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# Preparing for Europe's New In Vitro Diagnostic Medical Device Regulation

## The Essential Guide to EU IVDR Compliance

**WHITE** PAPER

# SECTION 1: INTRODUCTION

## Are You Ready for the IVDR Changes?

If you currently market and sell in vitro diagnostic medical devices in the European Economic Area (EEA) or are planning to do so in the near future—now is the time to get up to speed with the new In Vitro Diagnostic Medical Device Regulation (IVDR) to ensure compliance.

Published on May 25, 2017, the IVDR 2017/746[1,2] introduced an expansive set of new rules for how in vitro diagnostic devices are regulated in the European Union (EU). The goal was to replace decades-old legislation with regulations that are more in line with the latest technological advances and medical science and create a more transparent regulatory framework that helps improve patient safety.

The new regulation provides stricter oversight in many areas as compared to the EU's previous In Vitro Diagnostic Medical Device Directive (IVDD).

Some noteworthy changes include:

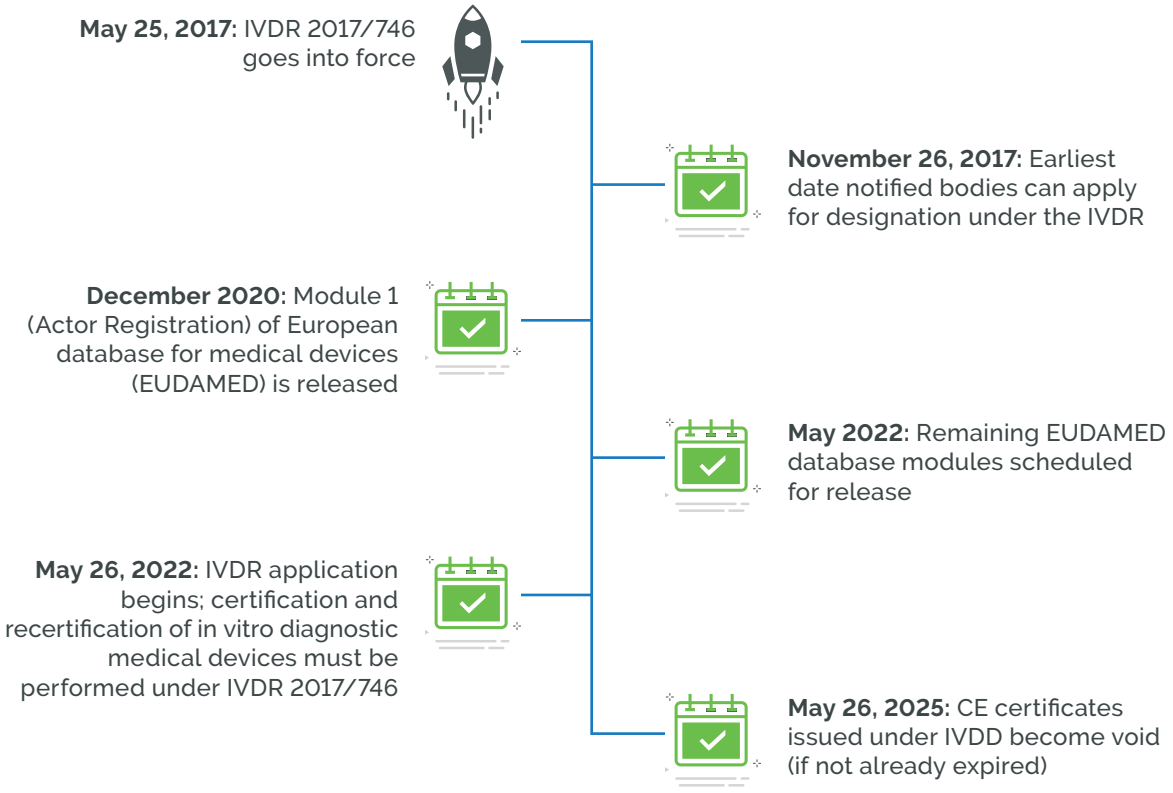
- Greater emphasis on the entire product lifecycle as opposed to just the pre-approval stage
- Expanded definition of in vitro diagnostic device to include genetic testing and software
- New risk-based classification system for in vitro diagnostic devices
- Greater emphasis on post-market surveillance
- More stringent requirements for clinical evidence
- Greater supervision over notified bodies

Effective May 26, 2022, new devices must be certified and existing devices recertified under the new IVDR. This will require manufacturers to revisit their quality management system (QMS) and update core processes to ensure compliance. Ultimately, manufacturers that fail to comply with the IVDR could face costly fines, litigation, design changes, product recalls, or lack of access to the EU market.

Navigating the new regulation and figuring out where to start can be daunting. In this guide, we highlight the new IVDR requirements that will have the greatest impact on your quality management processes and product portfolio. We also provide the key steps to making a successful IVDR transition, as well as some insights on how an enterprise quality management system (eQMS) solution can help simplify compliance.

## Important Dates for EU IVDR Transition

Manufacturers will need to recertify existing devices and certify new devices according to this timeline:




## Extended Transition Period for Certain In Vitro Diagnostic Devices

On March 20, 2023, the European Commission issued Regulation (EU) 2023/607, which provides an extension period for devices that were self-declared (i.e., no notified body involvement) under the EU's previous In Vitro Diagnostic Medical Device Directive (IVDD) as follows:

- Class D devices: May 26, 2025
- Class C devices: May 26, 2026
- Class B and Class A sterile devices: May 26, 2027

Furthermore, the sell-off date for IVDD-certified devices that were already placed on the market has been removed, enabling these devices to remain available for purchase in the EU.

