EFLM Position Statement on the Proposed 2025/0404(COD) IVDR Amendment of Article 5.5

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1. Context: Why the 2025 IVDR Reform Matters

On **16 December 2025**, the European Commission (EC) published a legislative proposal 2025/0404(COD) for a targeted revision of the EU2017/746 (IVDR) that has been plagued by major implementation challenges. For the marketing of commercial IVD tests (CE-IVD), the challenges comprise certification bottlenecks, device shortages, IVD withdrawals, delayed innovation affecting availability and competitiveness. Also, burdens disproportionately affect Small and Medium Enterprises (SMEs) in the diagnostic manufacturing field including providers of niche and orphan tests. For *in-house* tests (IH-IVD), hurdles are being experienced by the healthcare institutions providing them and are particularly related to harmful restrictions and disproportionate requirements as described in Art 5.5. of the IVDR. Although the EC aimed at bringing safe and effective medical tests to the EU-market, ~ 9,000 tests out of ~40,000 tests got lost in transition (1-7). From our perspective as professionals in Laboratory Diagnostics, the unintended consequences are patient harm due to shortages and inaccessibility are more pronounced, thereby missing IVDR´s key objectives of supporting safe and effective *in-vitro* medical tests on the EU-market in its current form.

At EFLM, the Committee for European Regulatory Affairs (CERA) has regularly pointed out IVDR-associated challenges in the past. Our position statement has patient safety and benefit at its centre. Here, we focus on pointing towards the strengths and weaknesses of the 2025/0404(COD) reform proposal as related to *In-House* tests described under Art 5.5. in the IVDR. We strongly advocate that EU Health Politics goes forward by adopting the amendments specified therein. To further the current practices already known to impede healthcare benefits, safety and timely diagnostic services with an enthusiastic “carry-on with the business” will continue not only to disadvantage a stakeholder group called “patients” that should have our central attention but will likely be detrimental for sustained leadership in innovation of diagnostic medicine in the European Union.

2. Key Reforms Proposed in IVDR 2025/0404 (COD)

The European Commission’s IVDR reform includes the following categories that directly reshape IVDR practice:

- *Simplification & Reduction of Administrative Burden* related to lowering risk classification of certain IVD groups, especially software and reusable instruments; more flexible Person Responsible for Regulatory Compliance (PRRC) requirements, particularly for Small and Medium Enterprises (SMEs); and by replacement of the fixed 5-year certificate cycle by risk-based periodic reviews.
- *Evidence & Clinical Performance Modernization* introducing acceptance of broader evidence types, including *silico*, bench, computational, ex vivo data and more proportionate evaluation pathways are allowed. Yet, it remains crucial to generate clinical evidence and guarantee fitness-for-purpose of medical tests as reviewed by Sally Lord et al. (8).
- *Innovation & Availability of provisions* for breakthrough / orphan / special patient-group niche IVD devices and efforts to avoid device shortages and improve timely access and user notification.
- *Digitalization and Coordination* is given attention to by means of increased system digitalization and a stronger coordination between competent authorities.

3. Critical Analysis of the Proposed IVDR Reforms

3.1. Strengths

- *Proportionality & Risk Alignment*

The downgrading of classification for specific IVDs and introduction of risk-based certification brings the system closer to the principle of proportionality than the original IVDR intended—but failed—in practice. This reduces low-value regulatory work that will gain little for low-risk IVDs while freeing capacities in notified bodies.

- *Improved Regulatory Capacity & Predictability*

Replacing the fixed 5-year recertification cycle with periodic reviews reduces recertification bottlenecks and supports continuous oversight rather than cyclical overload.

- *Enhanced Clinical Evidence Flexibility*

Allowing non-clinical evidence broadens opportunities for rapid innovation and supports small-scale laboratories and niche diagnostic developers.

