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Position Paper

Medical devices and in vitro diagnostics – targeted revision of EU rules

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CEN and CENELEC welcome the targeted revision of the Medical Devices Regulation (MDR) and In-Vitro Diagnostics Regulations (IVDR) with the aim to ensure that the Regulations original regulatory objectives 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 are achieved in a manner that is efficient, proportionate, and coherent.

CEN and CENELEC develop European Standards setting safety, quality, and performance requirements for medical devices that are put on the European market. A large number of those standards enable manufacturers to make their medical products compliant with the European legislation in the medical sector, for the ultimate benefit of all European citizens. For the targeted revision of the MDR and IVDR CEN and CENELEC would like to highlight the following points.

Time-limited certificates and the recertification approach

The proposed approach for certification and discontinuation of time-limited QMS certificates contradicts the fundamental principle outlined in the international standard ISO/IEC 17021-1 for bodies auditing and certifying management systems. Limitations of certificates and necessary re-certifications activities are further the basis of the harmonized standard EN ISO 13485 relevant in the MedTech Area for QMS certification, on which the MDSAP programme is also based. EN ISO 13485 is based on the principles of EN ISO 9001 for QM systems. Therefore, the current proposal is inconsistent with the EU's stated objective of strengthening international cooperation.

Definition of Clinical Data

To ensure coherence the proposed definition of clinical data in Article 2(48) should be aligned with existing European and international standards such as ISO 18969 (draft) and IMDRF (IMDRF MDCE WG/N55 FINAL:2019, formerly GHTF/SG5/N1R8:2007). In case the definitions are not aligned relevant data could be excluded that may provide evidence of the safety and performance of a medical device. As a result, manufacturers could be forced to generate new data unnecessarily, increasing costs, delaying market access and creating a disproportionate burden for users from whom such data would need to be requested and collected.

In addition, extending the concept of clinical data to include non-clinical data (in silico, NAMs) must not blur the line between clinical and non-clinical evidence, nor undermine the rigour of the clinical evaluation (see MDCG 2020-6 and 2020-13) or the benefit-risk analysis as defined by ISO 14971.

Sampling procedures

Procedures for the assessment of technical documentation should be based on scientifically sound and statistically robust sampling principles. Established methodologies reflected in ISO 2859-1:2026 may provide useful guidance and a suitable framework for defining representative sampling approaches. However, statistical sampling should be regarded as one element of the overall conformity assessment process. The scope and depth of technical documentation assessment should continue to be determined on the basis of the applicable regulatory requirements, taking into account factors such as device risk, technology, manufacturing processes, the manufacturer's compliance history and other relevant considerations under the MDR and IVDR.

It is neither appropriate that, for large groups, it would take 20 years until every technical documentation file has been assessed, nor is it appropriate that a technical documentation file is assessed annually if the group comprises only one product.

The content to be assessed by the notified body should be able to focus more strongly on the safety and performance of the devices and less on formal MDR requirements, such as translations. A risk-based approach to the assessment of parts of the technical documentation should be possible, instead of having to assess all technical documentation files with the same level of depth as a Class III device, returning to the approach commonly applied under the MDD.

The current proposal for the sampling of technical documentation carries the risk that the approach may shift from a preventive procedure to a reactive one, which would only take effect after serious safety incidents have become known. This would be detrimental to patient safety. At the same time, the proposal does not offer a satisfactory solution for reducing the currently, at times, disproportionate burden of assessment.

Article on Common Specifications

CEN and CENELEC acknowledges the Commissions intention to be able to develop common specifications if the standardization system cannot deliver the necessary harmonized standards. Common specifications are already imbedded in the EU MDR and IVDR conformity assessment framework in the context of EU reference laboratory testing and verifications, batch verifications mechanisms for Class D IVDs and Annex XVI products and revision should therefore carefully consider the practical implications for these existing mechanisms and avoid creating legal uncertainty or unnecessary disruptions to established processes, including unintended regulatory gaps or delays, particularly with respect to innovative technologies.

However, without a clear framing on when common specifications can be drafted could undermine the New Legislative Framework. Harmonized standards should remain the preferred choice as the established pillar of quality infrastructure, while resorting to common specifications should be only used as a restrictive fall-back solution.

Harmonized standards are developed through transparent, consensus-based processes involving a broad range of stakeholders, which ensures technical robustness, broad acceptance and international alignment. A broader reliance on Common Specifications may reduce stakeholder involvement and could weaken the long-term stability and predictability provided by the established European standardisation system.

Particular attention should also be given to the practical consequences for manufacturers and conformity assessment activities. Transitions between harmonised standards and Common Specifications, or vice versa, may require significant modifications to quality management systems, manufacturing processes, testing procedures, technical documentation and conformity assessment activities. Such changes can create additional regulatory burden, increase compliance costs and reduce planning certainty for economic operators.

