

IVDR Amendments



The European Union's In Vitro Diagnostic Regulation (IVDR, EU 2017/746) represents a significant overhaul of the In Vitro Diagnostic Directive (IVDD), introducing a far more rigorous framework for the development, assessment, and lifecycle management of in vitro diagnostic (IVD) devices. Designed to strengthen patient safety, improve clinical evidence standards, and increase transparency across the diagnostic ecosystem, IVDR reflects a broader global shift toward more robust oversight of medical technologies.

However, the phased implementation of IVDR has presented substantial challenges for manufacturers, laboratories, and regulators alike. Increased reliance on Notified Bodies, significantly expanded documentation and clinical evidence requirements, and complex transitional provisions have created bottlenecks, elevated costs, and introduced uncertainty across the market. These pressures have raised concerns about delayed patient access to diagnostics, reduced test availability, and a potential slowdown in innovation within the European life sciences sector.

Detailed examples of the challenges facing stakeholders include:

- **Notified Body (NB) Capacity Constraints**

With the changes in classification rules for IVDs, a significantly larger number of IVDs now require NB involvement, resulting in a bottleneck with certification efforts, as there are a limited number of notified bodies authorized to certify to IVDR. The limited number of notified bodies is attributed to the slow process for receiving IVDR designation in addition to the decision of several notified bodies to exit the market due to the over-burdensome constraints associated with the regulation.

- **Increased Regulatory Burden**

IVDR imposes significantly more complex and resource-intensive requirements, including extensive technical documentation, robust quality management systems (QMS), expanded post-market surveillance (PMS) obligations and new roles (e.g., Person Responsible for Regulatory Compliance). Additionally, the regulation has increased legal exposure and compliance accountability for economic operators such as authorized representatives and distributors, adding more complexity to their relationships with IVD sponsors.

- **Stringent Clinical Evidence Requirements**

IVDR stipulates stronger performance evaluation requirements for IVDs resulting in challenges with limited availability of clinical samples, difficulty demonstrating clinical performance for diagnosing rare diseases and restricted use of equivalence compared to the IVDD framework.

- **Risk of Test Discontinuation and Market Withdrawal**

With IVDR's high regulatory burden, IVD sponsors are prioritizing high-revenue tests over lower-volume or legacy assays, resulting in the risk of important IVDs being withdrawn from the EU market altogether.

- **Companion Diagnostics**

Companion diagnostics (CDx) face additional complexity as, in addition to the generally stringent IVD requirements, they require mandatory consultation with the EMA as part of the evaluation of the corresponding drug product. Moreover, the stringent IVDR requirements have made CDx/Drug co-development timelines difficult to control.

- **Health Institute In-House Test Restrictions**

Health Institutions developing in-house IVDs must meet strict conditions including documenting a justification for use of the in-house test over a CE marked equivalent and documenting the in-house test's compliance with the GSPR requirements stipulated in Annex 1 of the regulation.

Given the impact these challenges are having on the innovation and general availability of IVD solutions, stakeholders have called for a more proportionate and sustainable approach. The growing recognition that the current system may not be fully fit for purpose has driven momentum for regulatory reform, including recent proposals aimed at simplifying requirements while preserving the core objectives of safety and performance.

Specifically, on December 16, 2025, the European Commission published a long-awaited legislative proposal to amend the IVDR in an effort to eliminate structural inefficiencies without compromising patient safety. The proposed amendments to the IVDR are numerous, however the most significant changes impacting IVD stakeholders are summarized in Table 1.

