ptc

arena

Preparing for Europe's Evolving Medical Device Regulation

The Essential Guide to EU MDR Compliance

WHITE PAPER

SECTION 1: INTRODUCTION

Your MDR Transition Starts Now

Do you have a set roadmap for certifying your devices under the European Union (EU) Medical Device Regulation (MDR)? If you currently market and sell medical devices in the European Economic Area (EEA) or are planning to do so in the near future—now is the time to put the proper measures and systems in place to ensure compliance.

On May 25, 2017, the European Commission published the Medical Device Regulation (MDR) 2017/745[1,2], which introduced an expansive set of new rules for how medical 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 Active Implantable Medical Device Directive (AIMDD) and Medical Device Directive (MDD).

Some noteworthy changes include:

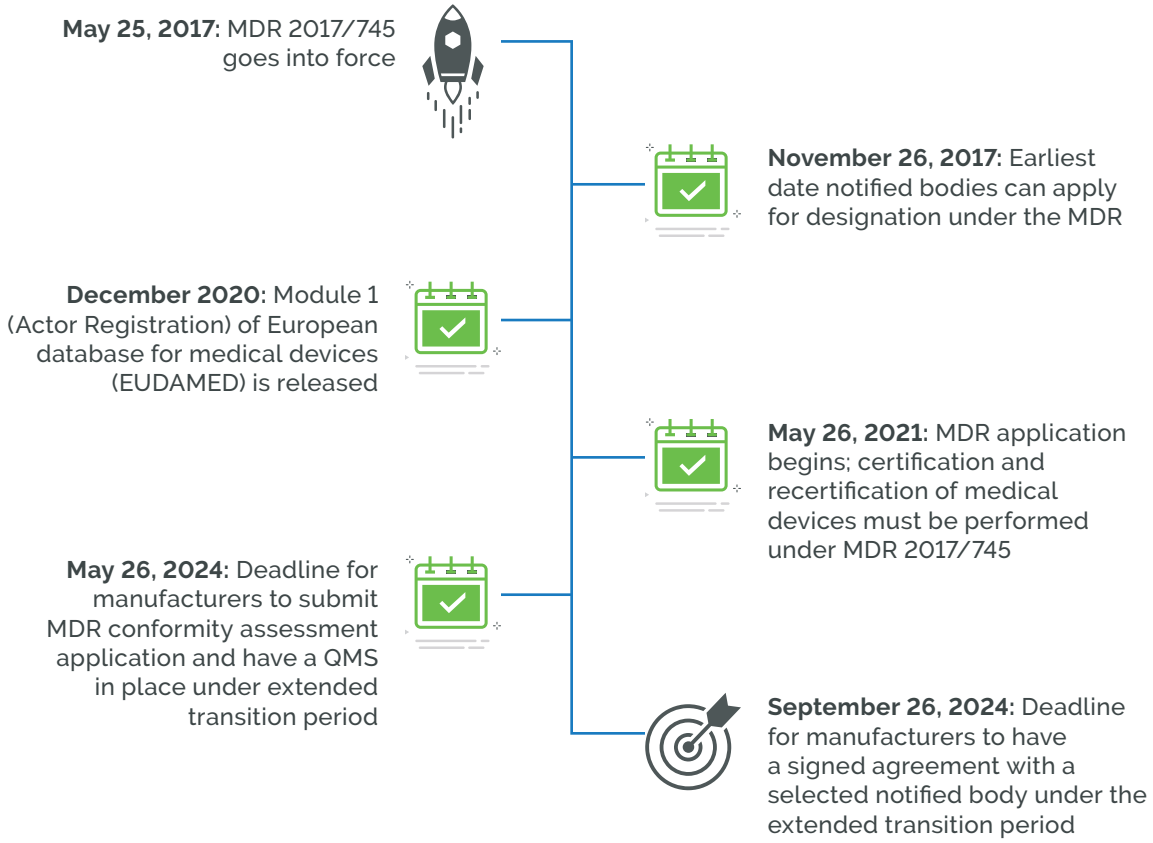
- Greater emphasis on the entire product lifecycle as opposed to just the pre-approval stage
- Broadened definition of medical device to include some non-medical and cosmetic devices
- Reclassification of some medical devices to higher risk categories
- Greater emphasis on post-market surveillance
- More stringent requirements for clinical evidence
- Greater supervision over notified bodies

As of May 26, 2021, new devices should have been certified and existing devices recertified under the MDR. This requires manufacturers to revisit their quality management system (QMS) and update core processes to ensure compliance. Ultimately, manufacturers that fail to comply with the MDR could face costly fines, litigation, design changes, product recalls, or lack of access to the EU market.

Navigating the regulation and figuring out where to start can be daunting. In this guide, we highlight the new MDR 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 MDR transition, as well as some insights on how an enterprise quality management system (eQMS) solution can help simplify compliance.

