

CE Marking Comprehensive Guide



MDR Requirements

- Medical Device Regulation 2017/745
- Technical documentation
- Conformity assessment



Risk Classification

- Class I, IIa, IIb, III
- Rule-based classification
- Notified Body involvement



Clinical Evaluation

- Clinical data requirements
- Benefit-risk analysis
- Clinical evaluation report



Post-market Surveillance

- PMS plan & reports
- Vigilance reporting
- PSUR requirements



UKCA Divergence

- Post-Brexit UK requirements • Separate conformity assessment





1. MDR Requirements

Medical Device Regulation 2017/745 Framework

Regulatory Framework

The Medical Device Regulation (MDR) 2017/745 replaced the Medical Device Directive (MDD) to ensure higher safety and performance standards for medical devices in the European market.

- Full application since May 26, 2021
- Stricter requirements for clinical evidence
- Enhanced post-market surveillance obligations
- Increased transparency through EUDAMED database

Technical Documentation

Comprehensive technical documentation must demonstrate compliance with all applicable requirements of the MDR.

- Device description and specifications
- Design and manufacturing information
- Risk management documentation (ISO 14971)
- Verification and validation reports
- Clinical evaluation and safety data

Conformity Assessment Procedures

Key Responsibilities

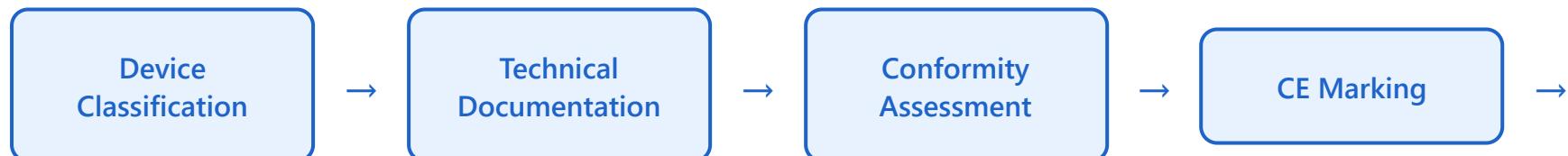
Manufacturers must follow specific conformity assessment routes based on device classification.

- Self-declaration for most Class I devices
- Notified Body involvement for Class IIa, IIb, III
- Quality management system certification
- Technical documentation review

Manufacturers must fulfill several ongoing obligations under MDR.

- Appoint an EU Authorized Representative (if outside EU)
- Implement Quality Management System (ISO 13485)
- Register devices in EUDAMED
- Issue Declaration of Conformity (DoC)
- Maintain technical documentation for 10+ years

MDR Compliance Pathway



Market Access

💡 Practical Example

A manufacturer developing a blood glucose monitoring system (Class IIb) must prepare comprehensive technical documentation including clinical data, work with a Notified Body for conformity assessment, implement ISO 13485 quality

management system, register the device in EUDAMED, and appoint an EU Authorized Representative before affixing the CE mark and entering the European market.



2. Risk Classification

Rule-Based Device Classification System

Classification Principles

Medical devices are classified according to their intended purpose and the risks they pose to patients and users, following 22 classification rules in MDR Annex VIII.

- Duration of contact with the body
- Degree of invasiveness
- Local versus systemic effect
- Whether the device is active or contains medicine

Classification Rules

The MDR contains 22 classification rules divided into four categories.

- Non-invasive devices (Rules 1-4)
- Invasive devices (Rules 5-8)
- Active devices (Rules 9-13)
- Special rules (Rules 14-22)

Notified Body Requirements

Classification Impact

Higher risk classes require third-party assessment by Notified Bodies.

- Class I: Generally self-certification
- Class IIa: Notified Body for technical documentation
- Class IIb: Notified Body for QMS and design examination
- Class III: Most stringent Notified Body involvement

Device classification determines regulatory requirements and time to market.