- *Alleviating Missing Specific Solutions for In-House Devices (Art. 5.5).*

Being one of the most debated articles in practice, Article 5.5—the *in-house* exemption for health-institution-manufactured IVDs—is currently addressed as follows:

a. The conditions for the manufacture and use of *in-house* tests as a diagnostic service of the respective single health institutions are made more flexible, e.g. allowing the transfer of *in-house* devices if this is in the interest of patient safety or public health (see 2025/0404(COD): pg.14; pg. 24 section (12); pg. 93 section (5/a/i/1)).
b. Under the new IVDR proposal, the condition that there is no equivalent device on the market is deleted (see 2025/0404(COD): pg.14; pg. 24 section (12); pg.93 section (5/a/i/3)).
c. Central laboratories manufacturing and using tests exclusively for clinical trials are added to the scope of the *in-house* device exemption (see 2025/0404(COD): pg.14; pg. 24 section (13); pg.93 section (5/a/iii)).

3.2. Weaknesses & Remaining Gaps

- *Lack of Clarity in Key Definitions*

"Same or similar" clinical evidence criteria (Annex XIII in the IVDR) lack detail, which may cause inconsistent implementation across Member States—the exact problem IVDR was meant to fix.

- *Risk of Divergent Interpretation*
  Without harmonized MDCG guidance, and without coordinated governance between Notified Bodies, Competent Authorities and Expert Panels *ambiguity* on risk classification and clinical evidence will remain rather than solving existing challenges.

4. Comparison of Article 5.5 in IVDR 2017/746 versus 2025/0404 (COD)

In the past years significant discussion arose around the provisions in Article 5.5 with its 9 subparagraphs (a-i). Next to rules for additional documentation, bureaucracy and justification efforts, Art. 5.5.a and Art. 5.5.d directly impact laboratory diagnostics at various operational levels specifically impeding the motivation to develop innovative medical diagnostic devices to meet patient needs unaccounted-for by the industrial diagnostic market (1-7).

Indeed, we need to emphasize that IH-IVD are most often manufactured and used by diagnostic laboratories with a strong scientific background and a particular interest to investigate small patient groups by measuring biomarkers, for which no commercial IVD is available or sufficient. These biomarkers represent different biomolecule classes including nucleic acids (DNA, DNA modifications and RNA species), proteins, lipids, carbohydrates and a multitude of metabolites. Consequently, IH-IVD testing comprises various technologies, methods and specimen types and is well-established in all *in-vitro* diagnostic disciplines investigating special patient groups. Indeed, IH-IVDs can account for up to 50% or more of medical laboratories´ biomarker portfolios in rare and niche IVD testing, for which the *in-vitro* diagnostic industry – for economic reasons - fails to take an interest (9-10).

The proposed IVDR reform apparently aims at flexibilization and contextualization but must pass European Parliament and the European Council before it becomes law. To fully appreciate the impact of the IVDR proposal 2025/404(COD), a *side-by-side* comparison of the current and proposed IVDR Art 5.5 requirements are presented in table 1.

1. Article 5.5 under the Current IVDR (Regulation (EU) 2017/746)

- *Definition & Scope:* Art 5.5 applies to *in-house* IVDs manufactured and used within a health institution if strict conditions are met. No CE-marking is required.
- *Core Provisions*
- in Art. 5.5.a: The in-house IVD may not be transferred to another legal entity. This has major implications for availability of innovative diagnostics not covered by the usual CE-IVDs. It is unclear, how many thousand lives have been saved, because the IH-IVD SARS-COV2 tests were made available to various legal entities urgently needing them at the start of the COVID pandemic. Furthermore, Art. 5.5.a in its current form has major implications for biosafety, data safety, preanalytics, costs and diagnostic delays.

- in Art. 5.5.d: Health institutions must have an appropriate quality management system (QMS) and must show that the *in-house* IVDs are developed and used under adequate quality control. Compliance with Annex I (General Safety and Performance Requirements) is needed and includes demonstrating scientific validity, analytical performance, clinical performance, doing risk management and meeting post-market surveillance obligations. Maintenance of IVD-specific technical documentation, proving compliance for each *in-house* test, and accepting audits by competent national authorities. Having justification for running *in-house* tests if an equivalent CE-marked test exists (a provision scheduled to apply from 2030), is considered an unfair requirement which is in contradiction with the professional Code of Conduct of academic Lab Professionals. This "equivalence justification requirement" is one of the most controversial elements and is strongly opposed by lab professionals in all diagnostic disciplines. It is considered an IVD-industry privilege.
- *Interpretation Challenges:* MDCG 2023-1 guidance exists but interpretation varies between Member States.