Important Dates for EU MDR Transition

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



Extended Transition Period for Certain Medical Devices

On March 20, 2023, the European Commission issued Regulation (EU) 2023/607, which extends the transition period for certain devices that were certified under the EU's previous Medical Device Directive (MDD) or Active Implantable Medical Device Directive (AIMDD) as follows:

- Class III and Class IIb implantable devices (except for sutures, staples, and certain dental devices): December 31, 2027
- Class IIa and Class IIb devices not covered above, Class Is, and Class Im devices: December 31, 2028
- Devices with a declaration of conformity dated prior to March 26, 2021: December 31, 2028

Furthermore, the sell-off date for MDD- and AIMDD-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 MDR

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 MDR. 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 MDR. 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 MDR, 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

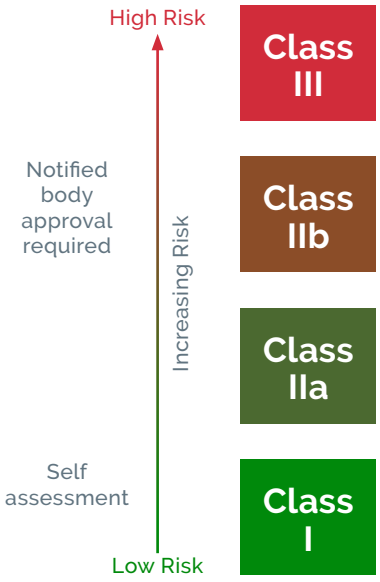
**A complete listing of designated notified bodies is maintained on the NANDO database*

Medical Device Classifications

Classification of medical devices is regulated by Annex VIII of the MDR. This classification system is based on the risk that the device poses to patient safety along with the following parameters:

- Duration of use (i.e., how long the device is in contact with the patient/user)
  - Transient: Intended for continuous use for less than an hour
  - Short-term: Intended for continuous use between an hour and 30 days
  - Long-term: Intended for continuous use for more than 30 days
- Whether the product is invasive or noninvasive
  - Invasive devices enter the body in whole or in part, either through an opening of the body or through the surface of the body
  - Noninvasive devices do not enter the body through any opening or surface of the body itself
- Whether the device is active or not
  - Active devices need a source of energy to work

Devices are classified as either Class I, IIa, IIb, or III:



Class III devices pose a high risk to patients. They are invasive and are intended to either support human life or prevent impairment of human health. Medical devices in this category require a conformity assessment by a notified body. Examples include pacemakers and prosthetic heart valves. Approximately 2% of devices in the EU market are Class III devices.

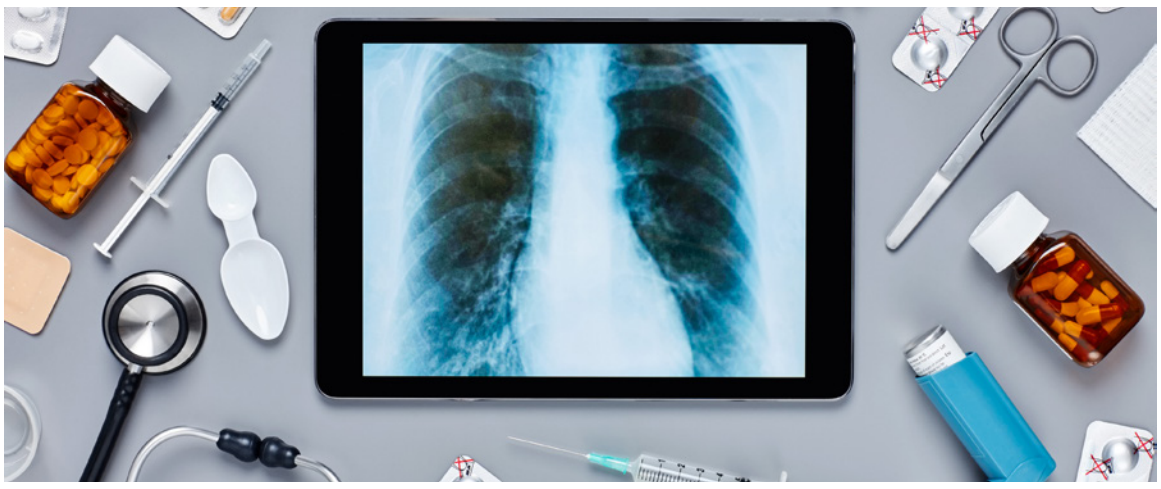
Class IIb devices pose a medium to high risk to patients. They are mostly invasive and may be installed in the body for more than 30 days. Medical devices in this category require a conformity assessment by a notified body. Examples include infusion pumps, ventilators, dialysis machines, and intensive care monitoring equipment. Approximately 8% of devices in the EU market are Class IIb devices.