- Level of clinical evidence required
- Conformity assessment procedures
- Post-market surveillance obligations
- Regulatory review timelines and costs

Medical Device Classification System

Class I

Low Risk

Bandages, examination gloves, walking aids, wheelchairs

Self-certification possible

Class IIa

Medium Risk

Hearing aids, dental fillings, ultrasound scanners

Notified Body review

Class IIb

Medium-High Risk

Blood bags, lung ventilators, X-ray machines

Full Notified Body assessment

Class III

High Risk

Heart valves, implants, drug-eluting stents

Most stringent assessment



Critical Consideration

If multiple classification rules apply to a device, the strictest rule determines the final classification. Manufacturers should conduct a thorough classification analysis early in development to understand regulatory requirements and plan accordingly.



3. Clinical Evaluation

Evidence-Based Safety and Performance Assessment

Clinical Evaluation Process

A systematic and planned process to continuously generate, collect, analyze and assess clinical data pertaining to a device.

- Literature review and analysis
- Equivalent device assessment
- Clinical investigation data
- Post-market clinical follow-up (PMCF)

Clinical Data Requirements

MDR Article 61 requires manufacturers to demonstrate compliance through clinical evidence.

- Pre-market clinical investigations where necessary
- Scientific literature on similar devices
- Post-market surveillance data
- Registries and real-world evidence
- Increased requirements for high-risk devices

Benefit-Risk Analysis

Comprehensive evaluation demonstrating that benefits outweigh residual risks.

- Identified risks and hazards
- Residual risks after risk mitigation

Clinical Evaluation Report (CER)

Comprehensive document demonstrating conformity with relevant general safety and performance requirements.

- Device description and specifications

- Clinical benefits for intended purpose
- Comparison with alternative treatments
- Acceptability of benefit-risk ratio

- Clinical background and state of the art
- Appraisal of clinical data
- Analysis of benefit-risk profile
- Conclusions and recommendations

Clinical Evaluation Lifecycle

Stage 1: Planning

Define scope, clinical evaluation plan, literature search strategy, and equivalence criteria if applicable.

Stage 2: Data Collection

Gather clinical data from literature, clinical investigations, post-market data, and equivalent devices.

Stage 3: Analysis & Appraisal

Critically analyze clinical data quality, relevance, and sufficiency to demonstrate safety and performance.

Stage 4: Report Generation

Compile Clinical Evaluation Report (CER) with benefit-risk analysis and conclusions.

Stage 5: Continuous Update

Regular updates through Post-Market Clinical Follow-up (PMCF) and periodic safety update reports.



Practical Example

For a new orthopedic knee implant (Class III), the manufacturer must conduct clinical investigations with at least 5-year follow-up data, perform extensive literature reviews on similar implants, establish equivalence claims with supporting evidence, conduct PMCF studies to monitor long-term performance, and update the CER annually based on new data. The benefit-risk analysis must demonstrate superior or equivalent outcomes compared to existing gold-standard treatments.



4. Post-Market Surveillance

Continuous Monitoring and Safety Management

PMS Plan & System

Systematic process to actively collect and analyze data about the quality, safety, and performance of devices throughout their lifecycle.

- Define data collection methods and sources
- Establish indicators and thresholds
- Customer feedback and complaint handling
- Systematic literature reviews
- Integration with quality management system

Vigilance Reporting

Mandatory reporting of serious incidents and field safety corrective actions to competent authorities.

- Serious incidents: Report within 15 days
- Trend reporting for non-serious incidents
- Field Safety Notices (FSN) to users
- Field Safety Corrective Actions (FSCA)
- Reporting through EUDAMED

PSUR Requirements

Periodic Safety Update Reports (PSUR) provide a risk-benefit evaluation based on post-market data.

