserved, ensuring reliance on certification by notified bodies and avoiding mechanisms that undermine legal certainty, delay patient access and weaken the EU's internal market.

2.8 A CE certificate issued by a notified body should therefore confer definitive regulatory status, with reassessment possible only where concrete and substantiated patient safety risks are demonstrated.

2.9 Along the same lines, EMA involvement in regulatory status and classification decisions under the MDR and IVDR should be carefully assessed, as the EMA's medicine-centric mandate and

expertise are not suited to medical devices and would introduce unnecessary procedural layers, delays and de facto centralisation inconsistent with the New Legislative Framework.

Argument in support of recommendation 1.5

2.10 Digitalisation of documentation, conformity assessment procedures and audits can improve efficiency and consistency only if it fully replaces existing processes. If introduced alongside parallel or duplicate requirements, it risks increasing administrative complexity and undermining simplification. At the same time, the wider use of digital tools and remote audits requires significant upfront investments in IT infrastructure, staff training and organisational adaptation. These costs may disproportionately affect small and micro-enterprises and, if not adequately anticipated and mitigated, may offset expected efficiency gains and limit the burden-reducing effect of digitalisation.

Argument in support of recommendation 1.6

2.11 The effective implementation of digitalisation measures depends on clear guidance, practical training and accessible technical support for workers and healthcare staff. Without these elements, digital tools risk increasing workload, creating uncertainty and reducing compliance. Adequate support is essential to ensure that digital solutions are used safely and consistently in real working environments, without disrupting clinical workflows or administrative processes, and that digitalisation contributes to efficiency and safety rather than introducing new operational risks.

Arguments in support of recommendation 1.7

2.12 The reduction of regulatory obligations will only deliver its intended benefits if it is accompanied by corresponding cost reductions. Increases in fees charged by notified bodies would risk neutralising the effects of simplification and undermining its credibility.

2.13 Fee levels and structures have a disproportionate impact on SMEs and micro-enterprises, for which compliance costs represent a significant share of operating expenses. Transparent, proportionate and SME-sensitive fee arrangements are therefore essential to ensure that simplification translates into real economic relief and supports innovation and market access.

Arguments in support of recommendation 1.8

2.14 Breakthrough and orphan devices often target small patient populations or high unmet needs, which can make investment less attractive under standard pathways due to higher development costs, regulatory uncertainty and lower expected market returns. Dedicated pathways can reduce avoidable uncertainty and improve the feasibility of bringing such technologies to patients.

2.15 Clear criteria, transparency on timelines and decision making, and publicly accountable safeguards are essential to ensure that accelerated or specialised routes do not create perceptions of preferential treatment or lowered standards. Public-interest orientation strengthens legitimacy and trust among patients, healthcare professionals and payers, and supports uptake once devices reach the market.

Arguments in support of recommendation 1.9

2.16 Working conditions in manufacturing, occupational health, safety and quality management systems are verified primarily through direct observation and on-site interaction, which allows auditors to assess real working practices, organisational culture and compliance beyond formal documentation.

2.17 While remote assessments can support efficiency and continuity, they have inherent limitations in detecting certain risks, particularly those related to working conditions, process deviations or safety culture. Maintaining the possibility of physical inspections is therefore necessary to ensure effective oversight alongside simplified procedures.

Arguments in support of recommendation 1.10

2.18 Healthcare professionals play a central role in the real-world use of medical devices and IVDs, and are often the first to identify performance, usability or safety issues. Insufficient pre-market evidence or unclear allocation of responsibilities can shift risk to clinical practice, increasing professional liability and uncertainty in daily decision-making.

2.19 Changes in evidence requirements that rely more heavily on post-market data require clear clinical guidance and well-defined roles in order to avoid placing additional monitoring or interpretative burdens on healthcare staff. Without such clarity, the intended flexibility may translate into operational pressure and inconsistent practices in clinical settings.

Arguments in support of recommendation 1.11

2.20 Transparency of safety and performance information is essential for informed decision making by patients and healthcare professionals and for maintaining confidence in the regulatory system. Any reduction of administrative, reporting or documentation requirements must not compromise the availability, clarity or timely communication of safety information. Clear and understandable information is particularly important for complex or high-risk devices, supporting appropriate use, compliance with guidelines and patient safety.

2.21 The European database on medical devices (EUDAMED) supports transparency and consistency by enabling access to safety and performance data and facilitating information exchange between national authorities, healthcare professionals, manufacturers and patients. Effective use of this database supports coordinated monitoring and strengthens confidence in decision making across the Union.

Arguments in support of recommendation 1.12

2.22 The increasing use of electronic instructions for use and digital information tools may limit accessibility for certain patient groups, including older persons, people with disabilities or those with limited digital skills or access to technology.

2.23 Ensuring safe and effective use of medical devices and IVDs requires that essential information remain accessible in formats suited to users' needs and capabilities. Without adequate alternatives or safeguards, digitalisation may inadvertently create inequality in patient safety and outcomes.

