

# How to get **legacy devices** to **IVDR compliance**

WHITE PAPER







## Summary

Many *In vitro* diagnostic (IVD) manufacturers have been trading for years under the *In Vitro* Diagnostic Medical Devices Directive (IVDD), most of which were self-declared devices. However, the release of the *In Vitro* Diagnostic Regulation 2017/746 (IVDR), has brought about an increase in requirements (for example, clinical performance data, and post-market surveillance),

which IVD manufacturers need to comply with, to continue trading within the European Union.

A Legacy Device is an IVD placed on the market under the previous IVDD before the IVDR date of application (May 26, 2022) and continues to be available during the transitional period.

# Transitional provisions

The EU has provided extended deadlines for different classes of IVDs, allowing more time for compliance. It is important to utilize this extension wisely and avoid leaving tasks until the last minute. Proper planning is essential to ensure all necessary changes are implemented to comply with the IVDR.

Proactively addressing these changes will help avoid delays and potential complications down the line. Initiating discussions with a Notified Body (NB) early in the process is crucial, as it allows for better alignment and understanding of the certification requirements. Be mindful of the potential bottleneck, as many manufacturers may be in the same situation, all trying to meet the deadline simultaneously. Thus, taking advantage of this extra time effectively will help to ensure that devices remain on the market, transition from IVDD to IVDR smoothly, and avoid facing regulatory challenges.

Regulation (EU) 2024/1860 was published on July 9, 2024 in the Official Journal of the EU. This publication applied from July 9, 2024, which extended the legacy period for IVDs further.

The new legacy provisions anticipate that IVDs meeting legacy requirements (either self-declared under IVDD or with an IVDD CE Certificate) can be placed on the market until the following dates:

- December 31, 2027 for devices now falling under Class D, and all IVDD-certified devices
- December 31, 2028 for devices now falling under Class C
- December 31, 2029 for devices now falling under Class B and A sterile
- No transitional period applies to non-sterile class A devices

However, there are conditions to these extensions. Manufacturers of legacy devices can continue to place products on the market to the above dates where they:

- Have made no significant changes to the device design and/or intended purpose during this period (MDCG 2022-6)
- Have a suitable Quality Management System (QMS) in place which is compliant with IVDR by May 26, 2025 (IVDR Article 10)
- Have submitted an application with an IVDR Notified Body within the following deadlines:

- May 26, 2025 for Class D and all IVDD-certified devices
- May 26, 2026 for Class C devices
- May 26, 2027 for Class B and Class A sterile devices
- Have a signed written agreement between the manufacturer and the Notified Body no later than September 26 of the corresponding year
- For devices with an IVDD certificate: the IVDD certificate must be valid and not withdrawn on July 9, 2024. If an IVDD certificate has expired before July 9, 2024, the legacy period still holds, so long as an agreement with a Notified Body was signed before the expiry date of the IVDD certificate OR the device is allowed on the market due to national derogation measures, for example, an extension was granted.

Upgrading legacy IVDs to meet the IVDR standards involves several key steps. Here's a general outline which SGS has compiled to help manufacturers navigate the process:

## Understand the IVDR requirements and identify applicable IVDR sections

*Relevant sections of the IVDR: Article 110(3)*

**Familiarize yourself with the specific requirements of the IVDR, including classification rules, Performance Evaluation, Post-Market Surveillance (PMS), and vigilance reporting.** The IVDR has more stringent requirements when compared to the previous IVDD. Determine which parts of the IVDR apply to your legacy devices.

## RISK CLASSIFICATION

Devices are now classified by a more stringent system than IVDD, via a risk-based approach, determined by their intended use and intended user. Legacy devices that were previously low risk under IVDD and therefore self-certified might now be classified as higher risk and require Notified Body approval.

If your device is reclassified as a higher-risk category, it will require additional clinical performance data and more detailed technical documentation.

*Relevant sections of the IVDR: Article 47 and Annex VIII*

## UDI SYSTEM

Legacy devices do not need to comply with the Unique Device Identification (UDI) system under IVDR during this transitional timeframe, however it will need to be accounted for by the time of conformity assessment.

*Relevant sections of the IVDR: Chapter III, Articles 24 and 26, Part C of Annex VI*

## LABELING AND INSTRUCTIONS FOR USE (IFU)

Once your performance evaluation is complete, remember to review the labeling, IFU, and product-specific information to ensure the information included within them is aligned with your technical documentation and in compliance with IVDR. The IFU must be provided in clear, easily understandable language for the intended users of the device and must contain all the necessary information for the safe and effective use of the device. Be aware of the languages of the member states where your device is marketed.