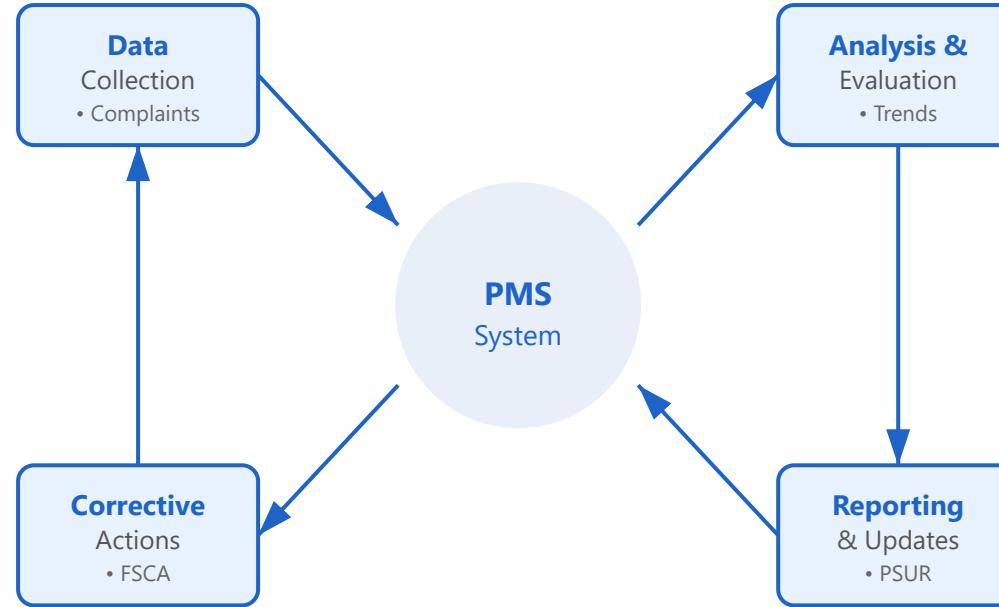
- Class IIa: At least every 2 years
- Class IIb: At least annually
- Class III: At least annually
- Summary of PMS data and trends
- Updated benefit-risk determination

PMCF Activities

Post-Market Clinical Follow-up is a continuous process to update clinical evaluation throughout device lifetime.

- PMCF plan as part of PMS plan
- Proactive data collection through studies
- Analysis of registries and databases
- PMCF evaluation report
- Mandatory for Class III and implantable devices

Post-Market Surveillance Cycle



Key Performance Indicators

Effective PMS systems track complaint rates, serious incident frequency, return rates, customer satisfaction scores, and trend analysis. Manufacturers must establish clear thresholds that trigger investigations and potential corrective actions to ensure ongoing device safety.



5. UKCA Divergence

Post-Brexit UK Regulatory Requirements

Post-Brexit Landscape

Following Brexit, the UK established its own regulatory framework requiring UKCA marking for devices placed on the Great Britain market.

- UKCA marking required since July 1, 2023
- UK MDR 2002 (as amended) applies
- Separate from EU MDR requirements
- Northern Ireland follows EU rules (CE marking)

UK Approved Bodies

UK Approved Bodies replace EU Notified Bodies for conformity assessment in Great Britain.

- UK Approved Body assessment required
- Cannot use EU Notified Body certificates for UKCA
- Re-certification may be necessary
- MHRA maintains list of UK Approved Bodies
- Different body numbering system

Dual Marking Strategy

Manufacturers selling in both markets must consider dual compliance strategies.

- CE marking for EU/EEA market access
- UKCA marking for Great Britain market

Key Differences & Requirements

While broadly aligned, some divergences exist between UK and EU requirements.

- UK Responsible Person instead of EU Authorized Rep

- Both markings may appear on device
- Separate technical documentation may be needed
- Cost and timeline implications

- MHRA registration instead of EUDAMED
- Different language requirements for IFU
- Potential future regulatory divergence
- Separate vigilance reporting systems

Market Access Comparison

EU/EEA Market

- CE Marking
- MDR 2017/745
 - Notified Body
 - EU Auth. Rep.
 - EUDAMED



UK (GB) Market

- UKCA Marking
- UK MDR 2002
 - UK Approved Body
 - UK Resp. Person
 - MHRA Registration



Different regulatory pathways - separate compliance required

💡 Strategic Consideration

A medical device manufacturer targeting both EU and UK markets must work with both an EU Notified Body and a UK Approved Body, appoint separate legal representatives (EU Authorized Representative and UK Responsible Person), maintain

dual registrations (EUDAMED and MHRA), and ensure labeling meets both CE and UKCA requirements. This dual compliance pathway significantly increases regulatory costs and complexity, requiring careful strategic planning for market entry.

Important Note

Northern Ireland remains aligned with EU regulations under the Northern Ireland Protocol. Devices for Northern Ireland market require CE marking and compliance with EU MDR, while Great Britain (England, Scotland, Wales) requires UKCA marking.

Manufacturers must carefully consider their target markets when planning regulatory strategy.