



EUROPEAN UNION MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering the EU market

START HERE: WHAT IS THE PRODUCT IN THE EU?

1 Confirm EU regulatory identity

Confirm intended purpose, claims, users, technology, accessories, software content, and whether the product is a medical device under MDR 2017/745 rather than another framework. Consider borderline and combination-product questions.



General medical device



Sterile / measuring / reusable



Software / active / implantable

2 Choose the MDR regulatory route

CLASS I



Low risk

Self-declaration for most non-sterile Class I devices.

CLASS Is / Im / Ir



Special Class I

Limited Notified Body involvement for sterile, measuring, or reusable surgical instruments.

CLASS IIa



Low-moderate risk

Notified Body conformity assessment required.

CLASS IIb



Moderate-high risk

Deeper Notified Body review and stronger clinical expectations.

CLASS III



Highest risk

Strongest conformity-assessment and clinical-evidence burden.

Classification is rule-based under MDR Annex VIII.
When more than one rule applies, the strictest applicable rule governs.

3 Build the EU market-access infrastructure



MDR / competent authority

Understand MDR 2017/745 requirements and leverage guidance from EU competent authorities and MDCG.



EU Authorized Representative

Appoint an EU Authorized Representative (if not established in the EU) with written mandate.



Notified Body / QMS

Engage the right Notified Body and operate an ISO 13485-aligned QMS that meets MDR QMS requirements.



EUDAMED / UDI / economic operators

Register in EUDAMED, obtain UDI-DI, and ensure economic-operator registrations are complete and current.

4 Build the evidence stack



Administrative

Technical documentation, device description, intended use, claims, and regulatory history.



Quality / QMS

ISO 13485-aligned QMS with design controls, supplier management, and CAPA.



Safety & performance

Demonstrate GSPR conformance with bench, biocompatibility, electrical, software, and usability evidence as applicable.



Clinical evaluation

Robust clinical evaluation per MDR; plan and execute PMCF as required.



Labeling / UDI

Compliant labeling, IFU, symbols, warnings, and UDI on device and packaging.



RA TRAP TO AVOID

Not all Class I devices are self-declared. Software, sterility, measuring functions, reusable surgical instruments, implantable or invasive characteristics, and accessories may move the route or require Notified Body involvement.



STRATEGIC INSIGHT

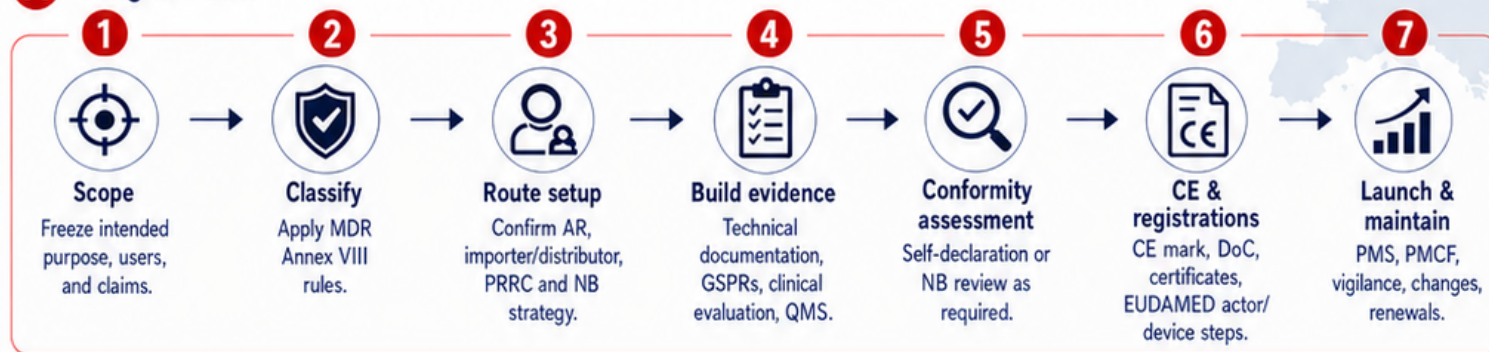
Freeze intended purpose and classification early. Then align the right Notified Body, evidence strategy, and economic-operator setup to keep your MDR market-access plan efficient and audit-ready.