Arguments in support of recommendation 1.13

2.24 The restructuring of the concept of reprocessing medical devices should be approached with caution. The introduction of a 'reprocessable by default' principle should not result in additional regulatory or administrative burdens for manufacturers, particularly micro, small and medium-sized enterprises. At the same time, the designation of a device as single-use should remain the responsibility of the manufacturer, based on the specific characteristics of the device and the clinical context in which it is intended to be used.

Arguments in support of recommendation 1.14

2.25 In-house devices are developed and used under diverse organisational, technical and resource conditions across healthcare institutions, which may lead to variability in design, validation and quality assurance practices.

2.26 Without common safeguards and effective oversight, increased flexibility may result in inconsistent levels of safety and performance, potentially affecting patient outcomes and undermining confidence in the regulatory framework across the EU.

Arguments in support of recommendation 1.15

2.27 Increased reliance on flexible or proportionate pre-market requirements places greater importance on continuous monitoring of device performance and safety in real-world use, where risks, usability issues and unanticipated adverse events are most likely to emerge.

2.28 Effective post-market surveillance and vigilance systems provide early detection and feedback mechanisms for manufacturers, authorities and healthcare professionals, enabling timely corrective actions and reinforcing confidence in the overall regulatory framework.

Argument in support of recommendation 1.16

2.29 The increasing technical complexity of medical devices and IVDs, including innovative and borderline technologies, requires specialised regulatory, scientific and technical expertise that is not uniformly available across Member States. Expert panels at Union level can support high-quality, consistent assessments, contributing to more uniform interpretation and implementation of the regulatory framework. This reduces fragmentation and divergent practices, while ensuring a more predictable regulatory environment and strengthening confidence among healthcare professionals and patients in EU decision making.

Arguments in support of recommendation 1.17

2.30 The implementation of regulatory reforms has direct and differentiated effects on workplaces, clinical practice and patient experience, which cannot be fully captured through formal reporting or quantitative indicators alone.

2.31 Structured involvement of organised civil society and professional stakeholders enables early identification of unintended consequences, improves the quality of monitoring and evaluation, and supports evidence-based adjustments to the framework over time.

3. PROPOSED AMENDMENTS TO THE LEGISLATIVE PROPOSAL OF THE EUROPEAN COMMISSION

Amendment 1
linked to recommendation 1.4

Add new paragraph 3a

Text proposed by the European Commission	EESC amendment
Article 4 Regulatory status of products	Article 4 Regulatory status of products 1. (..) 2. (..) 3. Where a competent authority of a Member State, after having performed an evaluation in accordance with Article 94, considers that a product that is CE marked in accordance with Article 20, does not fall within the scope of this Regulation, it shall consult the competent authorities of the other Member States regarding its envisaged measure determining the regulatory status of the product in question. ***3.a For products that are CE marked in accordance with Article 20 and for which the conformity assessment referred to in Article 52 involved a notified body, the procedure referred to in paragraph 3 shall apply only where the competent authority has substantiated evidence that the qualification of the product as a medical device represents an unacceptable risk as referred to in Article 94, point (a). The regulatory qualification of the product shall not, in itself, constitute such evidence.*** 4. (..)

Reason
Based on the proposed revision, the regulatory status of CE-marked products may be re-opened despite prior conformity assessment by a notified body. As entities designated under EU law, certification by notified bodies should be presumed to confirm regulatory status. Therefore, the use of the 'Helsinki procedure' (Article 4) should be limited to exceptional, safety-driven cases, as routine use would undermine certification and create legal uncertainty. A CE certificate should confer definitive regulatory status, with reassessment under Articles 4–4a, 51, 51b, 55 and 94 only where substantiated patient safety risks are demonstrated. This mechanism should apply on a case-by-case basis where there is evidence of an unacceptable risk under Article 94(a). It should apply only to devices certified by a notified body and exclude Class I devices. The powers of competent authorities under Articles 95 and 97 remain unaffected.

Amendment 2

linked to recommendation 1.13

Text proposed by the European Commission	EESC amendment
Article 17 Single-use devices and reprocessing of devices that are not for single use ***1. A device shall only be intended for single-use where the manufacturer, in light of the design, construction, material, chemical, physical and biological properties of the device, cannot ensure that the device continues to meet the relevant safety and performance requirements when reused in accordance with its intended purpose after appropriate reprocessing.*** The manufacturer's justification of an indication of single use shall be part of the technical documentation referred to in Annex II. ***2.*** If the device is not intended for single-use, the manufacturer shall provide information about the appropriate reprocessing process for allowing reuse in the instructions for use in accordance with Annex I, Section 23.4, point (n). ***3.*** Single- use devices and devices that cannot be further reprocessed may be subject to full refurbishing within the meaning of Article 2(31). The natural or legal person that carries out the full refurbishing shall be considered as	Article 17 Single-use devices and reprocessing of devices that are not for single use 1. ***It shall be the responsibility of the manufacturer to indicate whether a device is intended for single use or whether it may be reprocessed. This indication shall be included in the technical documentation referred to in Annex II.*** The manufacturer's justification of an indication of single use shall be part of the technical documentation referred to in Annex II. 2. If the device is not intended for single-use ***but is reusable, this shall be indicated on the label and*** the manufacturer shall provide information about the appropriate reprocessing process for allowing reuse in the instructions for use in accordance with Annex I, Section 23.4, point (n). 3. Single-use devices and devices that cannot be further reprocessed ***or devices that do not indicate whether they are single-use or reprocessable,*** may be subject to full refurbishing within the meaning of Article 2(31). The natural or legal person that carries out the full refurbishing shall be considered as