Furthermore, frequent changes of applicable technical requirements may adversely affect process stability and introduce risks associated with the implementation of revised specifications, particularly where testing methodologies, production controls or batch-related verification activities are concerned. From the perspective of product quality and patient safety, maintaining a stable and predictable regulatory framework is therefore of particular importance.

Following this reasoning, CEN and CENELEC would like to ensure the following characteristics for common specifications:

- That they remain a fallback solution to be used when all other options have been exhausted.
- Their application should be consistent across jurisdictions.
- The design should involve relevant stakeholders - especially the affected industry and societal actors - and be based on international standards.

- There should be clear rules on when the Commission is authorised to create common specifications and when these should be withdrawn (especially as soon as a harmonized standard is available or if a Member State objects).
- Like harmonized standards referenced in OJEU, common specifications should be voluntary and give presumption of conformity.

CEN and CENELEC support Article 16 of the Toy Safety Regulation 2025/2509 (Annex I) as a framework for the use of common specifications over the current proposed text in Article 9 of the Regulations on medical devices ((EU) 2017/745) and in vitro diagnostics (2017/746). The proposed Article 9 on Common Specifications differs from the articles agreed upon in other legislative negotiations, including the recently revised Toy Safety Regulation, Machinery Regulation (2023/1230) and the Cyber Resilience Act (2024/2847), creating misalignment between the different provisions on Common Specifications in different legislations.

The Article as in the Toy Safety Regulation was the basis for the negotiating mandate of the Council on the Omnibus IV common specifications and is preferred by a wide range of stakeholders because it clearly defines the above points, in particular the fact that:

1. Common specifications can only be issued when
- there is no harmonised standard covering the requirements published in the OJEU and no such reference is expected to be published within a reasonable period.
- a standardization request has been issued by the Commission, but the European Standardization Organizations rejected it.
- the standards requested have not been delivered within the set deadline.
- the standards requested do not comply with the request.
- the standards requested do not satisfy the requirements they aim to cover.

2. The Article also foresees
- consultation with all relevant stakeholders.
- common specification or parts thereof to be repealed or amended when reference of a harmonised standards that cover the same essential safety requirements is published in the OJEU.
- possibility to amend the common specification when Member State considers that the essential safety requirements are not entirely satisfied.

Unfortunately, the proposed Article on common specifications in the Regulations on medical devices and in vitro diagnostics removes several important guarantees for involvement, withdrawal and changes the decision-making procedure. The proposal gives the EC wider margin to interpret when to use common specifications.

CEN and CENELEC urge the Commission to preserve harmonised standards as the primary instrument and to use common specifications only as a last resort, framed in line with the Toy Safety Regulation.

Annex 1: Toy Safety Regulation (2025/2509) Article 16

Article 16

Common Specifications

1. Toys which are in conformity with the common specifications referred to in paragraph 2 or parts thereof shall be presumed to be in conformity with the essential safety requirements to the extent that those requirements are covered by those common specifications or parts thereof.

2. In exceptional cases, the Commission may adopt implementing acts establishing common specifications covering requirements that provide a means to comply with the applicable essential safety requirements.

Those implementing acts shall only be adopted where the following conditions are fulfilled:

(a) there is no harmonised standard covering the applicable essential safety requirements the reference of which is published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period; and
(b) the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European standardisation organisations to draft or to revise European standards for the applicable essential safety requirements and:
    (i) the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or
    (ii) the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:
    -are not delivered within the deadline set in the request;
    -do not comply with the request; or
    -do not satisfy the requirements they aim to cover.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 53(3).

3. Before preparing a draft implementing act as referred to in paragraph 2 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in that paragraph have been fulfilled.

When preparing a draft implementing act as referred to in paragraph 2 of this Article, the Commission shall take into account the views of the Expert Group on Toys Safety and shall consult all relevant stakeholders.

4. Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess the harmonised standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal or amend the implementing acts referred to in paragraph 2 of this Article, or parts thereof, which cover the same essential safety requirements as those covered by that harmonised standard.

5. Where a Member State considers that a common specification does not entirely satisfy the essential safety requirements, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, where appropriate, amend the implementing act establishing the common specification in question.

About CEN and CENELEC

CEN (European Committee for Standardization) and CENELEC (European Committee for Electrotechnical Standardization) are recognized by the European Union (EU) and the European Free Trade Association (EFTA) as European Standardization Organizations responsible for developing standards at European level, as per European Regulation 1025/2012. The members are the National Standards Bodies (CEN) and National Electrotechnical Committees (CENELEC) from 34 European countries. European Standards (ENs) and other standardization deliverables are adopted by CEN and CENELEC, are accepted and recognized in all of these countries. These standards contribute to enhancing safety, improving quality, facilitating cross-border trade and strengthening of the European Single Market. They are developed through a process of collaboration among experts nominated by business and industry, research institutions, consumer and environmental organizations, trade unions and other societal stakeholders. CEN and CENELEC work to promote the international alignment of standards in the framework of technical cooperation agreements with ISO (International Organization for Standardization) and the IEC (International Electrotechnical Commission).