EUROPEAN UNION MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

From classification to commercialization — with the decision points a newer RA professional should watch

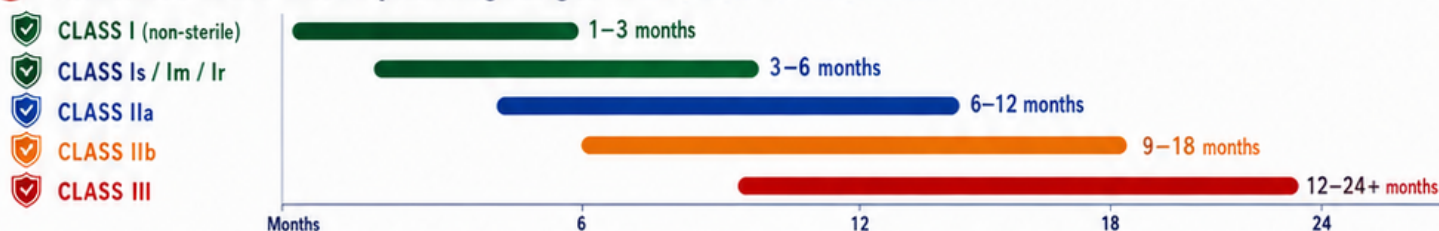
A Program flow



B What gets heavier as the class rises?

Signal	CLASS I	CLASS Is / Im / Ir	CLASS IIa	CLASS IIb	CLASS III
Pathway intensity	Self-declaration	Limited NB involvement	NB assessment	Deeper NB assessment	Strongest NB assessment
Evidence intensity	Lower	Moderate	Moderate	High	Very high
Clinical evidence	Clinical evaluation required but lighter	Focused evidence as applicable	Stronger clinical evaluation	Stronger clinical evidence	Strongest clinical evidence
QMS readiness	Basic-moderate	Stronger QMS	Stronger QMS	Very strong QMS	Highest QMS rigor
Post-market control	PMS lower	PMS moderate	PMS + PMCF as applicable	Higher PMS	Highest PMS and PMCF

C Indicative route-based planning ranges *Planning ranges only — not guarantees.*



Timing depends on classification, NB capacity, evidence maturity, translations, and product complexity.

D Labeling & language essentials

1 Member-State languages

Labeling and IFU must meet each target Member State's language rules.

2 Label & symbols

MDR Annex I information, CE mark, UDI where required, warnings, symbols.

3 IFU / eIFU / software UI

Ensure user information is clear; electronic IFU only where allowed; software/UI localization may matter.

4 Claims control

Claims must stay within intended purpose and be supported by evidence.

5 Traceability

Maintain UDI records, certificates, economic-operator data, and EUDAMED consistency.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- Regulation (EU) 2017/745 (MDR) — EUR-Lex
- European Commission Medical Devices pages — ec.europa.eu/health/medtech
- EUDAMED overview and modules — ec.europa.eu/tools/eudamed
- MDCG guidance on classification, software, clinical evaluation, PMS — ec.europa.eu/health/md_sector/new_regulations/guidance_en
- NANDO database for Notified Bodies — ec.europa.eu/growth/tools-databases/nando



