Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e. V.
Association of the Scientific Medical Societies in Germany

AWMF

Michael Vogeser
LMU University Hospital, Munich, Institute of Laboratory Medicine
for the Ad-hoc-Commission on In-vitro Diagnostics

Evaluation of the EU-Regulation on In-vitro-Medical Devices (IVDR)

Berliner Forum, 5 December 2025

Role and scope of in-vitro diagnostics

- Laboratory tests are by far the most frequently used technical procedure in medicine.
- An estimated 70% of all clinical decisions are influenced by laboratory results.
- They account for only around 3% of healthcare expenditure - enabled by high efficiency through automation and optimized logistics.
- In Germany, probably more than 3 billion tests are performed each year.
- Conditional for several medical fields (e.g., diabetology, haematology).

Non-industrial areas of laboratory diagnostics

- In addition to high-throughput laboratory diagnostics, there are crucial areas of specialised non-standard diagnostics which are developed in-house
- These services are not industrialised and rely on the medical expertise and practice of physicians.
- They are of particular importance in fields such as specialised haematology, clinical pharmacology, and genetics.
- Although they represent far less than 1% of all test results, they are fundamental for patient management in many cases, e.g., in the management of leukaemias.

Subject Matter and scope of the IVDR

L 117/176 EN Official Journal of the European Union 5.5.2017

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

- The Regulation lays down rules concerning the placing on the market, making available on the market or putting into service of in vitro diagnostic medical devices for human use in the Union (Art. 1 (IVDR)).
- It essentially regulates how IVD devices obtain CE marking for market entry (analyzer systems, reagents, calibration and QC materials, test kits, and software).
- IVDR sets out safety and performance requirements for these devices (Annex I).

Novelty of the IVDR

- IVDR has replaced IVDD (IVD-Directive 98/79/EC)
- Under IVDD: Manufacturers themselves certified that their products met the requirements of a corresponding Annex (= self-certification; with the exception of a few high-risk products (e.g. blood group tests))
- Under IVDR: a third party now assesses whether requirements are met – *Notified Bodies*
- Notified bodies are private, commercial companies that are subject to official supervision by the Member State in which they are based (in Germany ZLG)
- Self-certification now applied only for products in the lowest risk class A.
- No EU-authority involved in market access of IVD (unlike pharmaceuticals with EMA)
- For the first time, articles manufactured and used in diagnostic laboratories without being placed on the EU market are also addressed by EU law - Article 5 (5)

PRODUCT INFORMATION LEAFLET

Company XY

6PLUS1® Multilevel Plasma Calibrator Set

Mass Chrom ® Free Metanephrines in plasma

REF 81039

CE 0123 IVD

Evaluation of the IVDR

- EU regulations are in general subject to an evaluation after 10 years

> *Article 111*
>
> **Evaluation**
>
> By 27 May 2027, the Commission shall assess the application of this Regulation and produce an evaluation report on the progress towards achievement of the objectives contained herein including an assessment of the resources required to implement this Regulation. Special attention shall be given to the traceability of devices through the storage, pursuant to Article 24, of the UDI by economic operators, health institutions and health professionals. The evaluation shall also include a review on the functioning of Article 4.

- Due to recognised implementation problems, evaluation of IVDR was brought forward to 2024/2025.
- Evaluation focus: *effectiveness, efficiency, and proportionality*
- Further core objective: reducing administrative burden

Criticism – IVD industry

- Initial shortage of available Notified Bodies for up-date of IVD-CE certificates from IVDD to IVDR
  → Delayed designation/accreditation of NBs during the Covid period
- Significantly increased costs
  → More extensive documentation
  → Substantial fees charged by Notified Bodies
  → Increased post-market surveillance requirements
- Mandatory recertification every 5 years
  → Ongoing financial burden
- Additional costs are expected to reduce companies` investment into innovation
- Declining competitiveness of European IVD manufacturers
- Warning of supply shortages
  → Especially for niche products for rare diseases, at risk of market withdrawal for economic reason

Less mentioned advantages for the industry: Market access in the 27 individual MS greatly simplified

Criticism – non-industrial areas of laboratory diagnostics

- Extensive documentation requirements for in-house-manufactured devices, oriented more toward the resources of the IVD industry — Annex I
  (e.g., a *fully detailed* instructions for use for a quality-control sample; *annual* safety and performance review).