**Arena QMS Tip: Custom Attributes and Arena Training**
To keep track of upcoming certification dates for your medical devices, create a next-due-date custom attribute for each product and generate a report. Also assign product certification due dates to training plans so that owners receive automatic reminders.

# SECTION 2: KEY CHANGES UNDER NEW IVDR

## Notified Bodies

Notified bodies play a significant role in helping medical device manufacturers bring new products to the EU market. Their primary responsibility is to conduct conformity assessments and grant CE certificates for devices. This involves auditing the manufacturer's quality management system (QMS) and reviewing the technical documentation for the different classes of devices.

To issue CE certificates, notified bodies must be recertified and designated according to the new IVDR. The goal is to identify the notified bodies that are truly qualified to ensure the safety and effectiveness of the products that they are evaluating. Starting on November 26, 2017, notified bodies were able to submit applications to become designated under the IVDR. A complete listing of the notified bodies that are officially designated is maintained on the NANDO (New Approach Notified and Designated Organisations) database.

Under the IVDR, notified bodies will take on more responsibility in enforcing regulations through annual on-site assessments as well as unannounced audits of manufacturing processes, subcontractors, and suppliers.

The number of notified bodies has decreased significantly due to the new designation requirements[3]. This will most likely impact manufacturers' timelines for product certification as resources become more stretched.

**Action Item:**

Contact notified body to confirm its scope of designation and timeline for assessment

**A complete listing of designated notified bodies is maintained on the NANDO database*

## In Vitro Diagnostic Medical Device Classifications

IVDR 2017/746 (Annex VIII) provides a new risk-based classification structure for in vitro diagnostic devices. Devices are now categorized as Class A, B, C, or D. All existing IVD devices on the market will need to be reclassified according to this new system.


**Class D** Class D devices pose a high risk to individuals and high risk to public health. Examples include devices used for blood screening and the detection of high-risk diseases

**Class C** Class C devices pose a high risk to individuals and moderate risk to public health. Examples include devices used for cancer testing/ disease staging, companion diagnostics, and genetic testing

**Class B** Class B devices pose a moderate risk to individuals and low risk to public health. Examples include self-testing devices used to detect pregnancy, cholesterol levels, and glucose

**Class A** Class A devices pose a low risk to individuals and low risk to public health. Examples include laboratory devices, instruments, and specimen receptacles

The classification of the device will determine whether certification by a notified body is needed, as well as the conformity assessment route (i.e., Annex IX, X, or XI).

| In Vitro Diagnostic Device Classification | Risk | Assessment Requirements |
|---|---|---|
| **Class A** | Low to Individual and Public Health | Self-Certification/Self Declaration<br>Technical Documentation Required |
| **Class B** | Moderate to Individual.<br>Low to Public Health | Notified Body<br>Review of QMS and Technical Documentation (Annex IX) |
| **Class C** | High to Individual.<br>Medium to Public Health | Notified Body<br>Review of QMS and Technical Documentation (Annex IX), or Type-Examination (Annex X),<br>or Product Conformity Verification (Annex XI) |
| **Class D** | High to Individual and Public Health | Notified Body<br>Review of QMS and Technical Documentation (Annex IX), or Type-Examination (Annex X),<br>or Product Conformity Verification (Annex XI)<br>EU Reference Laboratory to Perform Testing |

**Note: If an IVD device does not readily fit into any of the classes listed above, it will be automatically classified as Class B and require notified body supervision. This may significantly increase the number of IVD devices that need to be certified under the new IVDR.*

In addition to classification changes, the IVDR has expanded its definition of in vitro diagnostic devices to include:

- Genetic testing or other tests to detect predisposition to a medical condition or disease
- Companion diagnostics used to predict treatment response or reactions for a specific patient
- Software

**Action Items:**

- Confirm the classification of your device under the new IVDR. Determine if any reclassification is needed
- Determine the conformity assessment route for your device based on its classification

## Economic Operator Roles and Responsibilities

A major change in the implementation of the new IVDR is the requirement for the registration of economic operators in the new European database for medical devices (EUDAMED). The economic operators are defined in Articles 10-15, and the EUDAMED database requirements are covered in Article 30.

Economic operators include:

- Manufacturers
- EU authorized representatives
- Importers
- Distributors
- Person with regulatory responsibility

Each of the above economic operators must also comply with new roles and responsibilities that are defined in the IVDR, and those activities must be implemented, documented, and maintained with standard operating procedures (SOPs). The goal of the economic operator designation is to establish greater accountability across the regulatory submission process as well as the supply chain and create a system of checks and balances for medical devices that are brought to market.

***Manufacturers***

Manufacturers must establish quality management and risk management systems in accordance with the IVDR, as well as the proper technical documentation for each medical device. Technical documentation, along with the EU declaration of conformity, must be made available to competent authorities in the Member States and translated into the appropriate language(s). In the event of a product nonconformity, the manufacturer must take the necessary corrective actions to resolve the issue or recall the device.

Manufacturers must register with the European database for medical devices (EUDAMED) and provide the necessary information, including unique device identifiers (UDIs). If a manufacturer's registered place of business resides outside the EU, it must designate an authorized representative to perform the tasks set forth by the IVDR. A mandate outlining the necessary duties must be agreed upon and signed by the authorized representative.

***Authorized Representatives***

An authorized representative must perform the tasks outlined in the mandate and agreed upon between it and the manufacturer to ensure compliance. This includes maintaining copies of the technical documentation and EU declaration of conformity for each medical device.

Authorized representatives must also register with EUDAMED and take necessary corrective actions to resolve product nonconformity issues.

