# IVDR requirements for near-patient and self-test devices

White paper

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## Introduction

Laboratory medicine has long been essential to medical diagnosis, evolving from physician-led, rudimentary tests to highly specialized, centralized laboratories. While consolidation improved accuracy and standardization, it also introduced accessibility challenges, particularly for patients in remote or underserved areas.

### The rise of near-patient testing

To address the need for rapid diagnostics, near-patient testing (NPT) emerged as a critical solution. Especially in emergency settings, NPT enables testing at or near the care site, bridging the gap between clinical decision-making and timely results, ultimately improving patient outcomes.

### Evolution of self-testing

In vitro diagnostic (IVD) tests became increasingly accessible to lay users during the 20th century, marking a significant shift in personal healthcare. The 1970s and 1980s saw the first self-test (ST) – the home pregnancy test – which empowered individuals to obtain critical health information privately and conveniently. This was followed in the 1980s and 1990s by blood glucose monitors, which revolutionized diabetes management by enabling patients to monitor their glucose levels in real-time. Since, the range of STs has expanded to include tools for detecting infections, tracking fertility and more.

This decentralization of diagnostics supports patient empowerment, improves access to care and enables earlier interventions. Looking ahead, integrating telehealth may further enhance self-testing.

### Regulatory landscape for NPT and ST devices

The In Vitro Diagnostic Medical Device Regulation 2017/746 (IVDR) is not the first European law to regulate NPT and ST devices. Under the previous In Vitro Diagnostic Medical Devices Directive (IVDD 98/79/EC), most IVDs were self-declared. Only the highest risk devices – those listed in Annex II – required Notified Body involvement and were certified. NPTs were historically seen as professional-use devices and regulated similarly to general IVDs, with Notified Body oversight limited to high-risk categories. All ST devices – not just those classified as high risk – were also subject to Notified Body supervision, unless they were intended solely for performance evaluation. However, this oversight usually focused solely on the device design under Annex III Section 6, without an audit of the manufacturer's quality management system (QMS).

The introduction of IVDR marked a shift to a risk-based classification system (classes A-D), significantly increasing regulatory oversight. Both NPT and ST devices now require Notified Body assessment, including technical documentation review and on-site QMS audits. The IVDR also imposes stricter requirements for clinical evidence, post-market surveillance and QMS.

NPT and STs receive particular attention under the IVDR, with dedicated provisions addressing their unique risks for use outside of the laboratory by individuals without professional laboratory training. These include clear labeling, usability, linguistic requirements and robust clinical validation. Overall, the IVDR enhances safety and standardization in decentralized diagnostics across the EU.

### Classification of NPT and ST devices

The IVDR considers three categories of devices:

| | Professional laboratory use | Near-patient testing | Self-testing |
|---|---|---|---|
| Intended user | Laboratory professional | Health professional | Lay user |
| Intended use environment | Clinical laboratory | Outside laboratory environment | Not defined |

NPT refers to IVDs used outside laboratories, typically in point-of-care settings, such as physician offices, emergency rooms, ambulances or hospital wards, and operated by trained professionals. They are classified based on their intended purpose, clinical risk and setting of use under Annex VIII Rule 4(b), which explicitly covers devices intended for NPT. This means that NPT devices are not automatically assigned a specific class. For example, typically, an NPT device used to measure cholesterol level or detect glucosuria, falls under Class B, but devices such as a fecal occult blood cassette for cancer screening or a troponin test detecting acute myocardial infarction in near-patient settings fall under Class C. NPT devices used to detect HIV or other high-risk transmissible agents are classified as Class D.

Note the difference between the IVDR and IMDRF definition for NPT. IMDRF/GRRP WG/N47 FINAL:2018 states that users of NPT can include lay or professional users, whereby the user of the IVD outside of a laboratory setting will be considered a lay user. This is not the same as the IVDR.

For STs, Annex VIII Rule 4(a) states that:

"Devices intended for self-testing are classified as class C, except for devices for the detection of pregnancy, for fertility testing and for determining cholesterol level, and devices for the detection of glucose, erythrocytes, leucocytes and bacteria in urine, which are classified as class B."

Most ST IVDs fall under Class C due to the potential risk of misinterpretation or misuse by laypersons. Class B STs include:

- Pregnancy tests
- Urinary tract infection (UTI) strips
- Ovulation tests

The wording of Rule 4(a) does not limit the applicable classes to B and C. Some ST devices fall under Class D, for instance, those intended to detect HIV infection (as per "the highest classification" 1.9 implementing rule).