IMPORTANT

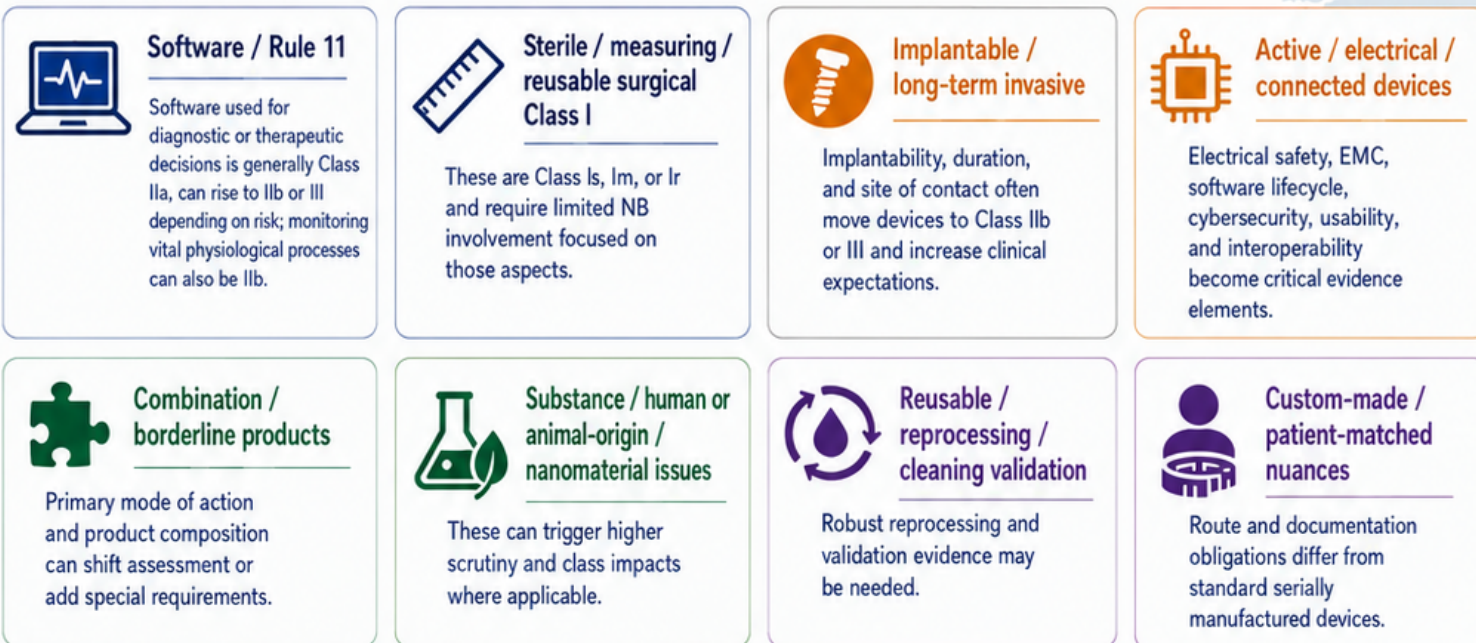
Product-specific MDR requirements, standards, Notified Body scope, and national language rules govern.
Confirm current requirements before execution.



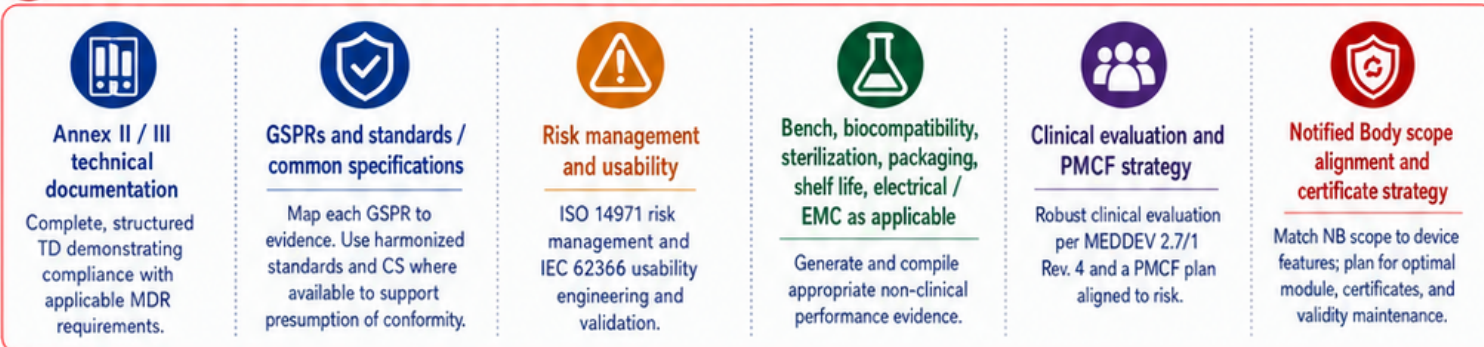
EUROPEAN UNION MEDICAL DEVICE: DEVICE-TYPE DECISION POINTS

Use this page to identify characteristics that change classification, evidence burden, or the conformity-assessment path.