***Importers***

Importers must maintain copies of technical documentation and EU conformity assessments for each medical device and provide to competent authorities of the Member States upon request. They must also ensure that the device is labeled in accordance with the regulations and include the necessary instructions for use. The importer's registered trade name, place of business, and contact information should also appear on the device labeling or packaging.

Importers must register with EUDAMED and ensure that necessary corrective actions are taken to resolve product nonconformity issues. Any complaints or reports of serious incidents should be forwarded to the manufacturer or authorized representative.

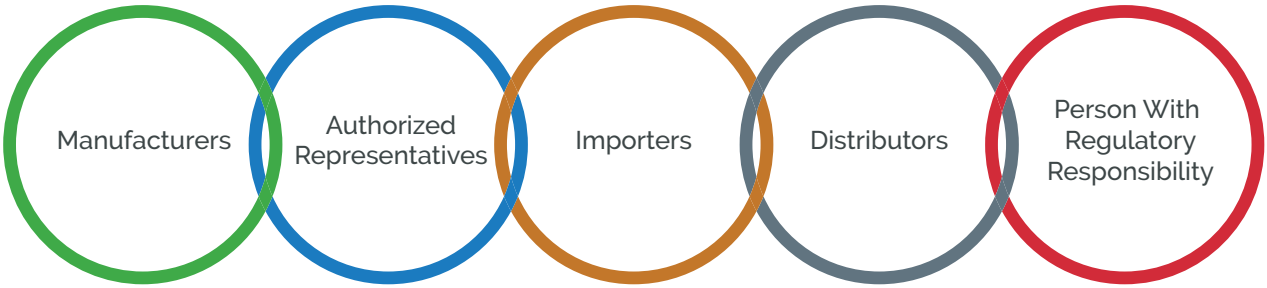
***Distributors***

Distributors should ensure that the appropriate CE marking, EU declaration of conformity, labeling, and instructions for use (in the appropriate languages) have been prepared for each device. They should also ensure that the manufacturer has assigned the appropriate unique device identifiers (UDIs).

Distributors should meet the manufacturer's device storage and transport requirements and take the necessary corrective actions to resolve product nonconformity issues. They must also inform the manufacturer, authorized representative, and importer of any complaints, serious incidents, device recalls, or withdrawals.

***Person With Regulatory Responsibility***

Manufacturers should assign at least one person within the organization to be responsible for regulatory compliance. This person should ensure that the conformity of the device is in accordance with the quality management system under which it is manufactured. This person should also ensure that the technical documentation and EU declaration of conformity are kept up to date, post-market surveillance obligations are compiled in accordance with Article 10, and that any serious incidents or field safety corrective actions are reported.




**Action Items:**

- Designate a "person responsible for regulatory compliance" from your organization
- If your registered place of business resides outside the EU, designate an authorized representative to perform the tasks set forth by the IVDR
- Register as an economic operator via the European database for medical devices (EUDAMED) and obtain a single registration number (SRN)
- Ensure that the proper agreements between authorized representative, importers, and distributors are in place

## Technical Documentation

Unlike past IVDD technical file requirements which were general in nature, the new IVDR (Annexes II and III) provides more specific requirements for technical documentation. It also specifies that the technical file "shall be presented in a clear, organized, readily searchable, and unambiguous manner."

Technical documentation should include:

- Device description and specifications
- Reference to previous and similar generations of the device
- Package labeling and instructions for use (in appropriate languages)
- Product design and manufacturing information (including listing of all supplier and contract manufacturer sites)
- General safety and performance requirements (Annex I)
- Benefit-risk analysis and risk management plan
- Product verification and validation, including:
  - Specimen type/handling
  - Analytical performance
  - Interfering endogenous/exogenous substances investigated
  - Clinical performance
  - Performance of self-testing devices/near-patient testing devices
  - Scientific validity
- Pre-clinical and clinical data (performance evaluation report)
- Post-market surveillance plan and reports

**Arena QMS Tip:**
**Supplier Approval Quality Template**

Use the supplier approval template to create a list of your approved suppliers and the parts they provide. This approved supplier list (ASL) is automatically linked to your product record and shows the history of any changes that are made. The ASL can be easily exported and included with your technical file.

**Arena QMS Tip:**
**Technical File Quality Template**

When building the technical file for your medical device, use the technical file template to avoid starting from scratch. The template covers all the essential IVDR requirements and can be customized to meet your needs. The technical file is automatically linked to your product record and shows the history of any changes that are made. The technical file can easily be exported for review by your notified body.

**Action Item:**

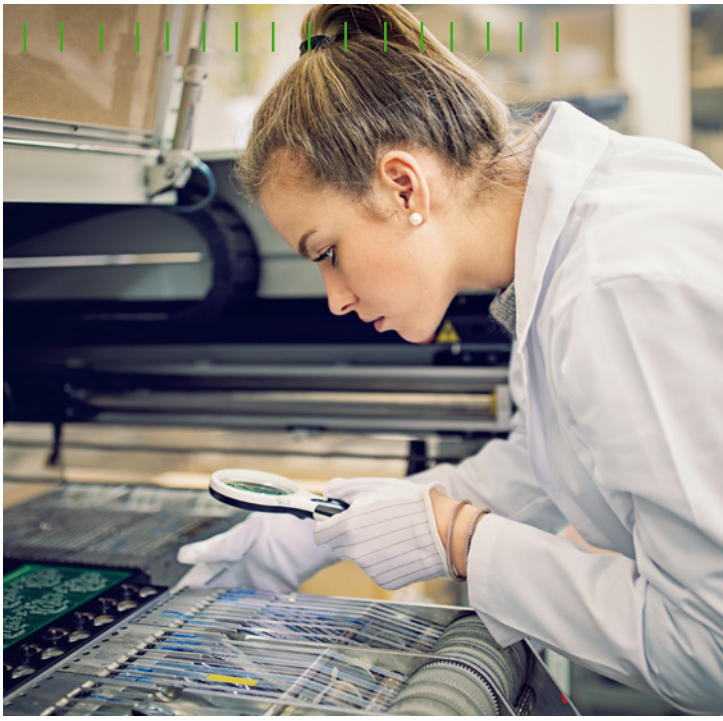
Ensure that the performance evaluation report and the post-market surveillance plan and report are included in your technical documentation