2. Article 5.5 in proposed 2025/0404 (COD)

In **table 1** relevant amendments and deletions are presented for current and proposed Art 5.5. in respectively the IVDR 2017/746 and the proposed 2025/0404(COD). Sources: EU 2017/746 (11) and 2025/0404 (COD) (12).

Key themes central in the current IVDR reform proposal are:
- *Equivalence-justification requirement is deleted* due to heavy criticism and impracticality.
- *Recognition that the current Article 5.5 imposes unnecessary administrative burden* on medical laboratories. The EC finally considers the QMS that medical labs have in place.
- *Expectation of greater national harmonization* due to the recognized variability in how Member States interpret Article 5.5.
- *Arguments in favor of the IVDR reform are the fact that the Commission acknowledges structural challenges* (administrative overload, misalignment with laboratory realities, regulatory friction) which negatively affect the use and accessibility of essential *in-house* tests.

3. Key Takeaways
- Article 5.5 today is too strict, documentation-heavy, and hinders development, validation and use of essential and precision/personalized diagnostic tests in clinical care pathways with recognized unmet clinical needs. Some examples of essential IH-tests are listed in the attached appendix.
- There is strong momentum toward modifying Article 5.5 because the Commission acknowledges administrative burden and structural challenges; stakeholders widely criticize the equivalence justification requirement as one of the most problematic challenges.

Anticipated changes revolve around removing the equivalence-justification requirement; reducing documentation obligations; harmonizing national interpretations, reducing burdens on medical laboratories and above all preventing patient harm.

4. Key Benefits of a revised Article 5.5 as proposed in 2025/0404 (COD)

- **Enhanced Patient Access to Diagnostics**
  By removing the obligation to prove lack of CE-marked equivalents, laboratories can rapidly deliver or adapt tests tailored to patient needs, especially where commercial options are inadequate.
- **Reduced Regulatory Burden Without Compromising Safety**
  Simplified documentation, reliance on ISO 15189 accreditation, and risk-based evidence maintain safety while reducing unnecessary bureaucracy.
- **Improved Harmonization Across the EU**
  Streamlined and clearer wording decreases variability in national interpretation, aligning with the Commission's objective of greater regulatory consistency.
- **Better Use of Healthcare Resources**
  Reduces duplication of documentation, administrative workload, and external consultancy dependence - especially important for SMEs and public hospitals, which the Commission highlighted as disproportionately affected by the current framework.
- **Safeguarding Patient Safety**
  The revised Art 5.5 maintains core safety and performance requirements; ensures validation through accredited quality systems; retains risk-based vigilance and competent authority oversight and enhances transparency through public notices. This achieves the original goals of the IVDR while eliminating unnecessary barriers.

The proposed simplified Article 5.5 maintains high safety standards while enabling medical laboratories to provide essential *in-house* diagnostic tests efficiently and equitably. The revised Art 5.5 supports the Commission's core reform objectives on proportionality, simplification, predictability and improved availability- and ensures that EU patients continue to receive timely, innovative, and high-quality diagnostic care.

5. Strong EFLM support for legalizing Art 5.5 as proposed in 2025/0404 (COD)

The December 2025 targeted revision represents an acceptable and workable recalibration of the original EU regulatory approach in IVDR. **EFLM Executive board and the EFLM committee on European Regulatory Affairs strongly support the European Commission's goals** of simplification, proportionality, innovation support, and continued *in-house* test availability particularly regarding a revised Art 5.5 in 2025/0404(COD). This explicit simplification and flexibilization of Article 5.5 are key so that the reform will resolve the most critical challenges faced by hospital laboratories and the patients they serve. Patients depend on timely, accurate, and context-appropriate diagnostics, which critically must include availability of IH-IVD for unmet diagnostic needs. It is inconceivable that high-end medical diagnostics could be sacrificed by making the "instrument of IH-IVD" unavailable to a well-regulated degree amongst special laboratories (see Art. 5.5.a) or permanently impeding diagnostic progress by unequal treatment of commercial and non-commercial providers of IVDs in *in-vitro* diagnostic healthcare. Medical laboratories are essential to delivering these. An improved, clear, and proportional Article 5.5, freed up from IVD-industry privileges that do not serve the patient and/or public health, is thus **not only a regulatory necessity—but a public- and patient-health imperative.**

6. References

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