Class IIa devices pose a medium risk to patients. They are typically invasive and are installed in the body for less than 30 days. Medical devices in this category require a conformity assessment by a notified body. Examples include hearing aids, ultrasonic diagnostic equipment, and catheters. Approximately 20% of medical devices in the EU market are Class IIa devices.

Class I devices are mostly noninvasive and pose a low risk to patients. Devices in this category are divided into the following subclasses:

- *Class I:* Products are non-sterile or have no measuring function (e.g., wheelchairs, hospital bed, bed pan)
- *Class Is:* Products are delivered sterile and must be either transported in a sterile condition or sterilized upon receipt (e.g., sterile gauze, personal protection kits)
- *Class Im:* Products have a measuring function (e.g., stethoscope, thermometer, weighing scale)
- *Class Ir:* This is a newly added subclass under the MDR that refers to reprocessed or reused products (e.g., surgical instruments and endoscope)

Approximately 70% of devices in the EU market are Class I devices.



The route in which a device obtains its CE Mark (i.e., Annex IX, X, or XI) is determined by its classification.

Conformity assessment routes:

- **Annex IX** (QMS and technical documentation) is used when a full QMS is implemented by the manufacturer. A review of technical documentation is also required with or without the issuance of a certificate.
- **Annex X** (type-examination) is used when a manufacturer wants to certify a device based on a representative sample. A notified body examines and/or tests the representative sample and associated technical documentation to determine if the device meets MDR requirements.
- **Annex XI** (product conformity verification) is used in association with Annex X or in combination with technical documentation for low-risk devices.

Medical Device Classification	Risk	Device Type/ Duration of Use	Assessment Requirements
Class I	Low	Non-Sterile Noninvasive	Self-Certification/Self Declaration Technical Documentation Is Required
Class Is	Low	Sterile Noninvasive	Notified Body Review of Technical Documentation and Limited QMS (Annex IX), or Product Conformity Verification (Annex XI)
Class Im	Low	Measuring Function Noninvasive	Notified Body Review of Technical Documentation and Limited QMS (Annex IX), or Product Conformity Verification (Annex XI)
Class Ir	Low	Reusable Noninvasive	Notified Body Review of Technical Documentation and Limited QMS (Annex IX), or Product Conformity Verification (Annex XI)
Class IIa	Medium	Invasive Short Term	Notified Body Review of Technical Documentation and Full QMS (Annex IX), or Product Conformity Verification (Annex XI)
Class IIb	Medium to High	Invasive or Active Long Term	Notified Body Review of Technical Documentation and Full QMS (Annex IX), or Product Conformity Verification (Annex XI)
Class III	High	Invasive or Active Long Term	Notified Body Review of Technical Documentation and Full QMS (Annex IX), or Type-Examination (Annex X) and Product Conformity Verification (Annex XI)

Under the MDR, the following medical devices have been reclassified to a higher risk category:

Medical Device	New Classification
• Nanomaterial devices • Devices intended to be introduced into the body through an orifice or applied to the skin • Total and partial joint replacements • In vitro contact with cells and/or embryos returning to the body • Active implantable medical devices (AIMD) and accessories • Spinal implants • Apheresis devices	**Class III**
• Devices that record diagnostic images	**Class IIa**
• Noninvasive in vitro fertilization (IVF) and assisted reproduction technologies (ART) products	**Class IIa or IIb**
• Reusable surgical instruments	**Class Ir**

In addition to classification changes, the MDR (Annex XVI) has introduced new manufacturing and surveillance requirements for these previously unregulated devices:

- Contact lenses
- Implants for cosmetic or anatomical modification
- Facial and other dermal or mucous membrane fillers
- Liposuction, lipolysis, or lipoplasty equipment
- Lasers and intense pulsed light equipment for skin resurfacing, tattoo or hair removal, or other skin treatment
- Equipment intended to modify neuronal activity in the brain

Action Items:

- Confirm the classification of your device under the new MDR. 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 MDR 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 comply with new roles and responsibilities that are defined in the MDR, 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 MDR, 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 MDR. 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.

