# NoBoCap

# Intended Purpose and Classification of IVD Devices under EU Regulation 2017/746

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# Contents

## Introduction

To legally place their IVD devices on the European market, manufacturers must meet the requirements of the regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). Among other obligations, the first step for manufacturers is to classify their IVD devices in accordance with the risk-based classification rules outlined in Annex VIII of the Regulation. The classification of devices is primarily based on the intended purpose of the device as intended by the manufacturer. This white paper provides a comprehensive overview of the concept of intended purpose and of the classification systems for in vitro diagnostic medical devices. It evaluates its practical and strategic implications for manufacturers and other stakeholders. While this document offers interpretative guidance, it is not intended to substitute for a complete and detailed review of the Regulation's requirements.

- **Regulatory background**

Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) was published on 5th May 2017 and entered into force on 26th May 2017, establishing a new regulatory framework to enhance patient safety and device performance. It was intended to replace the European Directive 98/79/EC (IVDD) and Commission Decision 2010/227/EU. While the regulation became fully applicable on 26th May 2022, a phased transition was introduced to mitigate disruption and allow manufacturers to adapt. Legacy devices certified under the previous IVDD could remain on the market until 26th May 2024, with additional "sell-off" provisions extending use until 2025. Recognising capacity constraints among Notified Bodies and delays in EUDAMED deployment, the European Commission further extended transitional periods. Regulation (EU) 2024/1860 introduced extensions for IVDD devices ("legacy devices") still in compliance:

- ✓ Class D devices must comply by 2025,
- ✓ Class C by 2026, and
- ✓ Class B and sterile Class A by 2027.

These extensions are conditional on maintaining IVDD compliance and avoiding significant design changes. This staged approach reflects the EU's commitment to balancing regulatory rigour with market stability, ensuring a smooth migration to a system emphasising clinical evidence, post-market surveillance, and traceability through UDI and EUDAMED.

- **Why a New Approach? From List-Based to Risk-Based Classification**

Under the former IVDD framework, device classification relied on a static list of categories, which often failed to reflect the diversity and evolving complexity of modern diagnostics. This approach created inconsistencies in regulatory oversight, as devices with similar risk profiles could be subject to different requirements. The IVDR introduces a risk-based classification system (Classes A, B, C, and D) aligned with the Global Harmonisation Task Force (GHTF) principles, ensuring proportional regulatory scrutiny based on potential impact on patient health and public safety. High-risk devices, such as those used for blood screening or

detecting life-threatening conditions, now fall under Class D, requiring the most stringent conformity assessment, while low-risk instruments are classified as Class A. This shift harmonises EU requirements with international standards, promotes global market alignment, and strengthens patient protection by linking regulatory obligations directly to clinical risk rather than arbitrary lists.

## Defining "Intended Purpose"

Under the IVDR (Regulation (EU) 2017/746), the "intended purpose" of an in vitro diagnostic (IVD) medical device is defined as the use for which the device is intended, based on manufacturer-provided information - such as the label, instructions for use, promotional materials, or performance evaluation details - as explicitly stated in Article 2(12) of the Regulation. This concept is foundational to the entire regulatory lifecycle, as it determines whether a product qualifies as an IVD, informs its risk-based classification under Annex VIII (Classes A–D), and guides essential components of its technical documentation, including labelling, clinical and performance evaluation, and conformity assessment. The IVDR requires that the intended purpose be clearly articulated in concise, clinically focused language, specifying what is detected or measured, its function (e.g., screening, diagnosis, monitoring), the target population, sample type, intended user, and testing environment. This precise definition ensures that regulatory oversight is tightly aligned with real-world clinical use.

- **Key Components of Intended Purpose**

The **key components** of the intended purpose are defined in *Annex II of the* Technical Documentation of the regulation. Point 1.1, Device description and specifications point out the Intended Purpose requirements.

*"(c) the intended purpose of the device which may include information on:*

> *(i) what is to be detected and/or measured;*
> *(ii) its function such as screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic;*
> *(iii)the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;*
> *(iv) whether it is automated or not;*
> *(v) whether it is qualitative, semi-quantitative or quantitative;*
> *(vi) the type of specimen(s) required;*
> *(vii) where applicable, the testing population;*
> *(viii) the intended user;*
> *(ix) in addition, for companion diagnostics, the relevant target population and the associated medicinal product(s)."*

- **Strategic importance of Intended Purpose**

The intended purpose is not merely a descriptive statement; it is a cornerstone of regulatory compliance under IVDR. It determines whether a product falls within the scope of the regulation as an in vitro diagnostic device and directly influences its risk-based classification under Annex VIII. This classification, in turn, dictates

the level of conformity assessment and Notified Body involvement required. Beyond classification, the intended purpose shapes the entire technical documentation package, including performance evaluation, risk management, and usability studies. It also drives labelling requirements, ensuring that instructions for use and warnings align with the declared clinical application. Furthermore, promotional materials and claims must remain consistent with the intended purpose to avoid misleading users and regulatory non-compliance. In essence, the intended purpose acts as the regulatory anchor, linking product design, evidence generation, and market communication to a clearly defined clinical role, thereby safeguarding patient safety and supporting transparent regulatory oversight.

## Intended Purpose as Regulatory Pivot

Within the IVDR framework, the intended purpose serves as the central regulatory pivot, influencing every stage of compliance.

