MedTech Europe
from diagnosis to cure

An Improved Regulatory Framework: What Do Europe's Diagnostics Need?

A supplement to MedTech Europe's position on the MDR/IVDR Revision

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Executive summary

- In vitro diagnostic medical devices (IVDs) are crucial for patient care, health system function and economic growth. They **provide essential information** for diagnosis, screening, treatment, and patient management. Demographic changes and rising demand mean that healthcare systems will rely more on IVDs, not less.
- A more risk-proportionate regulatory framework is essential to sustain innovation and ensure timely patient access to essential diagnostics. The European Commission's **proposal to revise the regulatory framework for IVDs**[1] is a positive step and many of its elements should be preserved. They will help safeguard a strong and competitive IVD sector in Europe and ensure continued access to safe and performing, state-of-the-art diagnostics for patients.
- Consistent with MedTech Europe's overall position, this supplement identifies elements of the proposal to **WELCOME** and to **STRENGTHEN**, focusing on the IVD-specific dimensions. The European Commission's proposal, together with the additional targeted solutions outlined here, will support availability of essential diagnostics, both new and those already in routine use, for patients and laboratories across Europe.

How this paper relates to MedTech Europe's overall position?

This paper is a supplement to MedTech Europe's overall position on the revision of the EU medical devices and in vitro diagnostic medical devices regulations (5 May 2026). It should be read together with that document, not in place of it.

The overall position sets out MedTech Europe's assessment of the European Commission's proposal using three categories: elements to **WELCOME**, elements to **STRENGTHEN**, and elements to **RETHINK**. This supplement applies the same framing to the issues that are specific to in vitro diagnostics. Topics that affect medical devices and IVDs in the same way, including the broader simplification package, international cooperation, digital health, artificial intelligence and cybersecurity, are addressed in the overall position and are only referenced here where IVD-specific nuance is needed.

The purpose of this supplement is to ensure that, in the co-legislative process, IVD-specific amendments receive the attention their importance to healthcare systems demands.

[1] European Commission's Proposal for a regulation to simplify rules on medical and in vitro diagnostic devices

Background

The value of IVDs lies in their ability to generate information that supports clinical decision-making by healthcare professionals and others. Clinical decisions are guided by IVDs alongside patient history, symptoms, and other clinical data. Since the main purpose of an IVD device is to provide information, any risks associated with IVDs are primarily linked to how that information is used in clinical decision-making. Patient safety for IVDs is assured through robust manufacturing quality systems, comprehensive performance evaluation, and the involvement of healthcare and laboratory professionals (e.g. in interpretation and use of results). The additional layer of laboratory oversight and validation, supported by External Quality Assessment schemes that create continuous performance benchmarking, is a key characteristic of many IVDs that distinguishes them from most other medical devices and diagnostic tools.

What are in vitro diagnostic medical devices?

IVDs are tests done on specimens taken from the human body (e.g. blood, hair, saliva) to provide medically useful information. They cover a wide range of technologies:

- Complex molecular diagnostics & laboratory-based tests
- Simple self-tests such as pregnancy tests
- Blood glucose meters
- Infectious disease testing (e.g. COVID-19, HIV, measles)

These tests are used in many areas, including **infectious diseases, cancer screening, genetic testing, blood transfusion safety,** and **personalised medicine**.

IVDs are non-invasive – they do not come into contact with the human body and carry no direct physical risk to the subject/patient. Testing may include sample taking that can act on a body involving medical devices (e.g. needles, swabs, which are not themselves IVDs).

Most IVDs are classified as low-medium risk devices under the IVD Regulation (~66%)[i], such as blood chemistry tests (e.g. magnesium), tests for common infections (e.g. yeast infections), fertility hormone tests etc. Only a small proportion of IVDs fall into the highest risk class, such as screening tests for blood transfusion safety.