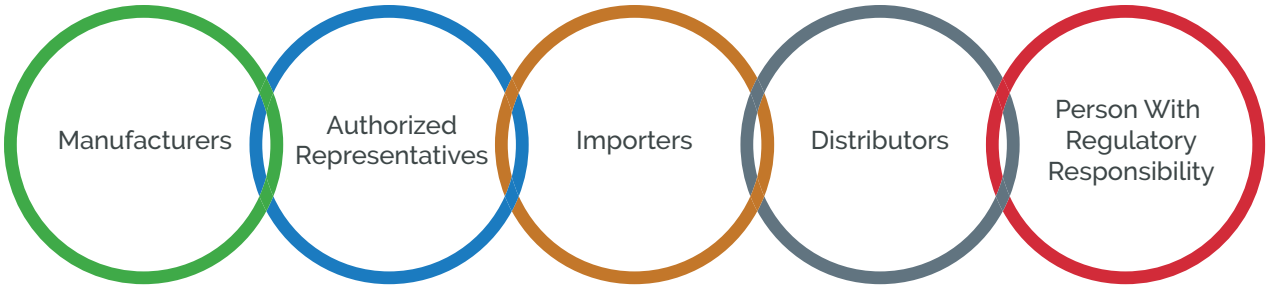
Distributors

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 MDR
- 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 MDD and AIMDD technical file requirements which were general in nature, the new MDR (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
- Pre-clinical and clinical data (clinical evaluation report)
- Post-market surveillance plan and reports

Arena QMS Tip:
Supplier Approval Quality Template

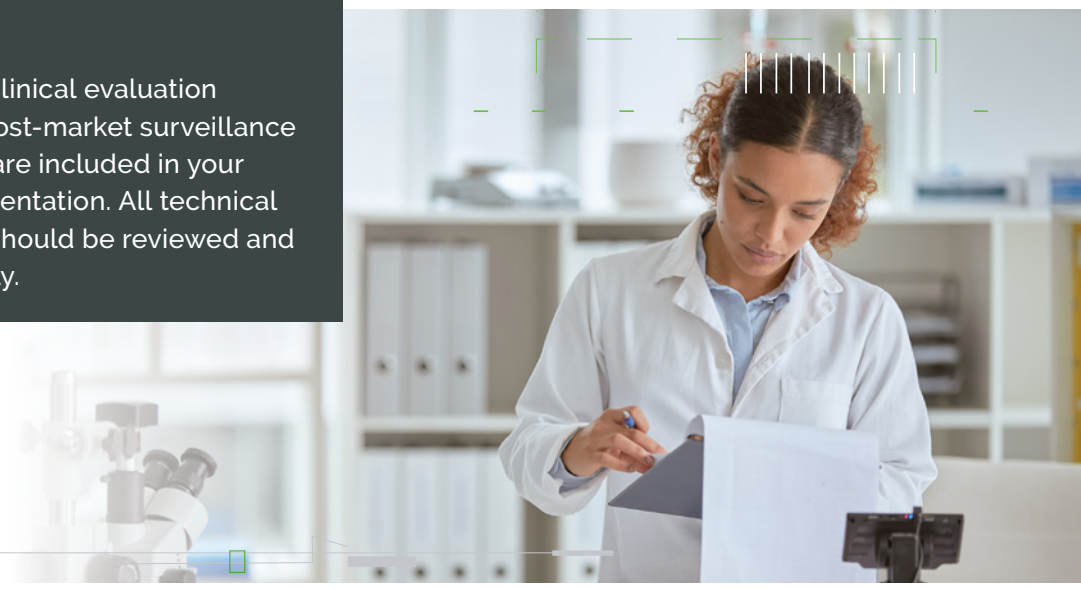
Use the supplier approval template to create a list of your approved suppliers and the parts they provide. This approved supplier list (ASL) is automatically linked to your product record and shows the history of any changes that are made. The ASL can be easily exported and included with your technical 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 MDR 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 clinical evaluation report and the post-market surveillance plan and report are included in your technical documentation. All technical documentation should be reviewed and updated regularly.



Clinical Evaluations and Post-Market Clinical Follow-up (PMCF)

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.

Clinical Evaluations

The MDR defines a clinical evaluation as "a systematic and planned process to continuously generate, collect, analyze, and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer."

Manufacturers should plan, conduct, and document a clinical evaluation in accordance with MDR (Article 61) and Annex XIV (Part A). Clinical evaluations must be thorough and consider 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.

Clinical Evaluation Plan (CEP)

The new regulation emphasizes the importance of early planning when it comes to clinical evaluations. As such, manufacturers will need to develop a clinical evaluation plan prior to gathering data. The clinical 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 and contraindications
- Intended benefits to patients with relevant clinical outcome parameters
- Methods to examine clinical safety with reference to the determination of residual risks and side effects
- Parameters to determine benefit-risk ratio acceptability for the various indications and intended purposes of the device
- Process for addressing benefit-risk issues relating to the use of components such as non-viable human or animal tissues
- Clinical development plan indicating the progression from exploratory investigations (e.g., feasibility and pilot studies) to confirmatory investigations (e.g., post-market clinical follow-up) with an indication of milestones and 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:

- Clinical investigation(s) of the device in question
- Clinical investigations(s) or other studies reported in scientific literature of a similar device for which equivalence can be demonstrated*
- Reports in published peer-reviewed scientific literature on other clinical experience of either the device in question or similar device for which equivalence can be demonstrated*
- Clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up

**Note: Although published articles and scientific journals are considered relevant sources for clinical data under the new regulations, a comprehensive and reproducible literature search should be conducted. The MEDDEV 2.7/1 Rev. 4 guidance document provides a detailed protocol for performing a scientifically valid literature search that meets compliance[4].*

For legacy devices (i.e., devices previously certified under the Medical Device Directive (MDD) or Active Implantable Medical Device Directive (AIMDD))—post-market clinical data, along with the clinical data generated for the conformity assessment under MDD/AIMDD, will serve as the basis of the clinical evaluation under the new MDR. In addition, manufacturers should perform a gap analysis with the general safety and performance requirements of the MDR to determine if additional or new data is necessary.

