



ITALY MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering Italy

1 Confirm EU / Italian regulatory identity

Confirm intended purpose, technology, and target users.
Determine whether the device is software, active, implantable, sterile, measuring, or reusable surgical.

Apply EU MDR classification rules and consider any Italian national execution overlays.



General device



Sterile / measuring / reusable



Software / active / implantable

2 Choose the regulatory route

CLASS I



Low risk

- Most Class I devices self-declare under MDR.
- Conformity assessment without Notified Body (NB) involvement.
- Class Is / Im / Ir have limited NB involvement.

CLASS IIa



Low-moderate risk

- Require Notified Body (NB) intervention.
- NB assesses technical documentation and QMS as applicable.

CLASS IIb



Moderate-high risk

- Require NB assessment of design dossier and QMS.
- Increased scrutiny of performance, safety, and clinical evidence.

CLASS III



Highest risk

- Require NB assessment of full design dossier, clinical evaluation, and QMS.
- Most stringent review and ongoing compliance.



Classification under EU MDR (Regulation (EU) 2017/745) drives the conformity assessment route.
Most Classes IIa–III require Notified Body assessment with increasing depth and oversight.

3 Build the Italian market-access infrastructure



EU MDR + Ministry of Health context

Devices must meet EU MDR requirements. Italy may apply national execution steps via Ministry of Health processes and databases.



EU Authorized Representative if outside EU

Non-EU manufacturers must appoint an EU Authorized Representative (AR) listed in EUDAMED SRN before placing on the Italian market.



EUDAMED / UDI / economic-operator setup

Register in EUDAMED (SRN), assign UDI-DI and UDI-PI, and ensure accurate economic operator data for smooth market access.



Italy national device-database / local execution readiness

Be prepared for Italy's device database and local execution requirements (e.g., registration, listing, language, post-market activities) as applicable.

4 Build the evidence stack



Administrative

Company, device, classification, intended purpose, risk analysis, and regulatory strategy documentation.



Quality / QMS

MDR-compliant QMS (ISO 13485) and applicable Annex IX assessment for the device class.



Technical verification

Design & performance verification, safety, biocompatibility, EMC, software lifecycle (as applicable).



Clinical evaluation / software / usability

Clinical evaluation per MDR, PMCF plan, software validation, usability engineering and risk management.



Labeling / IFU

Italian-language labeling and IFU, UDI on label, symbols, warnings, and storage conditions.



RA TRAP TO AVOID

Do not assume EUDAMED alone closes all local Italian execution steps. Confirm any current national database or Ministry of Health requirements.



STRATEGIC INSIGHT

Italy is MDR route plus local execution — align the CE path early, then localize for Italian language, national database expectations, and post-market readiness.



ITALY MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

From MDR classification to Italian market execution — with the issues 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	Low ● ● ● ● ●	Low–moderate ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Evidence intensity	Basic ● ● ● ● ●	Basic–moderate ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Clinical support	Not typically required ● ● ● ● ●	Limited ● ● ● ● ●	Moderate ● ● ● ● ●	Extensive ● ● ● ● ●	Extensive ● ● ● ● ●
QMS readiness	Basic ● ● ● ● ●	Basic–moderate ● ● ● ● ●	Moderate ● ● ● ● ●	Strong ● ● ● ● ●	Very strong ● ● ● ● ●
Post-market surveillance	Basic ● ● ● ● ●	Basic–moderate ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual timing depends on product complexity, evidence quality, Notified Body workload, and national processes.



D Labeling & local execution essentials

IT Italian-language labeling / IFU readiness All labeling, IFU, and patient information must be in Italian. Translations must be accurate, current, and validated.	Ministry of Health and national database context Device registration and database processes in Italy continue to apply alongside MDR obligations.	EUDAMED / UDI readiness Assign UDI-DI and UDI-PI. Be ready for EUDAMED data submission and actor registration requirements.	Importer / distributor and economic-operator obligations Ensure contracts, traceability, role clarity, and obligations for importers, distributors, and AR (if any).	Claims control Claims must be truthful, verifiable, supported by evidence, and compliant with Italian and EU rules.	Vigilance / FSQA readiness Maintain procedures for vigilance reporting, trend review, FSQA, and field safety corrective actions in Italian.
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While EUDAMED is mandatory for the first four modules from 28 May 2026, Italy continues to maintain important national device-database and Ministry operational processes that should be confirmed at execution.



PRIMARY RESOURCES USED FOR THIS TRAINING AID

- Regulation (EU) 2017/745 (MDR) — Official Journal of the EU — eur-lex.europa.eu
- European Commission — Medical devices sector — ec.europa.eu/health/medical-devices
- EUDAMED — Overview and timelines — ec.europa.eu/tools/eudamed
- Italy Ministry of Health — Medical devices registration pages — salute.gov.it (Dispositivi medici)
- Italian UDI system and national database pages — salute.gov.it (Banca dati dispositivi medici)



IMPORTANT

Current MDR and Italian operational requirements govern. Confirm classification, evidence, labeling, and submission obligations before execution.