MedTech Europe welcomes the European Commission's efforts to simplify and improve the EU In Vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR) while preserving safety and performance of devices. At the same time, the IVD demand is growing, and **it is essential that the negotiations to simplify the regulatory system are aligned to the nature of IVDs to maintain a strong diagnostics sector in Europe**. This paper highlights the essential role of in vitro diagnostics in Europe's healthcare systems and outlines the key areas where the European Commissions' IVDR revision proposals are essential to keep and where they can be further strengthened to support a **resilient, innovative, and competitive diagnostics sector in Europe**.

Why does the in vitro diagnostics sector matter?

The sector is a **highly innovative** part of the European medical technology industry that reinvests yearly approximately 1 billion euros in research and development (R&D)[ii]. The European IVD sector is largely **composed of and is driven by small & medium-sized enterprises** (SMEs). Worldwide, in vitro diagnostics is **the largest medical technology sector**, followed by cardiology and diagnostic imaging[iii]. A significant part of the IVD sector serves **specialised clinical needs** or **small patient populations.**

Diagnostics already inform an estimated **70% of clinical decisions** while representing only a small share of healthcare expenditure[ii]. **Healthcare systems will rely more on in vitro diagnostics, not less**.

Due to an **ageing population and the rise in chronic diseases** such as cancer, diabetes and cardiovascular diseases, **testing volumes and screening programmes are increasing** and so does the need for in vitro diagnostics. Prevention and early detection through **diagnostics**, such as cervical cancer and colorectal cancer screening to detect precancerous changes, **are key in reducing long-term healthcare costs**[iv]. Meanwhile, the **fundamental role of IVDs for disease control** has been effectively demonstrated by the COVID-19 pandemic. Thanks to innovation in the IVD sector, new COVID-19 tests were developed and deployed at unprecedented speed.

Demand for IVDs in Europe is rapidly accelerating[v,vi] and it **is rising faster than capacity.** Healthcare waiting lists are increasing, with the poorest populations most affected, while in some countries diagnostic waiting times have doubled over the past decade[vii,viii].

Ensuring Access to IVDs Through More Proportionate Regulation

The European Commission's revision proposal for medical devices and IVDs is a positive step towards a simplified, more risk-proportionate regulatory framework. It reduces reporting redundancies and improves overall system efficiency, while maintaining robust pre- and post-market controls comparable to other major global jurisdictions.

The urgency of delivering this simplification swiftly, and the broader case for patient access and European competitiveness, are set out in MedTech Europe's overall position. The following sections focus on the IVD-specific dimensions. They are structured around the same categories used in the overall position (WELCOME and STRENGHTEN).

Targeted solution 1 – Aligning regulatory oversight with how IVD risk arises and is controlled

The WHY

For IVDs, patient safety depends primarily on test performance, quality systems, controls ensuring the test works properly, and professional interpretation of results, rather than direct physical interaction with the patient.

The current IVDR does not reflect the specific risk profile of IVDs, as it applies largely uniform requirements across a predominantly low-risk sector.

IVDs are information-based (not invasive), yet they are subject to regulatory processes that are comparable in complexity to higher-risk medical technologies (such as implantable devices).

The HOW

Remove unnecessary burden through targeted measures, in line with MedTech Europe's broader simplification approach to:

- **WELCOME proportionate oversight for low-risk devices**: as set out in the Commission's revision proposal, focus checks, such as technical documentation (TD) sampling, on higher-risk devices, while reducing unnecessary scrutiny for lower-risk devices such as cholesterol tests, urine strips, and common infection tests.
- **STRENGTHEN clarity for well-established routine procedures**: clarify the legal provisions to avoid a full set of authorisation requirements for procedures such as routine blood draws and finger pricks.

This IVD-specific calibration reinforces, rather than departs from, the risk-based approach MedTech Europe welcomes in the overall simplification package in the revision proposal.

Targeted solution 2 – Fostering the IVD innovative drive

The WHY

The current IVDR rules are overly complex to navigate and comply with, which is decreasing companies' capacity and incentive to update IVD products and innovate. This is especially critical for SMEs, which often face investors turning away due to a lack of regulatory certainty.

The IVD sector's high level of R&D intensity and rapid innovation[ii] cycles, which enable the development of a wide range of diagnostics for diverse patient populations, is jeopardised.