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 clinical follow-up plan, and where appropriate, the post-market clinical 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 clinical evaluation plan, clinical evaluation report, post-market clinical follow-up report, and other critical documents. Once created, these documents 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 Investigations for Class IIb, Class III, and Implantable Devices

Clinical investigations carried out by the sponsor/manufacturer should serve as the key source of clinical data for Class III and implantable medical devices. All clinical

investigations should follow the good clinical practices set forth in ISO 14155.

These devices may be exempt from clinical investigation if:

- The design is based on a modification of a device that is already marketed by the manufacturer
- The modified device has been demonstrated by the manufacturer to be equivalent to the marketed device and has been endorsed by a notified body
- The clinical evaluation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements

For all Class III devices and Class IIb devices (referenced in MDR Article 54), manufacturers may consult with an expert panel regarding its intended clinical development strategy prior to conducting a clinical evaluation and/or investigation.

Summary of Safety and Clinical Performance (SSCP)[6]
Under the MDR, manufacturers will need to draw up a summary of safety and clinical performance (SSCP) for implantable Class IIb devices and for Class III devices, other than custom-made or investigational devices. The SSCP shall 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 fulfil the objectives of the MDR by enhancing transparency and providing adequate access to information about the safety and clinical performance of the device.

Demonstrating Equivalence
The MDR has more stringent requirements for claiming equivalence, especially for Class III and implantable medical devices. Devices with "sufficient clinical data" under the previous MDD/AIMDD regulations will most likely need additional clinical data under the new regulation.

If the clinical evaluation is based on clinical data from an already marketed device, manufacturers will need to demonstrate that they have access to sufficient levels of clinical data to claim equivalence. In addition, the equivalent device must share the same technical, biological, and clinical characteristics.

- Technical: Device has similar design, specifications, and properties, is used under similar conditions, uses similar deployment methods, has similar principles of operation and critical performance requirements
- Biological: The same device materials or substances are in contact with the same human tissues or body fluids for a similar duration
- Clinical: Device is used for the same clinical condition or purpose in a similar patient population and has the same kind of user

For Class III and implantable medical devices, manufacturers can claim equivalence to an already marketed device (from a different company), under the following conditions:

- Manufacturer has a contract in place with the other company to allow full access to technical and clinical documentation of the equivalent device on an ongoing basis
- The initial clinical evaluation of the equivalent device has been performed in compliance with MDR requirements
- The equivalent device is certified under the MDR

For non-implantable and non-Class III devices, manufacturers can claim equivalence to an already marketed device (from a different company) without establishing a contract; however, the manufacturer will need to demonstrate sufficient levels of access to clinical data.

Data Appraisal and Analysis

Once the clinical data has been collected, manufacturers should conduct a qualitative or quantitative appraisal to determine the methodological quality and scientific validity of each data set. This involves examining the methods used to collect the data and determining the extent to which factors such as bias, random error, and misinterpretation affect the performance or safety outcomes of the device. Other components of the appraisal include determining the relevance of the clinical data and weighting the contribution of each data set.

The analysis portion of the clinical evaluation involves assessing whether proof of the performance and safety of the device has been adequately established.

Detailed requirements for performing the data appraisal and analysis are outlined in the MEDDEV 2.7/1 Rev. 4 guidance document[4].

Clinical Evaluation Report (CER)

The results of the clinical evaluation must be documented in a clinical evaluation report and included with the technical documentation that is provided for the conformity assessment. Clinical evaluation reports should be updated once per year (at minimum) for high-risk devices (i.e., Class III and implantable devices). For lower-risk or well-established devices, the clinical evaluation report should be updated every 2 to 5 years. The frequency of updates should be justified in the clinical evaluation plan.

Post-Market Clinical Follow-up (PMCF)

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 clinical follow-up (PMCF) under the new MDR requirements.

The PMCF 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[7], which specifies the methods for proactively collecting and evaluating clinical data.

The findings of the PMCF should be analyzed and documented in a PMCF evaluation report[8] and included with the technical documentation.

Action Items:

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

Post-Market Surveillance (PMS)

The new MDR 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 regulations, 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 88
- 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 the device.