## Performance Evaluations, Performance Studies, and Post-Market Performance Follow-up

Under the new regulation, manufacturers will need to provide more in-depth clinical data to support safety and performance claims in both the pre- and post-market settings. Ultimately, more scrutiny will be placed on manufacturers to proactively collect and evaluate clinical data throughout the product lifecycle.

***Performance Evaluations***

The IVDR defines a performance evaluation as "a continuous process by which data is assessed and analyzed to demonstrate the scientific validity, analytical performance, and clinical performance of a device for its intended purpose as stated by the manufacturer."



Manufacturers should plan, conduct, and document performance evaluations in accordance with Article 56 and Annex XIII (Part A). Performance evaluations must be thorough and take into account both favorable and unfavorable data. The extent to which clinical data is collected should be in line with the nature, classification, intended purpose, and risk of the device, as well as the manufacturer's safety and performance claims.

***Performance Evaluation Plan (PEP)***

The new regulation emphasizes the importance of early planning when it comes to performance evaluations. As such, manufacturers will need to develop a performance evaluation plan prior to gathering data. The performance evaluation plan should include:

- General safety and performance requirements that need clinical data support
- Intended purpose of the device, as well as the intended target groups with clear indications, limitations, and contraindications
- Specification of the analyte or marker to be determined by the device
- Identification of certified reference materials or reference measurement procedures to allow for metrological traceability
- Statistical tools and methods used for the examination of the analytical and clinical performance of the device and of the limitations of the device
- Parameters to determine benefit-risk ratio acceptability for the intended purposes of the device
- For software qualified as a device, an identification and specification of reference databases and other sources of data used as the basis for its decision-making
- Sequence and means of determining the scientific validity, analytical, and clinical performance, including an indication of milestones and a description of potential acceptance criteria

***Clinical Data Sources***

Once a plan is established, manufacturers should identify all available clinical data that is relevant to the safety, performance, and intended purpose of the device. Sources of clinical data include:

- Relevant information on the scientific validity of devices measuring the same analyte or marker
- Scientific (peer-reviewed) literature
- Consensus expert opinions/positions from relevant professional associations
- Published experience gained by routine diagnostic testing
- Results from proof-of-concept studies
- Results from clinical performance and analytical performance studies

***Clinical Evaluation Assessment Report (CEAR)***[5]

The clinical evaluation assessment report must be a part of the manufacturer's quality management process. It should also be aligned with and reflected in other aspects of the technical documentation, such as:

- Interface of the clinical evaluation with the risk management process and its appraisal and analysis of the pre-clinical and clinical evaluation and their relevance for the demonstration of conformity with the relevant requirements in Annex I.1
- Post-market surveillance including any corrective and preventive actions involving the device
- Post-market performance follow-up plan, and where appropriate, the post-market performance follow-up report
- Instructions for use, which provide adequate information on intended purpose, proper use, and warnings about risks to patients and healthcare practitioners

**Arena QMS Tip: Quality Templates**

Leverage the Arena quality templates to help formulate your performance evaluation plan, performance evaluation report, post-market performance follow-up report, and other critical documents. Once created, they are linked to the product record and show the history of any changes that are made. Documents can be easily exported and included with your technical file.

***Clinical Performance Studies***

Clinical performance studies must be carried out by the sponsor/manufacturer if key aspects of the device's performance cannot be verified by analytical performance studies, literature, or previous experience gained by routine diagnostic testing.

***Summary of Safety and Clinical Performance (SSCP)***[6]

Under the new IVDR, manufacturers will need to draw up a summary of safety and clinical performance (SSCP) for Class C and D diagnostics, other than laboratory-developed tests or investigational diagnostics. The SSCP should be validated by a notified body and made available to the public via the European database for medical devices (EUDAMED).

The SSCP serves as an important source of information for intended users—both healthcare professionals and patients. It is intended to help fulfill the objectives of the IVDR by enhancing transparency and providing adequate access to information about the safety and clinical performance of the diagnostic.

***Performance Evaluation Report (PER)***

The scientific validity data, analytical performance data, clinical performance data, their assessment, and the derived clinical evidence must be documented in a performance evaluation report and included with the technical documentation that is provided for the conformity assessment.

PERs should be updated once per year (at minimum) for high-risk diagnostics (i.e., Class C and D).

***Post-Market Performance Follow-up (PMPF)***

To confirm the safety and performance of a device throughout its lifecycle and ensure the continued acceptability of identified risks, manufacturers will need to conduct a post-market performance follow-up (PMPF) under the new IVDR requirements.

The PMPF should be conducted using a device that is already placed on the market and bears the CE Mark. It should also be conducted according to a formalized plan, which specifies the methods for proactively collecting and evaluating performance data. The manufacturer must decide the frequency of carrying out PMPF and document this rationale in the PMPF plan[7].

The findings of the PMPF should be analyzed and documented in a PMPF evaluation report[8] and included with the technical documentation. The conclusions of the PMPF evaluation report should be taken into account for the performance evaluation and in the risk management. If, through the PMPF, the need for preventive and/or corrective measures has been identified, the manufacturer should implement them.