- First, it determines scope, clarifying whether a product qualifies as an in vitro diagnostic device under the regulation.
- Second, it drives risk classification, feeding directly into Annex VIII rules that assign the device to Classes A through D based on its clinical impact. This classification then dictates conformity assessment pathways, including whether Notified Body involvement is required and the depth of supporting evidence.
- Finally, the intended purpose ensures documentation alignment, acting as the reference point for instructions for use, labelling, performance evaluation, and promotional claims.

It is therefore very important that the intended purpose is specified very clearly and in detail, so that there are no blind spots for the user and so that the evaluation by the Notified Body is successful. To do this, each point of the intended purpose must be satisfied, both in terms of description and data to support it.

## Classification Framework under IVDR

The IVDR introduces a globally harmonised, risk-based classification system for in vitro diagnostic devices, replacing the static list approach of the previous IVDD. Devices are categorised into four classes based on their potential impact on individual and public health:

- Class A covers low-risk products such as laboratory instruments,
- Class B includes devices with moderate individual risk and low public health risk, such as self-testing kits for non-critical conditions,
- Class C applies to devices with high individual risk or moderate public health risk, including tests for infectious diseases or genetic disorders,

- Class D represents the highest risk category, encompassing devices critical for controlling serious public health threats, such as blood screening for HIV or hepatitis.

This structure ensures that regulatory scrutiny is proportionate to clinical risk, aligning EU requirements with international standards and strengthening patient safety through targeted conformity assessment and evidence requirements.
The rules governing device classification are detailed in Annex VIII. There are 10 implementing rules and 7 classification rules.

### Annex VIII: Implementing Rules

The ten implementing rules are quite direct and straightforward. There is no room for interpretation, as their purpose is to clarify the application of the classification rules. It is noteworthy that the first implementing rule directly refers to the intended purpose and how it should guide the classification process of a device. The implementing rules also clarify points regarding devices to be used in combination with the device in question, accessories, calibrators and controls, and finally, software. They also clarify that all rules should be considered when defining the risk class of a device, and that if multiple rules apply to a device, the rule with the highest resulting classification should be used. Finally, if multiple intended purposes are declared, resulting in different classifications of the device, in this case, too, the highest resulting classification must be applied. These rules must be applied to all devices, whether first-line, confirmatory, or supplemental assays.

### Annex VIII: Specific Classification Rules

The seven classification rules are based on the intended purpose of the device. Specifically, rule one classifies devices whose intended purpose is to detect transmissible agents in blood and/or tissue and for high-risk situations; such devices will fall into class D. The second rule identifies devices for blood typing or tissue typing to ensure immunological compatibility for transfusion or transplantation, which are classified as class C. Rule three identifies Class C devices as a rather broad range of devices whose intended purposes are:

- ✓ detecting the presence of a sexually transmitted agent (STD),
- ✓ cancer,
- ✓ genetic testing,
- ✓ companion diagnostics.

Rule four defines devices intended for self-testing and near-patient testing, while rule five identifies Class A devices. Rule six classifies all devices not covered by other rules into risk class B, and rule seven defines controls that do not have a qualitative or quantitative value assigned to them as class B devices.

It is crucial to note that a device using the same analyte or marker may fall into a different risk class based on its intended purpose. For this purpose, it is useful to use the Medical Device Coordination Group (MDCG) guidelines, which,

although not binding, can provide valuable information for the classification of IVD devices. One example is the MDCG 2020-16 Rev.4 guideline, updated in March 2025, which explicitly clarifies the distinction between professional-use tests and self-testing of devices for the identification of COVID-19 infections. This defines all SARS-CoV-2 tests intended exclusively for healthcare workers or professionals as Class B devices. SARS-CoV-2 self-test devices, although they may be based on the same technology and identify the same analyte, are classified as Class C IVD devices.

## Conformity Assessment Pathways

According to the IVDR, the conformity assessment of IVD devices depends on the risk class of the device itself. To demonstrate compliance with the regulation, manufacturers of non-sterile class devices can proceed with a self-declaration. Sterile class A devices, however, must undergo an assessment by a notified body, solely regarding sterility. Class B and C devices, on the other hand, must undergo a complete technical documentation review process by a notified body and a quality management system audit. Companion diagnostics also require consultation with the EMA. Class D devices, which are the highest risk devices, in addition to requiring a complete technical documentation review and a quality management system audit, must have each batch released by a European-accredited laboratory.

## Key Practical Insights

It must always be kept in mind that accuracy in the intended purpose is critical. Ambiguous or broad statements can lead to misclassification, undermine the alignment of clinical evidence, and ultimately lead to product noncompliance. For this reason, it is essential to harmonise the intended purpose and data across the IFU, claims, performance data and clinical evidence. Using up-to-date guidelines, such as the MDCG, helps ensure consistent interpretation of the rules, especially for those complex devices such as software kits or companion diagnostics.

## Practical Insights and Recommendations

In this final section, we will provide some practical guides and recommendations regarding the definition of the intended purpose and classification of devices. The first step is to define the intended purpose early, involving medical or laboratory experts. When defining your intended purpose, try to be as specific as possible. The next step is to classify the device by referring to Annex VIII and documenting the rationale for the classification. Verify that all technical documentation is aligned with the intended purpose and classification of the device, particularly the labels, performance evaluations, and clinical data. As a final step, you must choose the correct verification path: either through a self-declaration or through a notified body. Always remember that the IVDR now requires a lifecycle approach to a device. It is therefore important to update the intended purpose of a device in the post-marketing phases if this is necessary.

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