Post-Market Surveillance Report (PMSR)

Post-market surveillance reports (PMSRs) are required for Class I medical 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 on an as needed basis.

Periodic Safety Update Report (PSUR)

Periodic safety update reports (PSURs) are required for Class IIa, IIb, and III devices. In addition to the information contained in the post-market surveillance report, the PSUR should also include key findings from the post-market clinical follow-up (PMCF), conclusion of the benefit/risk determination, and data on sales volumes, user populations, and frequency of use. The report must be updated every two years (at minimum) for Class IIa devices and at least once a year for Class IIb and Class III devices.

Action Item:

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

EU MDR Documentation Maintenance Requirements[9]

Documentation	Class I	Class IIa	Class IIb	Class III/Implantable Devices
Clinical Evaluation Report (CER) [Article 6 1 (11), MEDDEV 2.7.1/4 (6.2.3)]	When Necessary	When Necessary or At Least Every 2-5 years		At Least Annually
Post-Market Clinical Follow-up (PMCF) Evaluation Report [Article 61 (11), Annex XIV Part B (7)]	When Necessary	When Necessary or At Least Every 2-5 Years		At Least Annually
Summary of Safety and Clinical Performance (SSCP) [Article 32, 61 (11)]	N/A	N/A	N/A	Annually (If Indicated)
Risk Management Report [Annex I (3)]	Regular Systematic Update			
Periodic Safety Update Report (PSUR) [Article 86 (1)]	N/A	At Least Every 2 Years	At Least Annually	At Least Annually
Post-Market Surveillance Report (PMSR) [Article 85]	When Necessary	N/A	N/A	N/A
Technical File	Continually			

Note: *Although all reports have different submission schedules depending on the device classifications, it is the PSUR that will trigger the updates of the other documents.*

Labeling

The new MDR 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 a 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 or implanting the device safely (i.e., year and month)
- Warnings and precautions related to the device
- Serial number and lot number (for implantable devices)
- Links to electronic instructions for use (eIFUs) and company website
- Indication of any carcinogenic, mutagenic, or toxic for reproduction (CMR) substances
- Indication of any substances having endocrine-disrupting properties
- Indication of medicinal substances, human blood or plasma derivatives, or tissues or cells of human or animal origin
- Number of reprocessing cycles (for single-use devices)

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 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 MDR, 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

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 regulation.

Action Item:

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

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 MDR. These new requirements 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 clinical evaluation and post-market clinical 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 clinical evaluation, post-market clinical follow-up, and post-market surveillance
- Develop your risk management plan
- Update your QMS per MDR requirements

SECTION 4: STEPS FOR A SUCCESSFUL EU MDR IMPLEMENTATION

1. Assign a dedicated team to oversee the MDR transition
2. Perform a gap assessment to determine the MDR 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 MDR
   - 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 clinical evaluation and/or post-market surveillance requirements or conduct new clinical investigations
   - 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 MDR compliance costs will impact your future revenue and return on investment (ROI)
3. Contact your respective notified body to gain an understanding of its MDR 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 MDR 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 MDR 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 clinical investigations as needed
8. Establish your plan and processes for clinical evaluation and post-market clinical follow-up (PMCF)
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 MDR requirements
14. Conduct company-wide training and involve key stakeholders in the MDR 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 MDR prior to your official inspection/recertification

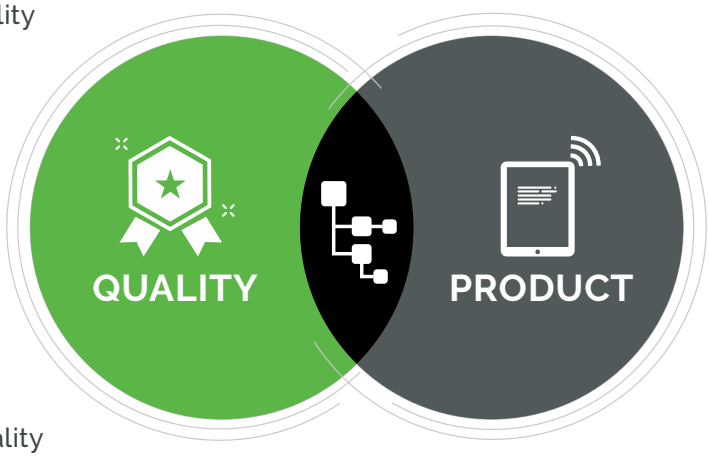
SECTION 5: MDR IMPLEMENTATION CHECKLIST

- ☐ Establish an MDR transition team
- ☐ Confirm medical device classifications under MDR
- ☐ Contact notified body to confirm scope of designation and timeline for assessment
- ☐ Develop MDR transition plan, budget, and timeline
- ☐ Designate “person responsible for regulatory compliance”
- ☐ Develop a risk management plan
- ☐ Prepare plans for clinical evaluation, post-market clinical follow-up (PMCF), and post-market surveillance
- ☐ Update QMS, technical file, and device labeling per MDR requirements
- ☐ Conduct company-wide training on new MDR 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 MDR 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 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 clinical evaluation reports, post-market surveillance reports, and other technical documentation necessary for MDR 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.