The HOW

WELCOME the Commission's simplification measures in full. Regulatory simplification is a necessary condition to preserve Europe's IVD innovation capacity. For IVDs, the following elements are particularly important and should be preserved in the final text:

- reducing upfront certification burden;
- moving away from redundant reviews (e.g. 5-year recertification) and technical documentation sampling for lower risk devices;
- eliminating duplicative reporting requirements;
- enabling greater flexibility for clinical evidence, including broader recognition of real-world evidence and in-silico studies.

Targeted solution 3 – Protecting a level-playing field

The WHY

Europe is at risk of creating a two-tier regulatory system for IVDs with different standards applying to commercially available CE-marked devices and health institution tests.

The current IVDR revision proposal would expand the possibility for health institutions to use their own tests even where suitable CE-marked alternatives are available. While this could mean more devices available to healthcare communities, it also means more devices in use that aren't regulated to the IVDR standard. Moreover, it discourages and undermines investment in high-quality, high-scale CE-marked diagnostics.

The HOW

STRENGTHEN the principle that CE-marked devices should remain the standard to ensure a high level of quality and patient safety.

Health institution tests should only be used where no suitable CE-marked alternative is available, and a clear justification is provided.

Targeted solution 4 – Aligning orphan IVDs with EU rare diseases definition

The WHY

The proposed threshold of 1 in 12,000 people per year which will define 'Orphan IVDs' is out of alignment with how Europe defines rare diseases. It will exclude important diagnostic tests that patients rely on, such as tests used to match rare blood groups for transfusions, identify compatible donors for transplants, guide treatment choices (companion diagnostics), monitor how medicines are working, and detect rare genetic conditions.

Companies developing niche/orphan IVDs are already facing increasing challenges under the IVDR. A narrow orphan IVD definition will further accelerate loss of niche tests. Many niche tests serve small or specialised patient groups, and high regulatory costs must be spread over a limited number of units, making them economically difficult to sustain.

The HOW

STRENGTHEN the alignment of the orphan IVDs definition with the European definition of rare diseases, which has a threshold of 5 in 10,000 individuals per year. This would better reflect the real needs of patients living with rare conditions. It would help ensure that these essential tests remain available, supporting timely diagnosis, safe treatments, and appropriate follow-up care. It also aligns with how orphan drugs are defined, making it easier to develop orphan diagnostics for those areas of medicine.

MedTech Europe's overall position calls for more fit-for-purpose innovation pathways, including for orphan and breakthrough devices. The IVD-specific threshold correction described here is the practical expression of that broader ask for the diagnostics sector.

Core IVD-specific aspects for IVDR Revision

The table below summarises MedTech Europe's position on IVD-specific provisions. Topics that apply equally to medical devices and IVDs are addressed in the overall position and are cross-referenced here rather than restated.

Topic	MedTech Europe Assessment	Recommendation
Open validity certificates with periodic risk-based reviews	Eliminates bottlenecks while maintaining ongoing oversight through periodic checks fully aligned to the device's risk profile. Recertification is highly redundant. For example, highest-risk IVDs are already subject to batch checks by EU reference laboratories.	**WELCOME** Preserve in final text. See overall position, section B.1
Risk-based sampling in conformity assessment	More appropriate scrutiny for lower and medium-risk devices such as better differentiation between class B and class C devices.	**WELCOME** Preserve in final text. See overall position, section B.1
Appropriate treatment of near-patient IVD tests	Aligning the regulatory pathway for near-patient tests with other professional-use diagnostics.	**WELCOME** Preserve in final text. IVD-specific; see also overall position, section B.1
Streamlined change control	Clearer distinction between changes that manufacturers can implement without prior notification and those requiring approval makes it faster and simpler to act.	**WELCOME** Preserve in final text. See overall position, section B.1, including MedTech Europe's amendment limiting pre-approval to changes with adverse impact
Broader recognition of clinical evidence	Acceptance of non-clinical evidence reflects the growing body of data sources on devices in routine diagnostic use.	**WELCOME** Preserve in final text. See overall position, section B.1
Digitalisation of the regulatory process	Digitalisation of regulatory documents and submissions, and digital provision of information, will reduce administrative burden and improve system efficiency.	**WELCOME** Preserve in final text. See overall position, section B.1
Digital labelling	Digital labelling will strengthen supply chain resilience and improve patient access to product information.	**WELCOME** Preserve in final text. See overall position, section B.1
New chapter on International Cooperation	Critical addition to the EU's regulatory framework serving important EU regulatory, strategic, and competitiveness interests.	**WELCOME** Preserve in final text. See overall position, section B.2
AI inclusion in IVDR	The intention of the Commission to reflect AI requirements into the IVDR is a positive step. A deadline should be added to ensure this happens in a timely manner.	**STRENGTHEN** A deadline is needed to ensure this approach delivers in practice. See overall position, section C.3
Labelling for active ingredients in IVDR	The proposal changes 'active ingredient(s)' to 'critical ingredient(s)' which is expected to cause unnecessary confusion and administrative burden without clear user benefit.	**STRENGTHEN** Retain "active ingredient" instead of introducing "critical ingredient". This will preserve regulatory consistency and support alignment with international terminology