Table 1: Summary of Major Amendments to IVDR

Topic	Current IVDR Requirements	Proposed Changes (Dec. 16, 2025)	Impact/Intent
Notified Body (NB) Certification	CE certificates valid for max 5 years with full recertification.	No fixed expiry; replaced by risk-based periodic reviews.	Reduces re-certification burden and bottlenecks with Notified Body reviews. For companion diagnostics, this represents a significant improvement with co-development efforts.
NB Surveillance Audits	Typically annual onsite audits.	Less frequent / flexible, including remote audits.	Improves efficiency, reduces costs.
Technical Documentation Review	Regular NB review of representative devices (esp. Class B/C/D).	Risk-triggered reviews only (not routine).	Reduces burden associated with periodic reviews and allows the NB to focus effort on higher-risk concerns.
Performance Evaluation / Clinical Evidence	Strict performance study and clinical evidence requirements; limited use of alternatives.	Expanded acceptance of non-clinical data (e.g., modeling, simulations) and more flexibility for establishing clinical equivalence with other CE marked IVDs.	Reduces operational and cost burdens associated with prospective performance studies and enables faster IVD development and innovation.
Performance Studies (IVDs)	Authorization and notification by local competent authority required for many studies.	Exemptions for low-risk studies (e.g., routine blood draws) and simplified requirements for CDx studies using leftover samples.	Exemptions eliminate the need for competent authority review and authorization for certain low-risk performance studies; Streamlines clinical evidence generation; reduces burden associated with IVD/Drug sponsor co-development.
Companion Diagnostics (CDx) Performance Studies	Separate regulatory processes for CDx performance studies and corresponding drug trials.	Single application for combined studies (device + drug) with coordinated assessment by regulators.	Reduces administrative burden and cost; accelerates development timelines; improves alignment between drug and CDx approval.

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Post-Market Surveillance (PMS) / PSUR	Frequent updates (e.g., annual for higher classes) and NB review obligations.	Reduced frequency (e.g., every 2 years) and less intensive NB review.	Reduces lifecycle regulatory burden.
In-house (Health Institution) IVDs	Strict conditions; generally no transfer outside institution.	More flexibility, including transfer in public health interest; removal of requirement that there is no CE marked equivalent on the market to justify use of in-house IVD.	Improves access and emergency preparedness;
Classification Rules	Conservative classification; many devices require NB involvement.	Adjusted classification rules, potentially lowering class for some products (e.g., software).	Down classification of IVDs reduces unnecessary NB involvement.
Conformity Assessment procedures for breakthrough devices or orphan devices	Limited flexibility for niche or innovative devices.	Criteria for breakthrough devices and orphan devices introduced; breakthrough devices and orphan devices will be subject to a priority and rolling review; manufacturers have access to expert panels' advice.	Introducing expedited pathways for IVDs with a breakthrough device or orphan device designation will accelerate development and commercialization efforts for these IVD types.
Software / Digital Health	Often classified at higher risk (Class C/D).	More proportionate classification for software.	Supports digital innovation.
Artificial Intelligence (AI)	Devices may fall fully under EU AI Act requirements.	Reduced overlap with AI Act; limited applicability.	Avoids regulatory duplication.
Person Responsible for Regulatory Compliance (PRRC)	Strict qualification requirements and availability obligations.	Relaxed requirements, especially for SMEs.	Reduces burden on small companies and allows more flexibility with identifying PRRC candidates.
Use of Electronic IFU (eIFU)	Limited acceptance.	Expanded use of eIFU.	Supports digital transformation and allows for instant implementation of labeling changes in cases where eIFUs are allowed. Manufacturing costs are also lowered.

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Structured Dialog with Notified Bodies	N/A	Requirement added for notified bodies to have documented procedures in place to offer and carry out dialog with the manufacturer before and after an application for conformity assessment .	The new requirement clarifies the need for notified bodies to have a formal process for structured dialog and for the notified bodies to offer structured dialog before and after applications for conformity assessment are filed. Prior to this, MDCG 2019-6 described limited scenarios where a sponsor could seek structured dialog with a notified body before an application is filed.
Advice from Expert Panels	N/A	For class C and class D devices, a sponsor may, prior to its performance study or clinical performance evaluation, consult an expert panel to solicit feedback on a study protocol prior to initiating the study. The guidance from the panel will be considered by both the sponsor and notified body when reviewing subsequent performance evaluation reports as part of the conformity assessment .	Introducing an expert panel review prior to initiating performance studies streamlines development efforts and avoids the potential for notified bodies to disagree with the study design during the conformity assessment review.

The amendment proposal for IVDR is indeed a pivotal step toward recalibrating the regulatory framework to simplify processes and alleviate the regulatory burden associated with developing and commercializing IVDs in the EU market. Importantly, the proposal does not deviate from the core principles of safety, performance, and transparency. Rather, it reflects a pragmatic shift toward a more sustainable and efficient system that better aligns regulatory expectations with real-world capabilities across manufacturers, Notified Bodies, and healthcare institutions. If successfully adopted and implemented, these reforms have the potential to accelerate innovation, improve the predictability of product development and conformity assessment timelines, and ensure that patients continue to benefit from timely access to state of the art IVD technologies.