MDR 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 MDR requirements are built into the template, so there's no guesswork on your end. 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.
Clinical Evaluations and Post-Market Clinical Follow-up	**Quality Templates** are provided to help you formulate your clinical evaluation plan, clinical evaluation report, post-market clinical follow-up report, and other critical documents. Clinical evaluation and post-market clinical follow-up documents 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.
Post-Market Surveillance (PMS)	**Quality Templates** are provided to help formulate your post-market surveillance plan and reports. PMS plans and reports 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.
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. Reports 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.
Quality Management System (QMS)	**Quality Templates** are provided to help you develop the necessary processes and procedures for your QMS. Quality documents 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.

SECTION 7: APPENDIX

Frequently Asked Questions

Does the EU MDR supersede all other EU medical device regulations?

Yes, the MDR supersedes both the Medical Device Directive (MDD) and Active Implantable Medical Device Directive (AIMDD).

Are any legacy devices grandfathered under the MDR?

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

What is the difference between a clinical investigation and clinical evaluation?

A clinical investigation is a one-time study conducted on humans to demonstrate the safety and performance of the medical device, whereas a clinical evaluation is a continuous process of generating, collecting, analyzing, and evaluating clinical data throughout the medical device's lifecycle to demonstrate conformance with general safety and performance requirements and its intended use[10].

What is considered "sufficient clinical data" for legacy devices under the new regulation?

The Medical Device Coordination Group (MDCG), an expert committee required by the MDR, has developed a guidance document, MDCG 2020-6, on sufficient clinical evidence needed for medical devices previously CE marked under the previous Medical Device Directive (MDD) and Active Implantable Medical Device Directive (AIMDD)[11].

According to the MDCG 2020-6 guidance document: Post-market clinical data as well as clinical data generated for the MDD/AIMDD conformity assessment are the basis for the clinical evaluation under the new regulation. In addition, manufacturers will need to conduct a gap assessment with the General Safety and Performance Requirements of the MDR to determine if any additional data is needed.

What happens to Medical Device Directive (MDD)- and Active Implantable Medical Device Directive (AIMDD)-certified medical devices that are lawfully placed on the market prior to, or after May 26, 2021?

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

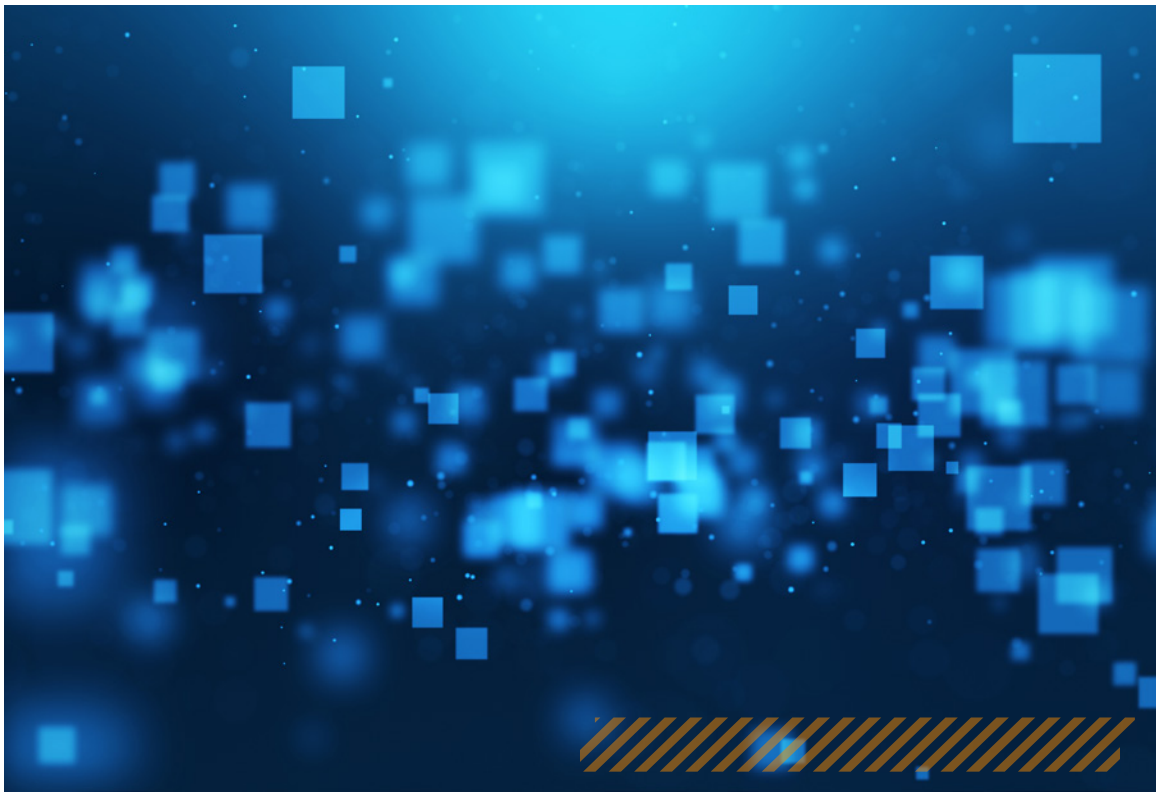
- Devices cannot undergo significant design changes, including changes to labeling/packaging, changes to the manufacturing process, or the addition of new features or functionality
- Manufacturers must develop and implement a quality management system (QMS) and procedures for risk management, clinical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

