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How to Get Legacy Devices to IVDR Compliance

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How to Get Legacy Devices to IVDR Compliance

Many in vitro diagnostic (IVD) manufacturers have operated in Europe for years under the In Vitro Diagnostic Medical Devices Directive (IVDD), with a significant proportion of devices being self-certified. However, the introduction of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) has established more stringent requirements, particularly regarding higher-risk devices, performance evaluation, clinical evidence, and post-market surveillance. To maintain access to the European Union market, manufacturers must demonstrate compliance with these enhanced regulatory obligations.
A legacy device is an IVD that was lawfully placed on the market under the IVDD before the IVDR date of application (26 May 2022) and remains available on the market during the applicable transitional period.

Transitional Provisions

The EU has introduced extended transitional timelines for certain IVD device classes, providing manufacturers with additional time to achieve compliance with the IVDR. However, this extension should be used strategically, as successful transition requires careful planning and timely implementation of any necessary changes. Early preparation helps mitigate the risk of delays, resource constraints, and unforeseen regulatory challenges.

Manufacturers are encouraged to engage with a Notified Body at an early stage to facilitate alignment on certification expectations and assessment requirements. Given the increasing demand for conformity assessments and the limited capacity of Notified Bodies, a proactive approach is essential. Effective use of the available transition period will support a smooth migration from IVDD to IVDR, help maintain market access, and reduce the risk of certification bottlenecks as regulatory deadlines approach. Regulation (EU) 2024/1860 was published on 9th July 2024 in the Official Journal of the EU. This publication applied from 9th July 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:

- **31 December 2027** for devices now falling under Class D
- **31 December 2028** for devices now falling under Class C
- **31 December 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 IVD legacy devices must:

- 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 **26th May 2025** (IVDR Article 10)
- Have submitted an application to an IVDR-notified body within the following deadlines:
    - **26 May 2025** for Class D and all IVDD-certified devices
    - **26 May 2026** for Class C devices
    - **26 May 2027** for Class B and Class A sterile devices
- Have a signed written agreement between the manufacturer and the notified body no later than 26 September of the corresponding year
- For devices with an IVDD certificate: the IVDD certificate must be valid and not withdrawn on 9th July 2024. If an IVDD certificate has expired before 9th July 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, a competent authority of a Member State has granted a derogation.

Upgrading legacy IVDs to meet the requirements of the IVDR involves several key steps. The following overview is intended to help manufacturers plan and manage the transition process effectively:

Understand the IVDR Requirements and Identify Applicable IVDR Section

Relevant sections of the IVDR: Article 110(3)

Gain a clear understanding of the IVDR requirements applicable to your devices, including areas such as device classification, performance evaluation, post-market surveillance, and vigilance activities. Compared with the IVDD, the IVDR introduces more robust regulatory expectations and evidence requirements. Identifying which provisions apply to your legacy devices at an early stage will help you focus your efforts, address any compliance gaps, and develop an effective transition plan.

Relevant sections of the IVDR: Article 47 and Annex VIII

Risk Classification: Under the IVDR, devices are classified using a more robust risk-based system that takes into account their intended purpose and the users for whom they are designed. As a result, some devices that were previously self-certified under the IVDD may now fall into a higher risk class and require assessment by a Notified Body. If your device is subject to a higher classification, you may need to provide additional performance evidence and expand your technical documentation to demonstrate compliance with the IVDR requirements.

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

UDI System: Legacy devices need to comply with the Unique Device Identification (UDI) system under IVDR, which helps track devices in the supply chain (Article 24(3) and Article 26 of the IVDR).

Labelling and Instructions for Use (IFU): Make sure your device labelling, Instructions for Use (IFU), and other product information are reviewed and updated to ensure they are consistent with your technical documentation and

meet IVDR requirements. The information provided should be **clear, accurate, and easy for the intended users to understand**, enabling the device to be used safely and effectively. It is also important to consider the **language requirements of each EU Member State** where the device is marketed and ensure that all required translations are available.

Quality Management System (QMS)

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

Ensure your Quality Management System (QMS) meets the requirements of the IVDR and supports all activities that can affect the quality, safety, and performance of your devices. Your QMS should cover the entire product lifecycle, from design and development through manufacturing, post-market surveillance, and continuous improvement. It is important to regularly review and update the system to ensure it remains effective and proportionate to the type and risk classification of your devices. A well-maintained QMS not only supports regulatory compliance but also helps drive consistent product quality and operational efficiency.

EN ISO 13485:2016, the internationally recognised standard for quality management systems in the medical device sector, has been harmonised under the IVDR. Although certification to this standard is not mandatory, adopting it can be a practical way to support compliance with your obligations as an IVD manufacturer. By implementing EN ISO 13485:2016, you can establish a structured and effective quality management system that aligns with IVDR expectations. In addition, compliance with this harmonised standard provides a presumption of conformity with the corresponding IVDR quality management system requirements, helping to simplify the demonstration of regulatory compliance.