## Quality Management System (QMS)

*Relevant sections of the IVDR: Article 10(8), Annex I*

**Ensure your QMS is compliant with IVDR requirements. The quality management system must encompass all areas of the**

**manufacturer's organization involved in the quality of processes, procedures, and devices. Manufacturers must establish, document, implement, maintain, update, and continuously improve a quality management system in the most efficient way, tailored to the risk class and type of device.**

EN ISO 13485:2016, the international medical device quality management systems standard, is now harmonized with the IVDR. While introducing this standard is not compulsory, it could be useful and should be considered to fulfil your manufacturer obligations under the EU UVDR.

Complying with this harmonized standard means those aspects of your QMS are presumed to meet the corresponding requirements of IVDR as per Article 8(1).

IVDR requires the following procedures to be in place:

- Ensuring conformity in production
- Controlling changes in product design (including any changes in harmonized standards or common specifications to which the product is declared to conform to, in a timely manner)





- Responsibility of the management:
  - Commitment to Quality
    - Clear and continuous
  - Development and communication of Quality Policies, which define the company's commitment to quality and customer satisfaction, reflecting the organization's purpose, the needs of its stakeholders, and continuous improvement efforts
  - Defining Quality Objectives
    - To be aligned with the business strategy and focus on customer satisfaction, performance improvement, and compliance with regulatory requirements
- Resource management
  - Selection and control of suppliers and sub-contractors
  - Management responsibility to provide training, equipment, software and any other resources required to achieve the quality objectives
  - Management is responsible for providing the necessary resources (human, financial, technical) to implement and maintain the QMS
- Risk management (Section 3 of Annex I)
  - Systems in place to identify, assess and manage risk covering all aspects of the device from design and development to PMS
  - Analyze potential issues that could affect the quality of products or services and take appropriate preventative and corrective actions
  - Focus on patient safety, product performance and potential hazards associated with the device
  - Risk control measures must be defined, implemented, and continuously monitored to mitigate identified risks
- Registration of economic operators (if applicable) and devices
- Handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders
- Processes for monitoring and measurement of output, data analysis and product improvement
  - Internal Audits and Reviews: Regular audits of your QMS will be necessary to ensure ongoing compliance with both IVDR and, typically, ISO 13485

## Performance Evaluation

*Relevant sections of the IVDR: Article 56, Annex I, and Annex XIII  
MDCG 2022-2*

**Conduct a thorough performance evaluation of your devices, including clinical performance studies if necessary. IVDR places a greater emphasis on the clinical performance of devices. For the vast majority of devices, you must gather evidence demonstrating that the device performs as intended and provides accurate, reliable results. This is crucial for demonstrating the safety and effectiveness of your IVDs under the new regulations.**

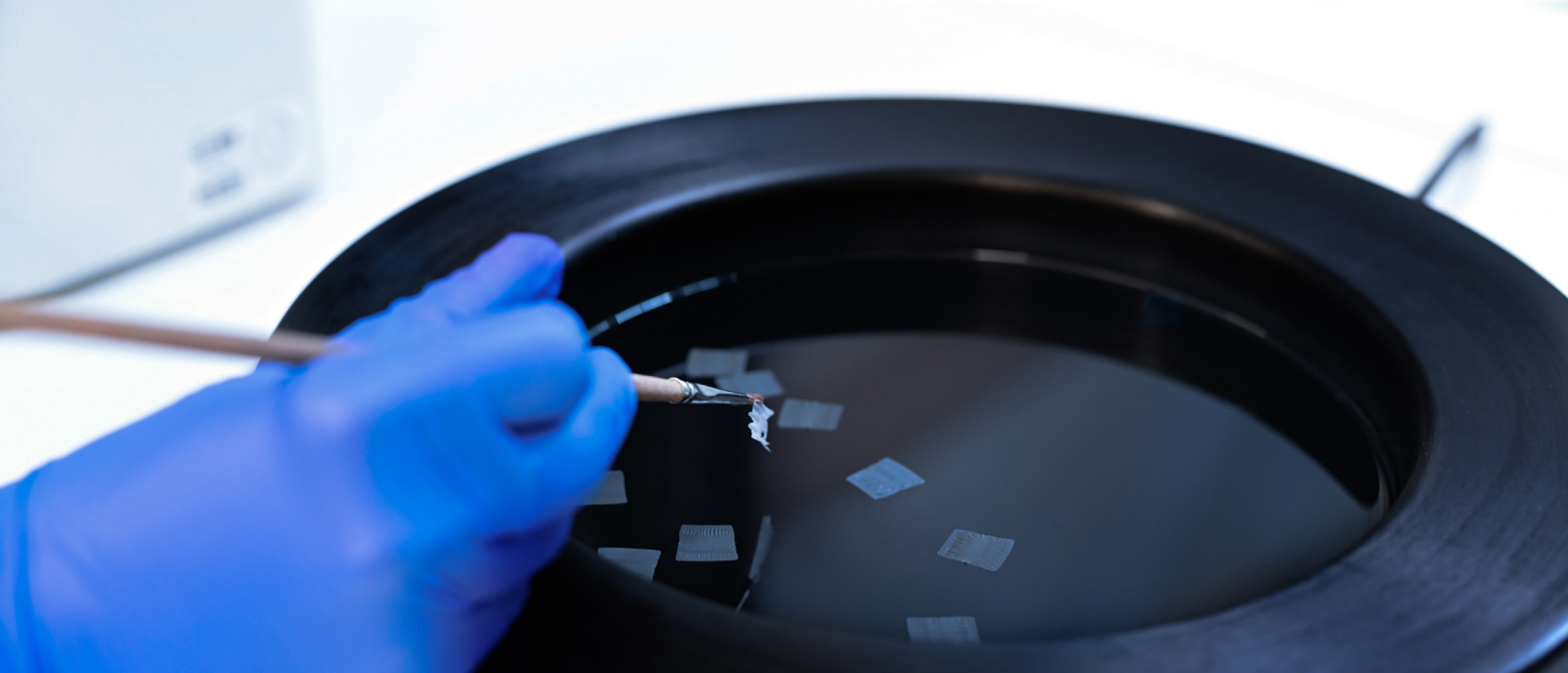
Manufacturers must identify all the applicable general safety and performance requirements (Annex I of IVDR) and address these requirements clearly within their documentation, by the end of the transitional period.