the manufacturer of the fully refurbished device. ***4.*** The Commission may adopt, in accordance with Article 9(1), CS on general requirements regarding reprocessing of devices or fully refurbishing of single-use devices.';	the manufacturer of the fully refurbished device. 4. The Commission may adopt, in accordance with Article 9(1), CS on general requirements regarding reprocessing of devices or fully refurbishing of single-use devices.';

Reason
The proposal aims to clarify when a manufacturer may designate a device as single-use, including obligations to justify this in the technical documentation referred to in Annex II and to provide reprocessing information in the instructions for use in accordance with Annex I, Section 23.4, point (n). It also clarifies that reprocessing entails the assumption of manufacturer status by the reprocessor. First, the wording of Article 17(1), which presumes reprocessability, is not consistent with the MDR's risk-based framework. The designation of a device as single-use or reusable should remain the responsibility of the manufacturer, based on its design, intended purpose and risk profile. Secondly, the proposal lacks requirements to indicate reusability on the label and to include justification in the technical documentation referred to in Annex II. Furthermore, there is no requirement to maintain a reprocessing log, unlike for single-use devices under Annex I, Section 23.2(n), which is necessary to ensure traceability and safe reuse, nor does it address cases where reusability is not specified.

Amendment 3

linked to recommendations 1.4 and 1.16.

Text proposed by the European Commission	**EESC amendment**
Article 106b Support by the EMA 1. The EMA shall, on behalf of the Commission, provide ***scientific, technical and*** administrative support to the national competent authorities designated under this Regulation and under Regulation (EU) 2017/746 to facilitate the exchange of experience, cooperation and coordination with a view to ensuring a uniform application of such Regulations, in particular in the following areas: (a) ***regulatory status of products and classification of devices in accordance with Articles 4, 4a, 51, 51a and 51b of this Regulation and Articles 3, 3a, 47, 47a and 47b of Regulation (EU) 2017/746;*** (b) derogations from the applicable conformity	Article 106b Support by the EMA 1. The EMA shall, on behalf of the Commission, provide administrative support to the national competent authorities designated under this Regulation and under Regulation (EU) 2017/746 to facilitate the exchange of experience, cooperation and coordination with a view to ensuring a uniform application of such Regulations, in particular in the following areas: (a) derogations from the applicable conformity assessment procedures in accordance with Articles 59 and 59a of this Regulation and Articles 54 and 54a of Regulation (EU) 2017/746;

assessment procedures in accordance with Articles 59 and 59a of this Regulation and Articles 54 and 54a of Regulation (EU) 2017/746; (c) clinical evaluation, clinical investigations, performance evaluation and performance studies in accordance with Chapter VI of this Regulation and Chapter VI of Regulation (EU) 2017/746, including support to the coordinating Member State for the coordinated assessment procedure for clinical investigations and performance studies referred to in Article 78 of this Regulation and Article 74 of Regulation (EU) 2017/746; (d) vigilance and market surveillance in accordance with Chapter VII of this Regulation and Chapter VII of Regulation (EU) 2017/746, including support to the coordinating competent authority for the coordinated procedure referred to in Article 89(9) of this Regulation and Article 84(9) of Regulation (EU) 2017/746.	(***b***) clinical evaluation, clinical investigations, performance evaluation and performance studies in accordance with Chapter VI of this Regulation and Chapter VI of Regulation (EU) 2017/746, including support to the coordinating Member State for the coordinated assessment procedure for clinical investigations and performance studies referred to in Article 78 of this Regulation and Article 74 of Regulation (EU) 2017/746; (***c***) vigilance and market surveillance in accordance with Chapter VII of this Regulation and Chapter VII of Regulation (EU) 2017/746, including support to the coordinating competent authority for the coordinated procedure referred to in Article 89(9) of this Regulation and Article 84(9) of Regulation (EU) 2017/746.

Reason
The introduction of the EMA into the evaluation of the regulatory status and classification of medical devices is not compatible with the objective of simplification and competitiveness and raises significant concerns. The EMA, as a medicines agency, has a pharma-centric perspective, which may lead to a structural mismatch in borderline cases (device vs. medicinal product). It also lacks the specific competence and framework to assess non-pharmacological devices. Furthermore, its involvement would add an additional procedural layer alongside notified bodies, increasing costs and delays.

Brussels, 29 April 2026.

The president of the European Economic and Social Committee
Séamus BOLAND