IVDR requires the following procedures to be in place:

- Ensuring conformity in production
- Controlling changes in product design (including any changes in harmonised standards or common specifications to which the product is declared to conform, promptly)
- 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 organisation'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 is responsible for providing 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 post-market surveillance
    - Analyse 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 comprehensive performance evaluation of your device to confirm that it consistently delivers accurate, reliable, and clinically relevant results. Under the IVDR, greater emphasis is placed on demonstrating that a device performs as intended throughout its lifecycle. Depending on the type and risk class of the device, this may involve generating additional performance evidence, including clinical performance studies where appropriate.

Building a strong body of performance data is a key part of the transition to IVDR compliance, as it helps demonstrate the device's safety, effectiveness, and suitability for its intended use. Reviewing existing evidence early and identifying any gaps will allow you to plan any necessary studies and avoid delays later in the certification process.

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

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

- Performance Evaluation Plan, and
- Performance Evaluation Report, incorporating:
    - Scientific Validity
    - Analytical Performance and

- Clinical Performance.

Scientific validity provides the foundation for demonstrating that your device is relevant to its intended medical purpose. It establishes the relationship between the analyte or biomarker being measured and the disease, condition, or physiological state the device is intended to detect, diagnose, or monitor. This evidence is typically supported through scientific literature, published studies, clinical guidelines, or proof-of-concept investigations.

Analytical performance, in contrast, focuses on how well the device measures or detects the target analyte or biomarker. It demonstrates that the device can produce accurate, reliable, and consistent results under the intended conditions of use. This is typically shown through laboratory testing that evaluates characteristics such as accuracy, precision, sensitivity, specificity, reproducibility, and limits of detection.

Together, scientific validity and analytical performance help demonstrate that the device is both scientifically justified and technically capable of delivering dependable results for its intended purpose.

One area that many IVD manufacturers find challenging when transitioning to the IVDR is demonstrating the clinical performance of their devices. Clinical performance refers to the ability of a device to achieve its intended purpose in a clinical setting by providing results that are meaningful, accurate, and reliable for patient care and decision-making.

To demonstrate clinical performance, manufacturers need to show that the device performs as intended under real-world conditions. This can be supported by a range of evidence, including clinical studies, published scientific literature, and other relevant clinical data linked to the intended use of the device.

For legacy devices, existing clinical evidence may often be leveraged. For example, manufacturers may have accumulated valuable data over time through comparative studies, routine use, or other post-market activities. Although such data may not have been generated specifically under the IVDR framework, it can still contribute to the demonstration of **clinical performance**, provided any gaps are identified and appropriately addressed. Where the available evidence is insufficient to support the intended use, additional clinical performance studies may be needed to strengthen the performance evaluation and demonstrate compliance with IVDR requirements.

Performance evaluation is not a one-time activity. Under the IVDR, it should be continuously reviewed and updated throughout the device lifecycle using information gathered from Post-Market Surveillance (PMS) and Post-Market Performance Follow-Up (PMPF) activities. For Class C and Class D devices, these updates are generally expected at least annually, while for Class A and Class B devices, they should be performed whenever new information indicates an update is needed.

By making effective use of existing data, generating additional evidence where necessary, and engaging with their Notified Body early in the process, manufacturers can build a robust performance evaluation that demonstrates their devices remain safe, effective, and fit for their intended purpose throughout their lifecycle. This proactive approach can help streamline the transition to IVDR compliance and support continued access to the European market.

Risk Management

The safety and performance of an IVD device are central principles of the IVDR. Manufacturers are therefore expected to demonstrate how risks are identified, evaluated, controlled, and monitored within their Quality Management System (QMS) and Performance Evaluation activities. This helps ensure that devices are designed, manufactured, and maintained in a way that protects patients, users, and other individuals while consistently delivering reliable results for their intended purpose.

Risk management under the IVDR is a continuous, lifecycle approach. It involves systematically identifying potential hazards, assessing the associated risks, implementing appropriate risk control measures, and monitoring their effectiveness over time. Risk management should be integrated into all stages of a device's lifecycle, from design and development through manufacturing, post-market surveillance, and ongoing performance evaluation.

By maintaining a robust risk management process and regularly reviewing data from real-world use, manufacturers can demonstrate that the benefits of their devices continue to outweigh any residual risks and that the devices remain safe, effective, and suitable for their intended use.

Key elements of risk management under the IVDR include:

- **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 analysing 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.
- **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.

EN ISO 14971:2019, the internationally recognised standard for medical device risk management, has been harmonised under the IVDR. While its use is not mandatory, it provides a practical framework for developing and maintaining risk management documentation. The standard helps manufacturers identify hazards, assess and control risks, and monitor their effectiveness throughout the device lifecycle. However, manufacturers should also ensure that their risk management processes address IVDR-specific requirements, including performance evaluation, clinical performance, vigilance, and post-market surveillance activities. By combining the principles of EN ISO 14971:2019 with the requirements of the IVDR, manufacturers can establish a robust risk management process that supports device safety, performance, and regulatory compliance.