Topic	MedTech Europe Assessment	Recommendation
Use of health institution tests	Support simplification for health institutions. The principle that the default should be the use of the CE-marked device where available should be maintained.	**STRENGTHEN** Health institutions should use the approved CE-marked test where available, with flexibility to justify use of their own test where needed. IVD-specific; see also overall position, section C.5
Blood draws in performance studies	Support the intent to remove authorisation for low-risk specimen collection, but the current legislative provision should be clarified to ensure that routine procedures like blood draws and finger pricks are not unintentionally in scope.	**STRENGTHEN** Amend Article 58(1) IVDR to clarify that that full authorisation requirements apply only when an invasive procedure presents significant clinical risk. IVD-specific; see also overall position, section C.4
Orphan device threshold alignment with rare disease definition	The proposed IVDR threshold (1 in 12,000) may exclude essential rare diagnostics.	**STRENGTHEN** Align it with the EU rare disease threshold (5 in 10,000 individuals per year)
Cybersecurity reporting	Support proposed cybersecurity requirements. Vigilance and cybersecurity are distinct domains with different primary objectives; their reporting requirements should therefore be clearly differentiated.	**STRENGTHEN** Maintain the existing level of requirements and safeguards while creating a distinct section on "Cybersecurity"

References

[i] Based on the Gesundheit Österreich GmbH (GÖG) survey on the monitoring of the availability of devices, which was commissioned by the European Commission, total IVDs undergoing IVDR conformity assessment by October 2023

[ii] MedTech Europe. (2025). *European IVD market statistics report 2025*. https://www.medtecheurope.org/resource-library/european-ivd-market-statistics-report-2025/

[iii] MedTech Europe. (2025, September 4). *Market*. https://www.medtecheurope.org/datahub/market/

[iv] OECD/European Commission. (2024). *Health at a glance: Europe 2024: State of health in the EU cycle*. OECD Publishing. https://www.oecd.org/content/dam/oecd/en/publications/reports/2024/11/health-at-a-glance-europe-2024_bb301b77/b3704e14-en.pdf

[v] OECD – Health at a Glance Europe. https://www.oecd.org/health/health-at-a-glance-europe/

[vi] MarketsandMarkets. (n.d.). *Europe In Vitro Diagnostics Market Report 2026-2031, By Product & Service, Technology, and Geo*. MarketsandMarkets. https://www.marketsandmarkets.com/Market-Reports/europe-in-vitro-diagnostics-market-20552722.html?utm_source=chatgpt.com

[vii] *NHS diagnostics data analysis*. (n.d.). The British Medical Association Is the Trade Union and Professional Body for Doctors in the UK. https://www.bma.org.uk/advice-and-support/nhs-delivery-and-workforce/pressures/nhs-diagnostics-data-analysis

[viii] Eurostat. (2025, August 20). 3.6% experience unmet needs for medical care in 2024. *Eurostat*. https://ec.europa.eu/eurostat/web/products-eurostat-news/w/ddn-20250820-2?utm_source=chatgpt.com