Classification may differ solely based on the intended user. For example, a rapid antigen test for diagnosing COVID-19 falls under Class C when intended for self-testing, whereas a similar device intended for professional use falls under Class B. Similarly, instruments, such as meters and strips for self-testing of blood glucose, fall under Class C, in contrast to meters for professional use, which may fall under Class A, and strips under Class C.

Due to their use by laypersons, ST IVDs must meet enhanced usability and labeling requirements, ensuring that laypersons can use them safely and effectively. Clinical evidence presented for ST and NPTs must align with the specified use environment, which is usually distinct from a well-controlled laboratory environment.

## Users of NPT and ST devices

The IVDR requires manufacturers to consider the technical knowledge, experience, education and training of the intended users. Manufacturers must ensure that the information and instructions provided specify the level of training, qualifications and/or experience required for proper use. Additionally, the performance evaluation included in the technical documentation must present the results of studies conducted with the intended users.

## Usability requirements under IVDR

Under the IVDR, usability is a key factor in ensuring the safe and effective performance of IVDs, especially those intended for self-testing and near-patient use. Although the term "usability" is not explicitly mentioned in the regulation, its principles are embedded throughout Annex I – General Safety and Performance Requirements (GSPRs).

In line with GSPR 3 and GSPR 5, devices must be designed and manufactured to ensure they do not compromise the clinical condition or safety of patients, users or others when used under intended conditions. Risks must be acceptable when weighed against the benefits and align with a high level of health and safety protection. Furthermore, devices must be suitable for their intended purpose under normal conditions of use, demonstrating safety and effectiveness. These foundational requirements underpin all usability and risk management activities, and reinforce the importance of robust design and performance validation, particularly for devices used outside traditional laboratory settings.

Under GSPR 9, manufacturers must demonstrate that device performance is not adversely affected when used by laypersons outside laboratory environments. Usability studies should confirm that the intended performance is maintained under real-world conditions. Devices must be designed to minimize risks associated with user error, considering their technical knowledge and experience, and the environment of the intended use.

In accordance with GSPR 19.2, manufacturers must consider all stages of device use, including preparation, operation, result interpretation and disposal. They must provide necessary training and information to reduce the risk of user error. Risk control measures should be designed to support safe and accurate use across all intended settings, and usability testing must confirm that users can reliably perform each step of the procedure. According to GSPR 19.3, NPT and ST devices should, where feasible, include mechanisms to alert users if a valid result has not been obtained.

To support this, manufacturers should consider various types of use during design and risk analysis:

- Normal use refers to operation and routine handling according to the instructions for use or accepted practice
- Correct use is normal use without any user error
- Use error involves unintended actions or omissions that lead to incorrect results. These may arise from mismatches between the user, interface, task or environment, and may be unnoticed by the user
- Abnormal use is a conscious violation of intended use, such as sabotage or deliberate misuse, and is beyond reasonable risk control
- Reasonably foreseeable misuse includes unintended or intentional use not specified by the manufacturer, but predictable based on typical human behavior. This applies to both lay and professional users

These categories help manufacturers anticipate and mitigate risks through design features, labeling and instructions that guide safe and effective use.

Within the technical documentation, manufacturers must provide detailed design information that supports the device's suitability for self-testing or near-patient use. This includes justifying how the design mitigates risks associated with the user group and environment, and describing features, such as intuitive interfaces, ergonomic design and safeguards against misuse.

Manufacturers must ensure that clinical and analytical studies reflect real-world use, according to GSPR 9.4. This includes verifying that self-test devices perform as intended when operated by lay users, and that NPT devices maintain performance in diverse professional settings, such as ambulances, hospital wards or long-term care facilities, when used for their intended purpose. Usability and performance evaluations must be conducted under normal conditions of use to demonstrate that the device operates reliably and safely across all intended environments.

IEC 62366-1:2015 and IEC/TR 62366-2:2016 provide usability engineering principles. Although not harmonized with the IVDR, these standards are widely accepted for demonstrating compliance with usability-related requirements. It involves conducting summative usability testing, preparing a Usability Engineering File and validating that instructions for use are clear, accessible and effective. These practices help reduce misuse, enhance safety and ensure diagnostic results are reliable across diverse user populations and settings. Moreover, Common Specifications outline additional requirements that apply exclusively to Class D devices. For further guidance on evaluating and communicating safety-related information, manufacturers may refer to EN ISO 14971:2019 and its application guidance (ISO/TR 24971). These documents provide recommendations for identifying hazards, assessing risks and ensuring that safety information, such as warnings, precautions and instructions, are effectively conveyed to users. They are widely recognized as a valuable resource for supporting risk management and usability engineering activities.