MDR Quick Guide

Below are key sections of MDR 2017/745 that will most likely impact your quality management processes and documentation. Familiarize yourself with these sections to determine how your business will be impacted.

MDR Section	Topic
Article 10	General obligations of manufacturers
Article 12	Change of authorized representative
Article 15	Person for regulatory compliance
Article 19	EU declaration of conformity
Article 27	Unique device identification system
Article 29	Registration of devices
Article 30	Electronic system for registration of economic operators
Article 31	Registration of manufacturers, authorized representatives, and importers
Article 32	Summary of safety and clinical performance
Article 51	Classification of devices
Article 52	Conformity assessment procedure
Article 53	Involvement of notified bodies in conformity assessment procedures
Article 54	Clinical evaluation consultation procedure for certain class III and IIb devices
Article 61	Clinical evaluation
Article 62	General requirements regarding clinical investigations conducted to demonstrate conformity of devices
Article 83	Post-market surveillance system of the manufacturer
Article 84	Post-market surveillance plan
Article 85	Post-market surveillance report
Article 86	Periodic safety update report
Article 87	Reporting of serious incidents and field corrective actions
Article 88	Trend reporting
Article 89	Analysis of serious incidents and field corrective actions

MDR Section	Topic
Article 92	Electronic system on vigilance and on post-market surveillance
Annex I	General safety and performance requirements
Annex II	Technical documentation
Annex III	Technical documentation on post-market surveillance
Annex VIII	Classification rules
Annex IX	Conformity assessment based on a QMS and on assessment of technical file
Annex X	Conformity assessment based on type examination
Annex XI	Conformity assessment based on product conformity verification
Annex XIV	Clinical evaluation and post-market clinical follow-up
Annex XV	Clinical investigations
Annex XVI	List of groups of products without an intended medical purpose



References

1. EU Medical Device Regulation (MDR) 2017/745
   https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&from=IT#d1e40-1-1
2. European Commission Factsheet for Manufacturers of Medical Devices
   https://ec.europa.eu/docsroom/documents/31201
3. Update on Notified Body Designated Under MDR/IVDR
   https://brandwoodckc.com/update-on-notified-bodies-designation-under-mdr-ivdr/
4. MEDDEV 2.7/1 Rev. 4. Clinical Evaluation: A Guide for Manufacturers and Notified Bodies. June 2016
5. MDCG 2020-13: Clinical evaluation assessment report template
   https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_clinical_evaluation template_en.pdf
6. MDCG 2019-9: Summary of safety and clinical performance. A guide for manufacturers and notified bodies
   https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2019_9_sscp_en.pdf
7. MDCG 2020-7: Post-market clinical follow-up plan template. A guide for manufacturers and notified bodies
   https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2020_7_guidance_pmcf_plan_template_en.pdf
8. MDCG 2020-8: Post-market clinical follow-up evaluation report template. A guide for manufacturers and notified bodies
   https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2020_8_guidance_pmcf_evaluation_report_en.pdf
9. Rimsys and PA Consulting. Post-EU MDR Compliance: Key Insights and Activities to Maintain Compliance After Device Certification
   https://www.rimsys.io/library/post-eu-mdr-compliance-key-insights-and-activities-to-maintain-compliance-after-device-certification
10. I3CGLOBAL. Clinical investigation vs. clinical evaluation of medical devices
    https://www.i3cglobal.com/clinical-evaluation-and-clinical-investigation/
11. MDCG 2020-6 Regulation 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC. A guide for manufacturers and notified bodies
    https://ec.europa.eu/docsroom/documents/40904
12. MEDDEV 2.12-1 Rev. 8. Guidelines on a Medical Devices Vigilance System
    https://ec.europa.eu/docsroom/documents/32305/attachments/1/translations

ptc arena