If a manufacturer has determined that a PMPF process is not required for a specific device, then they must provide a justification and document it within the performance evaluation report (PER).

Notified bodies are expected to review the PMPF process, procedures, and reporting when they review the performance evaluation process and, also, how the data from the PMPF is used to update the performance evaluation report (PER) and risk management file.

The conclusions of the PMPF will be documented in the performance evaluation report (PER). For the higher risk class devices, such as Class C and D, the PER is expected to be updated at least annually, which means that the PMPF report should be updated annually as well. Important updates of the PMPF report should also be included in the periodic safety update report (PSUR) for Class C and D devices and in the summary of safety and clinical performance (SSCP), which should be updated as soon as possible, where necessary.

**Action Items:**

- Determine if you need to collect additional data to meet the new IVDR performance evaluation and/or post-market surveillance requirements
- Determine if new/additional clinical performance studies are needed to support your higher risk devices (i.e., Class C and D devices)
- Develop your performance evaluation plan
- Prepare performance evaluation and post-market performance follow-up reports to include with your technical file

## Post-Market Surveillance (PMS)

The new IVDR places greater emphasis on post-market surveillance (PMS) with the aim of continuously monitoring the quality, performance, and safety of a device throughout its entire lifecycle. PMS enables manufacturers to quickly identify issues with the design, manufacture, or use of the device and ultimately enhance patient safety.

Under the new regulation, manufacturers need to develop a PMS plan and report as part of their technical documentation.

The PMS plan should include:

- Proactive and systematic process for collecting data related to serious incidents, product trends, customer complaints, user feedback, etc.
- Effective and appropriate methods to assess collected data
- Indicators and threshold values for assessing risk-benefit and effective risk management
- Methods and tools for investigating complaints and other market-related information gathered in the field
- Methods and protocols to manage events subject to the trend report, as outlined in Article 83
- Protocols for communicating with competent authorities, notified bodies, economic operators, and users
- Reference to procedures that fulfill manufacturer obligations for the PMS system, PMS plan, and periodic safety update report (PSUR)
- Processes and procedures for implementing corrective actions
- Tools to effectively trace potentially defective products

**Arena QMS Tip: Quality Templates**

Leverage the Arena quality templates to help formulate your post-market surveillance plan and reports. Once created, they are linked to your product record and show the history of any changes that are made. Documents can be easily exported and included with your technical file.

The PMS reporting requirements will depend on the classification of device.

***Post-Market Surveillance Report (PMSR)***

Post-market surveillance reports (PMSRs) are required for Class A and B devices. The PMSR should provide a summary of results and conclusions about post-market surveillance data defined in the PMS plan, as well as the rationale and description of any corrective or preventive actions taken. The report should be updated when necessary and made available to the notified body and competent authorities upon request.

***Periodic Safety Update Report (PSUR)***

Periodic safety update reports (PSURs) are required for Class C and D devices. In addition to the information contained in the post-market surveillance report, the PSUR should also include key findings from the post-market performance follow-up (PMPF), conclusion of the benefit/risk determination, and data on sales volumes, user populations, and frequency of use. The report must be updated annually (at minimum) and made available to the notified body and competent authorities.

**Action Item:**

Prepare a post-market surveillance plan and a post-market surveillance/periodic safety update report to include with your technical file

## Labeling

The new IVDR has expanded labeling requirements to increase transparency and traceability of medical devices. These changes will most likely impact manufacturers' labeling processes and may require the use of different labeling equipment.

Device labeling must include:

- Device name and trade name
- Standardized symbol to indicate that the product is an in vitro diagnostic medical device
- Package contents and intended purpose
- Contact information of authorized EU representative (for non-EU based manufacturers)
- Unique device identifier (UDI)
- Time limit for using the device safely (i.e., year and month)
- Warnings and precautions related to the device
- Serial number and lot number
- Links to electronic instructions for use (eIFUs) and company website
- Indication of any special storage and/or handling conditions
- Indication of sterile state of the device or any special microbial state
- Indication if the device is intended for single use
- Indication if device is intended for self-testing, or near-patient testing
- Type of specimen(s) required to perform the test (e.g., blood, urine, saliva)

**Arena QMS Tip: Change Order Custom Attributes**

When initiating change orders for product labels, create a change order custom attribute for impact analysis to help identify all instances where the addition of a unique device identifier (UDI) and other labeling changes will apply.


The unique device identifier (UDI) requirement is a significant change that has been introduced under the new regulation. Comprised of a series of numeric or alphanumeric characters, the UDI allows for the unambiguous identification of specific devices on the EU market and enables better traceability and monitoring by authorities. In addition to being added to device labeling, the UDI information must also be listed on the declaration of conformity and uploaded to the European database for medical devices (EUDAMED).

All in vitro diagnostic medical device labels should be presented in a human-readable format. As such, manufacturers may need to increase the sizes of labels or use internationally recognized symbols (per ISO 15223-1) to accommodate more information.

**Action Items:**

- Review existing labels and packaging to identify where/how new UDI and other information should be applied
- Review current SOPs and labeling systems for inclusion of UDI and other required information
- Include UDI information on your declaration of conformity
- Upload UDI information to the EUDAMED database

## European Database for Medical Devices (EUDAMED)

As part of the new IVDR, the European Commission developed a secure database called EUDAMED to improve transparency and coordination of information regarding medical devices on the EU market.