As is now much more clearly defined, technical documentation under IVDR now needs to be presented via:

- Performance Evaluation Plan
- Performance Evaluation Report, incorporating
  - Scientific validity
  - Analytical performance
  - Clinical performance

Scientific validity relates to the scientific foundation of the device, specifically the link between the analyte or biomarker and the condition or disease it is intended to detect. This is typically established via a systematic literature search or proof of concept studies. On the other hand, analytical performance demonstrates the device's ability to accurately and reliably detect or measure the intended analytes or biomarkers, which is shown via laboratory tests to define sensitivity, precision, accuracy etc.

An aspect that some IVD manufacturers have struggled with is the concept of establishing the 'clinical performance of their device'. Clinical performance for IVDs is defined as the ability of the device to achieve its intended purpose in terms of diagnostic accuracy, sensitivity, and specificity. Manufacturers must demonstrate that their IVD device performs as intended under real-world conditions, which can be established via clinical studies, clinical literature, or other scientific data supporting its intended use. For legacy devices, this could include leveraging existing clinical data.



For example, comparative studies, which the manufacturer has collected over the years and would be termed 'other sources of clinical evidence', as they weren't completed under IVDR, may still be sufficient to establish the clinical performance of the device after addressing all the gaps. If this evidence is inadequate, further clinical performance studies may be required.

Performance evaluation is to be updated throughout the life cycle of the device, based on input by the Post-Market Surveillance (PMS) and Post-Market Performance Follow-Up (PMPF). For class C & D, this should be at least annually, while for class A & B devices, updates are as necessary. By leveraging existing data, conducting necessary studies, and working closely with their IVDR Notified Body, manufacturers can demonstrate that their devices are safe, effective, and suitable for their intended use as required by IVDR.

## Risk Management

The safety and performance of IVDs are highlighted numerous times throughout the regulation, and therefore it is important to demonstrate how risk has been evaluated within your QMS, and your Performance Evaluation, to ensure that IVD devices are designed, manufactured, and monitored in a way that minimizes potential risks to health and safety while ensuring their effectiveness and reliability for their intended use.

Risk management per the IVDR refers to the systematic process of identifying, assessing, controlling, and monitoring risks associated with IVDs throughout their lifecycle. The IVDR emphasizes the need for manufacturers to integrate risk management into the development, manufacturing, and post-market phases to ensure the safety and performance of IVD devices.

Key elements of risk management under the IVDR include:

- **Risk Management Plan:** Establish a comprehensive risk management plan that outlines how risk management activities will be conducted throughout the lifecycle of the device, ensuring ongoing compliance with the IVDR
- **Risk Analysis:** Identify potential hazards and assess the risks associated with the IVD device, including potential harm to patients, users, or others (like public health risk), based on the device's intended use and foreseeable risks
- **Risk Evaluation:** Evaluate the identified risks to determine their significance and whether they fall within acceptable levels, considering the device's intended purpose and the benefits it provides
- **Risk Control:** Implement measures to eliminate or reduce identified risks to an acceptable level. This may involve modifying the design, adding protective features, or introducing additional controls in manufacturing and use
- **Residual Risk Evaluation:** Assess any remaining risks after risk control measures have been applied, to ensure that these residual risks are acceptable, taking into account the overall benefit-risk ratio of the device

- **Post-Market Surveillance:** Continuously monitor the device after it has been placed on the market to detect any new or emerging risks. This includes collecting and analyzing data on the device's performance, safety, and potential failures in real-world use
- **Documentation:** Properly document the risk management process, including risk analyses, risk evaluations, decisions on risk controls, and any post-market findings, as part of the technical documentation required by the IVDR

EN ISO 14971:2019 is harmonized with the IVDR.

