ITALY IVD REGULATORY MAP

A practical orientation for global RA teams entering Italy

START HERE: WHAT IS THE PRODUCT IN ITALY?

1 Confirm Italian regulatory identity

Confirm intended use, whether the item is an IVD reagent, analyzer/instrument, or software/other, and determine classification under EU IVDR as applied in Italy. Italy follows Regulation (EU) 2017/746 (IVDR) with national implementation under Legislative Decree 138/2022.

- IVD reagent
- Analyzer / instrument
- Software / other

2 Choose the regulatory route

CLASS A	CLASS B	CLASS C	CLASS D
Lowest risk	Moderate risk	Higher risk	Highest risk
Generally self-declared for non-sterile Class A.	Notified Body conformity assessment required.	Notified Body conformity assessment required; stronger evidence and technical-document scrutiny.	Strongest regulatory scrutiny; Notified Body assessment and highest-risk route.

This is the EU IVDR class framework used in Italy. Regulatory route intensity increases from Class A (lowest) to Class D (highest).

3 Build the Italy market-access infrastructure

EU IVDR / Italy environment

CE-marked IVDR pathway. Ministry of Health oversight and national implementation under Legislative Decree 138/2022.

EU Authorized Representative (where needed)

Required for non-EU manufacturers. Authorize and maintain mandate; ensure scope and contact details are current and valid.

EUDAMED / operator setup

Economic operator registration, SRN, UDI/device registration, and importer/distributor readiness. As of 28 May 2026, the Actor, UDI/Device, Notified Bodies & Certificates, and Market Surveillance modules in EUDAMED are mandatory.

Italian labeling / commercialization readiness

Prepare Italian-language labeling and IFU. Establish distribution setup and confirm market-launch readiness in Italy.

4 Build the evidence stack

Administrative
MAH/manufacturer details, SRN, mandates, product configuration.

Quality / QMS
IVDR QMS requirements, processes, risk management, CAPA.

Analytical performance
Performance evaluation plan, methods, studies, results.

Clinical / scientific performance
Clinical performance evaluation, PMCF, literature, state-of-the-art, CDx claims.

Labeling & IFU
Italian-language labeling & IFU, symbols, UDI, content verification.

RA TRAP TO AVOID

Don't start with a timeline. Start with classification -> economic-operator setup -> labeling (Italian) -> evidence -> regulatory route. Getting the order wrong creates rework.

STRATEGIC INSIGHT:

Italy is an IVDR route plus country-specific language and implementation details. Get the class right first, then localize smartly.

Training overview — verify current product-specific requirements with official IVDR and Italian Ministry of Health sources. Not legal advice.

ITALY IVD: HOW THE WORK ACTUALLY FLOWS

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

A Program flow

1. **Scope** — Define intended use and product family.
2. **Classify** — Apply EU IVDR classification (Classes A–D) as used in Italy.
3. **Route selection** — Confirm self-declaration for non-sterile Class A or Notified Body pathway for Classes B–D.
4. **Local setup** — Confirm EU Authorized Representative if needed, economic-operator setup, and importer/distributor readiness.
5. **Evidence** — Analytical performance, clinical/scientific performance, technical documentation, and labeling package.
6. **Submit / register** — CE/IVDR conformity route, EUDAMED registrations, certificates as applicable.
7. **Launch / maintain** — Market authorization, post-market surveillance, vigilance, changes, and commercialization.

B What gets heavier as the class rises?

Signal	CLASS A	CLASS B	CLASS C	CLASS D
Pathway intensity: Class A self-declaration (non-sterile A); Classes B–D Notified Body assessment.	Self-declaration (non-sterile A) ●○○○○	Notified Body assessment ●●○○○	Notified Body assessment ●●●○○	Notified Body assessment ●●●●●
Analytical performance	Basic ●○○○○	Moderate ●●○○○	High ●●●○○	Very high ●●●●●
Clinical / scientific support: Performance evaluation required across classes; burden increases with risk.	Basic ●○○○○	Moderate ●●○○○	High ●●●○○	Very high ●●●●●
QMS readiness	Basic ●○○○○	Moderate ●●○○○	High ●●●○○	Very high ●●●●●
Post-market control	Lower ●○○○○	Moderate ●●○○○	Higher ●●●○○	Highest ●●●●●

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual timing depends on device complexity, evidence quality, Notified Body access, and dossier completeness.

These are planning ranges, not official review clocks. Actual duration varies by product, Notified Body workload, and completeness of submission.

D Labeling & language essentials

- **Italian-language support** — Labels and IFU should be available in Italian for the Italian market.
- **Product labeling** — Include required identifiers, warnings, precautions, and applicable symbols.
- **Instructions for use** — Provide complete, understandable IFU in Italian.
- **Claims control** — Claims must be supported by evidence and consistent with intended use.
- **Product identifier / traceability docs** — Implement UDI and maintain traceability documentation.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- European Commission — EUDAMED Overview
- European Commission — Actor registration / UDI-Device registration
- Ministero della Salute — Procedure di valutazione della conformità dei dispositivi medico-diagnostici in vitro
- Ministero della Salute — UDI system / device identification
- Hopestone Capital & Consulting — hopestonecapital.com

IMPORTANT

Product-specific Italian and EU IVDR requirements govern. Current official sources should always be confirmed before execution.

Training overview — verify current product-specific requirements with official IVDR and Italian Ministry of Health sources. Not legal advice.