Postmarket surveillance

Relevant sections of the IVDR: Articles 78, 79, 82, 83 and 84; Annex III Section 5; Annex XIII Part B.

Manufacturers of legacy devices are required to establish and maintain a **Post-Market Surveillance (PMS)** system based on a documented PMS plan. This system should enable the ongoing collection and review of information from real-world use of the device, helping to confirm that it continues to be safe, performs as intended, and remains compliant with applicable regulatory requirements.

A key element of this process is **Post-Market Performance Follow-Up (PMPF)**, through which manufacturers proactively collect and evaluate performance data and relevant scientific information throughout the device lifecycle. PMS and PMPF activities should be regularly reviewed and updated in light of new information, feedback, and post-market experience.

In addition, manufacturers of legacy devices must have appropriate procedures in place for managing and reporting serious incidents, implementing field safety corrective actions where necessary, monitoring trends, and responding to market surveillance activities. A robust PMS system not only supports regulatory compliance but also helps ensure the ongoing safety, performance, and effectiveness of the device in everyday use.

Notified Body Surveillance

Relevant sections of the IVDR: Article 110(3)

For legacy devices covered by certificates issued under the IVDD, the relevant Notified Body continues to perform surveillance activities during the transition period. This surveillance is generally based on the existing IVDD framework while also taking into account the additional obligations that apply to manufacturers under the IVDR transitional provisions.

In practice, the scope and level of Notified Body involvement may vary, as Notified Bodies responsible for overseeing legacy devices during the transition are not necessarily designated to conduct conformity assessments under the IVDR. Manufacturers should therefore maintain regular communication with their Notified Body to ensure a clear understanding of the applicable requirements and expectations throughout the transition period.

Training

End User Training

Legacy devices must continue to meet applicable safety and performance requirements throughout their lifecycle. Although the IVDR does not introduce specific training requirements for legacy devices, manufacturers should consider whether users need training to ensure the device is used correctly and safely, particularly where there are known risks that should be avoided or mitigated.

Effective training can help users understand the device's intended use, operate it correctly, interpret results appropriately, and recognise any limitations or precautions. This is especially important where updates have been made to the device, its labelling, or its Instructions for Use (IFU). By providing appropriate training and support, manufacturers can help reduce the risk of user error, promote safe and effective device use, and contribute to maintaining compliance with regulatory requirements.

Manufacturer Training & Person Responsible for Regulatory Compliance (PRRC)

Relevant sections of the IVDR: Article 15

Legacy devices placed on the market under the IVDD are also required to have a Person Responsible for Regulatory Compliance (PRRC). The PRRC plays an important role in ensuring that the manufacturer continues to meet applicable regulatory requirements throughout the device lifecycle, including activities related to design, manufacturing, documentation, and post-market surveillance. Any changes to the device, such as design updates, labelling revisions, or other modifications, should be appropriately assessed to ensure continued compliance with the relevant regulatory requirements.

Equally important is ensuring that personnel remain knowledgeable about the IVDR and its evolving requirements. Investing in training and continuous professional development helps teams understand their responsibilities, implement compliant processes, and stay up to date with regulatory expectations. A well-informed team is a key factor in maintaining compliance and supporting a successful transition from the IVDD to the IVDR.

Notified Body Involvement

Engage with a Notified Body as early as possible when planning your transition to IVDR certification. Early discussions can help clarify certification requirements, timelines, and expectations, allowing manufacturers to better prepare their technical documentation and compliance activities. As demand for IVDR conformity assessments continues to grow, manufacturers are encouraged to plan and allocate sufficient time for the certification process. Taking a proactive approach can help avoid unnecessary delays, support a smoother transition to IVDR compliance, and facilitate continued access to the European market.

Conclusion

To ensure a successful transition to the IVDR, manufacturers should begin their planning activities as early as possible. The transition involves a range of regulatory expectations, including performance evaluation, post-market surveillance, labelling updates, quality management activities, and ongoing demonstration of device safety and performance. Taking a structured approach will help identify any compliance gaps and allow sufficient time to implement the necessary changes.

Manufacturers should also ensure that appropriate regulatory responsibilities are in place, that personnel are adequately trained on applicable requirements, and that processes are established to maintain compliance throughout the device lifecycle. Relevant guidance documents published by regulatory authorities can provide valuable support in understanding and implementing the requirements that apply during the transition period.

Early engagement with a Notified Body and other regulatory stakeholders can further facilitate the transition process by helping manufacturers understand certification expectations and timelines. By planning proactively, leveraging existing evidence where appropriate, and addressing compliance requirements promptly, manufacturers can support continued market access, minimise the risk of disruptions, and achieve a smoother transition to IVDR compliance.

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