The system is comprised of six modules:

1. Actor Registration: Enables economic operators (i.e., manufacturers, authorized representatives, and importers) to register their information
2. Unique Device Identification (UDI): Maintains device-specific information. Economic operators are responsible for managing all UDI attributes and transferring the data to EUDAMED
3. Certificates: Maintains EU certificates for each product group

4. Clinical Investigation: Maintains information regarding the collection and analysis of clinical data
5. Vigilance: Maintains serious incident reports
6. Market Surveillance: Maintains post-market surveillance reports

**Action Item:**

Register as an economic operator via the EUDAMED database (Actor Registration Module) and obtain a single registration number (SRN)

The Actor Registration module went live on December 1, 2020. Economic operators are encouraged to register with the system and obtain a single registration number (SRN) to meet the requirements of the regulations. The operation of all six modules is necessary for full IVDR implementation and is scheduled for May 2022.

## Serious Incident and Corrective Action Reporting

Under the new regulation, manufacturers will need to report all serious incidents and field safety corrective actions to competent authorities via the EUDAMED database.

Serious incidents must be reported within these timeframes:

- Immediately, but no later than **2 days** post incident if it represents a serious threat to public health
- Immediately, but no later than **10 days** post incident if it involves a death
- Immediately, but no later than **15 days** post incident if it has little to no consequence to patient or user *(*Note: The reporting period was 30 days under previous regulations)*

If necessary, a partial report can be submitted initially to meet these deadlines.

Field safety corrective actions must be reported to a competent authority before implementation, unless the safety of the patient is at risk and the corrective action needs to be taken immediately.

**Arena QMS Tip: Quality Templates**

Leverage the Arena quality templates to prepare your serious incident and field safety corrective action reports. Once created, they are linked to your product record and show the history of any changes that are made. Documents can be easily exported and included with your technical file.

**Action Item:**

Establish protocol for reporting serious incidents and field safety corrective actions within the established timeframes. Reports should be submitted via the EUDAMED database

# SECTION 3: QUALITY MANAGEMENT SYSTEM (QMS) REQUIREMENTS

Implementing and maintaining a quality management system (QMS) is mandatory for manufacturers looking to market and sell medical devices in the EU. Several new QMS requirements have been introduced under the IVDR. These new requirements will apply to both existing and new devices that are brought to market.

The QMS should address the following under the new regulation:

- Defined strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of device modifications
- Designated "person responsible for regulatory compliance"
- System for identifying all applicable general safety and performance requirements
- Product realization—planning, design, development, production, and service provision
- Management of resources (i.e., infrastructure and equipment) and supply chain
- Development of a risk management plan
- Process for post-market surveillance
- Process for performance evaluation and post-market performance follow-up
- Periodic safety update reporting
- System for serious incidents and corrective action reporting
- System for managing corrective and preventive actions (CAPAs) and verifying their effectiveness
- Processes and procedures to support UDI requirements
- Processes for product improvement, monitoring and measurement of output, and data analysis
- Process for handling communications with competent authorities, notified bodies, economic operators, customers, and other stakeholders

**Arena QMS Tip: Quality Templates**

Leverage the Arena quality templates to develop the necessary quality processes and procedures for your QMS. Once created, these documents are linked to your product record and show the history of any changes that are made. Documents can be easily exported for review by your notified body.

**Action Items:**

- Designate a "person responsible for regulatory compliance" from your organization
- Establish processes for performance evaluation, post-market performance follow-up, and post-market surveillance
- Develop your risk management plan
- Update your QMS per IVDR requirements

# SECTION 4: STEPS FOR A SUCCESSFUL EU IVDR IMPLEMENTATION

1. Assign a dedicated team to oversee the IVDR transition
2. Perform a gap assessment to determine the IVDR impact on your existing product portfolio, quality management system (QMS), and internal resources
   - Determine your responsibilities as an economic operator (i.e., manufacturer) under the new IVDR
   - Confirm the classification of your devices. Do any of them require reclassification under the new regulation?
   - Determine if you will need to collect additional data to meet the new performance evaluation and/or post-market surveillance requirements or conduct new clinical performance studies
   - Identify any documentation or processes that need to be updated and/or added to your QMS and technical file
   - Review current supply chain activities and contracts. How will your supply chain be impacted by the new requirements? What changes are needed?
   - Assess time, resources, and costs that will need to be allocated to certifying your medical devices under the new regulation
   - Determine how the IVDR compliance costs will impact your future revenue and return on investment (ROI)
3. Contact your respective notified body to gain an understanding of its IVDR designation status. If it has not yet gained a designation, you may need to seek out a different notified body. If it is already designated, obtain some clarification regarding its scope of designation and timelines.
   - Does the scope of designation cover your entire product portfolio?
   - When will the notified body be ready to review your technical documentation?
   - How long will it take for the notified body to complete its review?

4. Formulate an IVDR transition plan, timeline, and budget based on the findings from your gap assessment and notified body
5. Review the General Safety and Performance Requirements as outlined in Annex I of the IVDR to determine the requirements that are applicable to your medical device
6. Develop and implement a risk management plan in accordance with ISO 14971
7. Plan and coordinate performance studies as needed
8. Establish your plan and processes for performance evaluation and post-market performance follow-up (PMPF)
9. Establish your plan and processes for post-market surveillance (PMS)
10. Ensure the proper labeling is in place for your medical device(s), including the creation of unique device identifiers (UDIs)
11. Access the EUDAMED database (Actor Registration Module) to register as an economic operator (e.g., manufacturer) and obtain a single registration number (SRN)
12. Ensure that the proper agreements between authorized representatives, importers, and distributors are in place
13. Update your technical file and QMS according to the new IVDR requirements
14. Conduct company-wide training and involve key stakeholders in the IVDR implementation and new QMS requirements. Build additional teams as needed
15. Conduct a series of internal audits to verify that all requirements are met under the new IVDR prior to your official inspection/recertification