## Information supplied with the device

As outlined in GSPR 19.1, manufacturers must consider variations in user technique and environment. All information supplied with the device must be easy to understand and free from misleading content, ensuring accessibility for the intended user group.

For NPT or ST devices, the information provided to the user should be in the language determined by the Member State where the device is available. Usually, it is the language spoken in that country. The European Commission and Member States have published a non-binding overview of these requirements, to be downloaded here:
https://health.ec.europa.eu/publications/overview-language-requirements-manufacturers-medical-devices_en

Additionally, near-patient and self-tests are excluded from exemptions listed by Annex I (see 20.1(e & f)), so instructions in paper format must be provided with each device.

Information supplied with the device must be tailored to the intended user. Labels and Instructions for Use (IFU) are required to include additional information that supports safe and effective use. For STs, this means clear, accessible language and visual instructions that enable laypersons to use the device correctly, encompassing all the steps from sample collecting to result interpretation, with advice to the user on action to be taken depending on the obtained result and the need to consult a healthcare professional before making any medical decision (if not previously trained to do so). GSPR 20.4.2 describes additional specific requirements for IFUs of STs. For NPTs, the IFU must specify the level of training or qualifications required for proper use by healthcare professionals.

## Legacy NPT and ST IVDs

The legacy IVDs for near-patient and self-testing fall within the general transitional provisions set out in Article 110 of the IVDR. Consult our other white paper to learn more:
https://www.sgs.com/en-gb/whitepapers/how-to-get-legacy-devices-to-ivdr-compliance-form

## NPT/ST-dedicated Notified Bodies

The IVDR requires Notified Bodies to have specially qualified personnel to be designated for assessing devices for NPT and STs. If successfully designated, it is reflected by IVS 1001 and 1002 codes listed in the NANDO database. SGS Belgium N.V. – Notified Body 1639 – is designated to assess the conformity of near-patient and self-testing IVDs.

Although IVS 1001 and 1002 codes are common among Notified Bodies, the total number of IVDR Notified Bodies is limited. Due to the increased number of IVDs that now require Notified Body oversight, there is a bottleneck in IVDs obtaining IVDR certification and thus accessing the market with IVDR CE marking. Given the backlog of devices awaiting certification, early engagement with a Notified Body is crucial.

Contact SGS as soon as possible to discuss our IVDR certification process.

## Conclusion

The transition to the IVDR marks a pivotal shift for NPT and ST IVD manufacturers. While the regulation introduces more rigorous requirements, such as enhanced clinical validation, usability testing and Notified Body involvement, it also drives improvements in safety, reliability and patient access.

Manufacturers must now design devices that are not only technically sound but also user-friendly and secure, especially as diagnostics move to bedsides, homes and community settings. The rise of connected health technologies brings added responsibility for data privacy and cybersecurity, making compliance with regulations like the General Data Protection Regulation (GDPR) essential.

Despite these challenges, the market outlook is promising. With growing demand for decentralized diagnostics and advances in digital health, manufacturers who invest in innovation, regulatory alignment and user-centric design are well-positioned to lead. The IVDR is not just a compliance hurdle – it is a catalyst for shaping the future of accessible, secure and patient-driven healthcare.

## SGS as your IVDR Notified Body

As a designated IVDR Notified Body, we can perform conformity assessments against the IVDR in your country. Our expert auditors and product assessors can support you in bringing a wide range of IVDs to the EU market, including:

- Immunogenetics, genetics of cancer and inherited conditions
- Cancer markers
- Infectious disease markers
- Clinical biochemistry and other general analytes
- Sterile IVDs
- In vitro diagnostic medical device software (IVD MDSW)
- Self-tests and near-patient tests

We will issue you a certificate for your in vitro diagnostic medical device following a successful conformity assessment. This enables you to affix the CE mark to your device and legally place it on the EU market. The certificate must be renewed every five years and is subject to annual surveillance, post-market follow-up, sampling and/or testing.

For more information: IVDR Certification Services section on www.sgs.com or email globalmedical@sgs.com

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