While harmonized standards are not mandatory, this document can aid you in compiling your risk management documentation. However, while this standard provides a structured approach to risk management, manufacturers must ensure that they are addressing specific regulatory requirements in the IVDR, especially when it comes to clinical performance, vigilance and post-market activities.

## Post-market Surveillance

*Relevant sections of the IVDR: Articles 78, 79, 82, 83 and 84; Annex III; Annex XIII Part B.*

**Manufacturers of legacy devices need to set up a Post-Market Surveillance (PMS) system based on a PMS plan, (except for aspects related to pre-market requirements which do not apply to legacy devices).**

Manufacturers must “proactively collect and evaluate performance and relevant scientific data from the use of a device” via Post-Market Performance Follow-up (PMPF). The PMS plan and PMPF are to be updated continuously, and as necessary, throughout the product's lifetime based on input from the PMS plan. Furthermore, legacy devices must have the applicable requirements and procedures related to serious incidents, field safety corrective actions, trend reporting, and market surveillance provisions.

## Notified Body surveillance

*Relevant sections of the IVDR: Article 110(3)*

**Regarding legacy devices covered by certificates issued under the IVDD, their IVDD notified bodies conduct the ‘appropriate surveillance’ in accordance with the 5th subparagraph of Article 110(3) IVDR, which essentially is a continuation of the previous surveillance activities under the IVDD,**

**taking into account the new requirements that apply to manufacturers resulting from the transitional provisions.**

However, flexibility is required concerning the involvement of notified bodies when reviewing the relevant requirements as part of their ‘appropriate surveillance’, as notified bodies responsible for conducting the appropriate surveillance under Article 110(3) of the IVDR are not necessarily designated to carry out conformity assessments under the IVDR.

## Training

### END USER TRAINING

Legacy devices must continue to meet the safety and performance standards under the IVDR, and while the IVDR does not explicitly specify new training for legacy devices, appropriate training for users should be taken into consideration, on how to correctly utilize the device, and avoid or mitigate risks. Providing training ensures that users can still operate the devices effectively, minimizing the risk of errors or adverse events. Training ensures that users understand the device's functionality, how to interpret results, and any updates that may have occurred under the new regulation, particularly if there have been changes in device labeling or instructions for use (IFU).

### MANUFACTURER TRAINING & PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE (PRRC)

*Relevant sections of the IVDR: Article 15*

Legacy devices under the IVDR require a Person Responsible for Regulatory Compliance (PRRC) by the end of the transitional timelines. This person is responsible for ensuring that the device is following the relevant regulatory requirements and that the manufacturer's obligations are met throughout the device's lifecycle, including design, manufacturing, and post-market activities.

For example, if the device undergoes any changes, such as design modifications or updates in labeling, the PRRC ensures that these changes are evaluated in compliance with the full requirements of the IVDR.

Ensure your team is well-trained in the new requirements and processes under the IVDR. Continuous education is essential for maintaining compliance.

## Notified Body involvement

### Engage with an IVDR Notified Body as soon as possible to obtain IVDR certification.

Notified bodies play a critical role in the certification process under the IVDR.

As there are a limited number of notified bodies available designated for IVDR assessment, and 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.

## Conclusion

### It is strongly advised to begin planning and implementing the necessary IVDR requirements promptly.

There are several requirements for legacy devices during the transition period to IVDR compliance, including updated conformity assessments, clinical performance evaluations, PMS, and labeling. Manufacturers of legacy devices need to appoint a PRRC by the time they apply for IVDR certification, provide training on any new requirements, and ensure that the devices continue to meet safety and performance standards throughout the transitional period. The Medical Device Coordination Group (MDCG)

guidance document **MDCG 2022-8** further outlines which IVDR requirements are mandatory for legacy devices. If more detailed guidance is required, consulting with regulatory experts can be very helpful. Furthermore, initiate discussions with a NB as soon as possible, to ensure a smooth transition to your IVDR CE certification. This proactive approach will not only ensure compliance with the IVDR but also support a smoother transition to your IVDR CE certification, minimizing the risk of disruptions to your market access and product timelines. By following these steps, you can navigate the regulatory landscape more effectively, systematically upgrade your legacy IVDs to meet the new IVDR standards, and ensure continued success in the marketplace.

#### *Disclaimer! Check Your Situation*

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