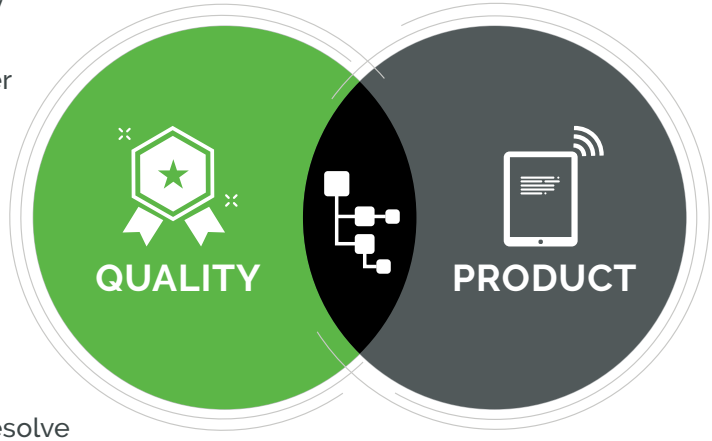
## SECTION 5: IVDR IMPLEMENTATION CHECKLIST

- ☐ Establish an IVDR transition team
- ☐ Confirm medical device classifications under IVDR
- ☐ Contact notified body to confirm scope of designation and timeline for assessment
- ☐ Develop IVDR transition plan, budget, and timeline
- ☐ Designate “person responsible for regulatory compliance”
- ☐ Develop a risk management plan
- ☐ Prepare plans for performance evaluation, post-market performance follow-up (PMPF), and post-market surveillance
- ☐ Update QMS, technical file, and device labeling per IVDR requirements
- ☐ Conduct company-wide training on new IVDR and QMS
- ☐ Conduct internal audit to verify that all requirements are met

# SECTION 6: HOW ARENA CAN HELP

As you start to revisit your current quality processes and compile all the necessary product data for IVDR compliance, you may find it overwhelming to manage, especially if you are working with manual, paper-based, or siloed systems.

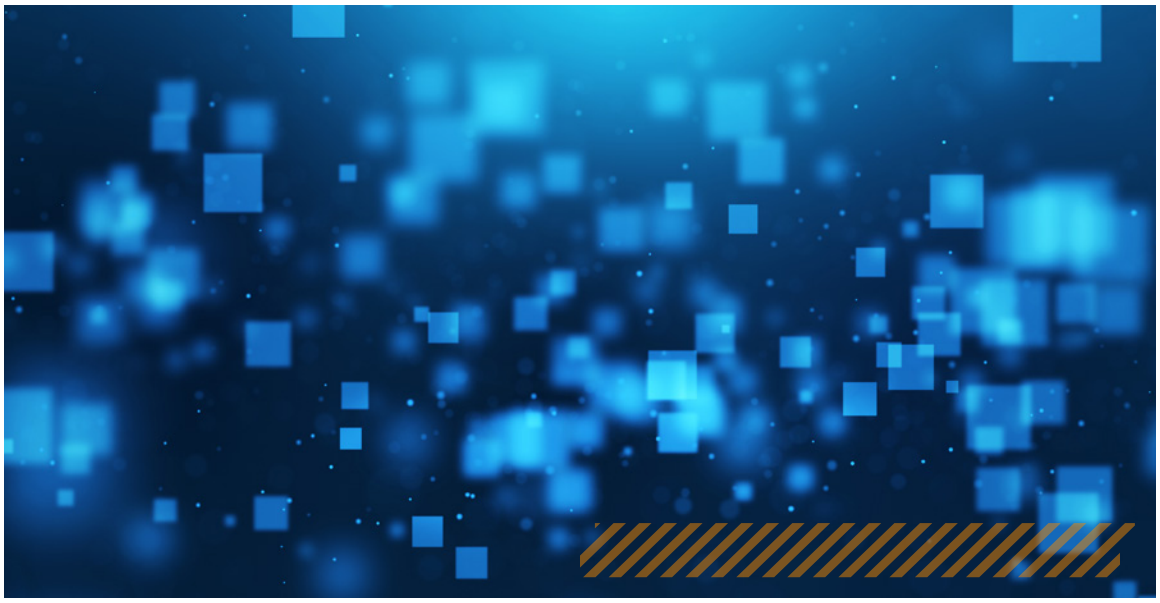
Using an enterprise quality management system (eQMS) like Arena's cloud-based QMS reduces the burden of meeting compliance by linking all of your product information and quality processes in one shared platform. Unlike traditional document-based systems, which fail to manage the complete product record, Arena QMS manages linked relationships between device master records (DMRs), design history files (DHFs), bills of materials (BOMs), approved manufacturer/vendor lists (AMLs/AVLs), technical documentation, product history, and any changes or quality issues. This product-centric approach to QMS enables greater visibility, traceability, and control throughout the entire product lifecycle and reduces compliance risks.




With access to a single, unified system, dispersed product teams and supply chain partners can easily collaborate anytime and anywhere. This eliminates silos and enables impacted teams to quickly identify, analyze, and resolve quality issues. And because all the performance evaluation reports, post-market surveillance reports, and other technical documentation necessary for IVDR compliance are connected and easily extractable—you can be confident that product data is always accurate and audit-ready.