- "Industry privilege" in Article 5(5)(d): devices may only be manufactured *in-house* if no „equivalent" product is available on the EU market.

Fundamental overinterpretation of the IVD in the non-industrial diagnostics area

- The IVDR regulates **devices** manufactured within diagnostic laboratories (= reagents, calibrators, QC-materials, kits, instruments, software).

  The IVDR contains **no** wording indicating that it intends to regulate the *application* of medical devices or *diagnostic procedures* as medical services — e.g., performing FACS analyses.
- The IVDR does **not** regulate LDTs; however, this was claimed by parts of the IVD industry and the consultancy sector.
- Healthcare processes (such as diagnostic procedures) must be regulated by the Member States, **not** by the EU — Article 168 Treaty on the Functioning of the EU

European Commission consultation procedure

- Opportunity for public consultation was provided by the EC from 12/2024 to 3/2025 and again in 10/ 2025.
- All submitted statements are publicly available on the European Commission website.

Position statement by the AWMF ad hoc commission IVD – Essence

- Self-declaration under the IVDD was inacceptable; the IVDR represents a major improvement with regard to patients' safety.
- No evidence of IVD supply shortages so far, despite isolated market withdrawals of IVDs.
  No critical clinical IVD-gaps observed so far
  (Note: A transition period still applies to some of the products on the market)
- Analytical instruments should not fall under Class A self-certification. (under-regulation!)
- The industry privilege in Article 5(5)(d) IVDR contradicts medical responsibility for choosing the most appropriate diagnostic method.
- In-house manufactured IVD not intended for placing on the EU market should **not** be subject to EU-level regulation.
- **Consequently, Article 5(5) should be deleted without replacement.**
- Its deletion would clearly support the reduction of bureaucracy and the avoidance of overregulation.

European Commission

Log in EN Search on Europa Search

Law

Feedback from: AWMF, Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e. V. Association of the Scientific Medical Societies in Germany

Have your say - Public Consultations and Feedback > Published initiatives > EU rules on medical devices and in vitro diagnostics – targeted evaluation >

Feedback from:

Feedback reference	F3522812
Submitted on	21 February 2025
User type	Academic/research Institution
Organisation	AWMF, Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaf Association of the Scientific Medical Societies in Germany
Organisation size	Large (250 or more)
Transparency register number	057783748990-59
Country of origin	Germany
Initiative	EU rules on medical devices and in vitro diagnostics – targeted evaluation

DE GRUYTER Clin Chem Lab Med 2025; aop

Opinion Paper

Michael Vogeser*, Monika Brüggemann, Ulrich Sack, Christoph Weinstock, Stefan Zimmermann and Albrecht Stenzinger, for the Association of the Scientific Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V. (AWMF))

Expert opinion within the context of the targeted evaluation of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices pursuant to Article 111 and Regulation (EU) 2024/1860

Outlook

- Unclear whether our statement will influence the process
- National societies are systematically *not* consulted by the European Commission
- EC engages with defined stakeholders on the EU-level only – for laboratory diagnostics:

  EFLM, BiomedAlliance, MedTechEurope
- Health ministries of EU Member States likely have the strongest influence
- Position of the German Federal Ministry of Health is unknown
- EC proposal for an *amending regulation* expected in the coming days
- Legislative consultation by the European Parliament and the Council likely in 2026

Thank you very much for your attention !

michael.vogeser@med.uni-muenchen.de