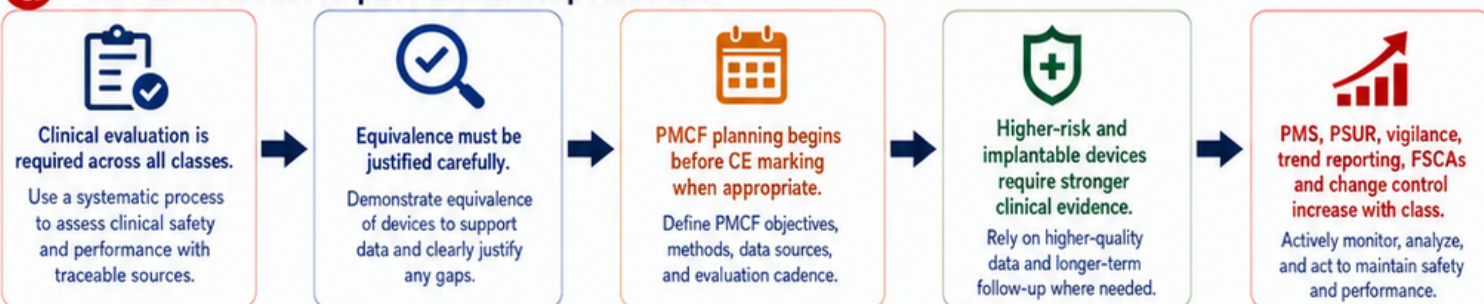
E High-impact device-type decision points



F Technical documentation & evidence focus



G Clinical evidence & post-market expectations



STRATEGIC INSIGHT

Many EU timelines are driven less by authority clocks and more by classification, the availability and scope of the right Notified Body, and the maturity of the technical and clinical evidence. Start with the right classification and evidence plan.





EUROPEAN UNION MEDICAL DEVICE: EXECUTION READINESS

Operational details that most often affect launch timing, compliance readiness, and post-market control.

H 2026 EUDAMED readiness

As of 28 May 2026, the first four EUDAMED modules are mandatory to use:



Actor registration

Register your organization and maintain accurate organization data.



UDI / Device registration

Register devices, assign UDI-DI and link to basic device data.



Notified Bodies & Certificates

View and rely on NB and certificate data published in EUDAMED.



Market Surveillance

Access and exchange information to support market surveillance.



Note: Vigilance / PMS and Clinical Investigations modules are not yet mandatory in May 2026.

I Economic operators & role clarity



Manufacturer

Legally responsible for conformity, technical documentation, and compliance.



EU Authorized Representative

Acts on behalf of the manufacturer for regulatory obligations in the EU.



Importer

Places a device from outside the EU on the EU market and takes related responsibilities.



Distributor

Makes devices available on the EU market in the supply chain; not a legal manufacturer.



PRRC

Person Responsible for Regulatory Compliance (where required).

J Change, certificate, and lifecycle control



Significant changes can affect certificates or require reassessment.



Maintain NB communication and certificate validity.



Keep EUDAMED and UDI data current.



Manage complaints, vigilance, FSCA, CAPA, and trends.



Renew and update documentation as required.

K Regulatory readiness checklist



Intended purpose frozen enough to classify reliably.



Annex VIII rationale documented.



Class Is / Im / Ir and Rule 11 assessed where relevant.



NB selected for the correct scope.



AR / importer / distributor / PRRC responsibilities assigned.



Technical documentation and GSPR evidence are ready.



Clinical evaluation / PMCF strategy is proportionate.



Language, IFU, UDI and EUDAMED plans are launch-ready.



PMS / vigilance / change-control system is established.



RA TRAP TO AVOID

Do not assume the EU is a single-country launch from a labeling or economic-operator perspective. Member-State language rules, operator setup, and NB scope can all change the practical path.



USE THE TIMELINES AS PLANNING RANGES, NOT REGULATORY PROMISES

Actual timing depends on class, evidence maturity, NB availability, testing, translations, and product complexity. Build a device-specific EU critical path before committing launch dates.