Ultimately, with Arena QMS your team can spend less time managing documents and focus on delivering innovative, safe, and effective products that improve the quality of patients' lives.

| IVDR Requirement | How Arena QMS Helps |
|---|---|
| **Technical File** | **A Technical File Quality Template** enables you to easily build your technical file without having to start from scratch. All the essential IVDR requirements are built into the template, so there's no guesswork on your end.<br>The technical file is automatically linked to your product record and shows the history of any changes that are made. It can be easily exported for review by your notified body. |
| **Performance Evaluations and Post-Market Performance Follow-up** | **Quality Templates** are provided to help you formulate your performance evaluation plan, performance evaluation report, post-market performance follow-up report, and other critical documents.<br>Performance evaluation and post-market performance follow-up documents are linked to the product record and show the history of any changes that are made.<br>Documents can be easily exported and included with your technical file. |
| **Post-Market Surveillance (PMS)** | **Quality Templates** are provided to help formulate your post-market surveillance plan and reports.<br>PMS plans and reports are linked to your product record and show the history of any changes that are made.<br>Documents can be easily exported and included with your technical file. |
| **Labeling** | When initiating change orders for product labels, you can create a **Change Order Custom Attribute** for impact analysis to help identify all instances where the addition of a UDI and other labeling changes will apply. |
| **Serious Incident and Field Safety Corrective Action Reporting** | **Quality Templates** are provided to help you prepare serious incident and field safety corrective action reports.<br>Reports are linked to your product record and show the history of any changes that are made.<br>Documents can be easily exported and included with your technical file. |
| **Quality Management System (QMS)** | **Quality Templates** are provided to help you develop the necessary processes and procedures for your QMS.<br>Quality documents are linked to your product record and show the history of any changes that are made.<br>Documents can be easily exported and included with your technical file. |



# SECTION 7: APPENDIX

## Frequently Asked Questions

***Does the EU IVDR supersede all other EU in vitro diagnostics medical device regulations?***

Yes, the IVDR supersedes the In Vitro Diagnostic Medical Device Directive (IVDD).

***Are any legacy devices grandfathered under the IVDR?***

No. Manufacturers with grandfathered devices under previous regulations no longer maintain their grandfather status under the IVDR.

***What happens to In Vitro Diagnostic Medical Device Directive (IVDD)-certified medical devices that are lawfully placed on the market prior to, or after May 26, 2022?***

Manufacturers can continue to distribute medical devices certified under the IVDD; however, the following will apply:

- Devices cannot undergo significant design changes, including changes to labeling/packaging, changes to the manufacturing process, or the addition of new features or functionality
- Manufacturers must develop and implement a quality management system (QMS) and procedures for risk management, performance evaluation, and post-market surveillance (PMS)/post-market performance follow-up (PMPF) that are in line with the new regulation
- IVDR registration requirements for all economic operators must be completed
- Agreements between the manufacturer, authorized representative, importer, and distributor must be in place

## IVDR Quick Guide

Below are key sections of IVDR 2017/746 that will most likely impact your quality management processes and documentation. Familiarize yourself with these sections to determine how your business will be impacted.

| IVDR Section | Topic |
|---|---|
| Chapter II | Making available on the market, and putting into service of devices, obligations of economic operators, CE marking, free movement |
| Article 10 | General obligations of manufacturers |
| Article 11 | Authorized representative |
| Article 12 | Change of authorized representative |
| Article 13 | General obligations of importers |
| Article 14 | General obligations of distributors |
| Article 15 | Person responsible for regulatory compliance |
| Article 17 | EU declaration of conformity |
| Chapter III | Identification and traceability of devices, registration of devices and economic operators, summary of safety and clinical performance, European database on medical devices |
| Article 24 | Unique device identification system |
| Article 26 | Registration of devices |
| Article 27 | Electronic system for registration of economic operators |
| Article 28 | Registration of manufacturers, authorized representatives, and importers |
| Article 30 | European database for medical devices |
| Chapter IV | Notified bodies |
| Chapter V | Classification and conformity assessment |
| Article 47 | Classification of devices |
| Article 48 | Conformity assessment procedure |
| Article 49 | Involvement of notified bodies in conformity assessment procedures |
| Chapter VI | Clinical evidence, performance evaluation, and performance studies |
| Article 56 | Performance evaluation and clinical evidence |

| IVDR Section | Topic |
|---|---|
| Article 57 | General requirements regarding performance studies |
| Chapter VII | Post-market surveillance, vigilance, and market surveillance |
| Article 78 | Post-market surveillance system of the manufacturer |
| Article 79 | Post-market surveillance plan |
| Article 80 | Post-market surveillance report |
| Article 81 | Periodic safety update report |
| Article 82 | Reporting of serious incidents and field corrective actions |
| Article 83 | Trend reporting |
| Article 84 | Analysis of serious incidents and field corrective actions |
| Article 87 | Electronic system on vigilance and on post-market surveillance |
| Chapter VIII | Cooperation between member states, medical device coordination group, EU reference laboratories, and device registers |
| Annex I | General safety and performance requirements |
| Annex II | Technical documentation |
| Annex III | Technical documentation on post-market surveillance |
| Annex IV | EC declaration of conformity |
| Annex V | CE marking of conformity |
| Annex VI | Information to be submitted upon the registration of devices and economic operators in accordance with articles 26(3) and 28, core data elements to be included in the UDI database together with UDI-DI in accordance with articles 25 and 26 of the UDI system |
| Annex VII | Requirements to be met by notified bodies |
| Annex VIII | Classification rules |
| Annex IX | Conformity assessment, based on a quality management system and on assessment of technical documentation |
| Annex X | Conformity assessment based on type examination |

| IVDR Section | Topic |
|---|---|
| Annex XI | Conformity assessment based on production quality assurance |
| Annex XII | Certificates issued by a notified body |
| Annex XIII | Performance evaluation, performance studies, and post-market performance follow-up |
| Annex XIV | Interventional clinical studies and certain other performance studies |

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