SPAIN IVD REGULATORY MAP

A practical orientation for global RA teams entering Spain

START HERE: WHAT IS THE PRODUCT IN SPAIN?

1 Confirm Spanish regulatory identity

Confirm the intended use, specimen type, and whether the item is an IVD reagent, analyzer/instrument, software, or other. Classification and registration obligations depend on the degree of risk to human health under the EU IVDR framework.

- IVD reagent
- Analyzer / instrument
- Software / other

2 Choose the regulatory route

CLASS A
Lowest risk

Self-declaration route

Non-sterile Class A devices are self-declared under the EU IVDR with an internal technical documentation file.

CLASS B
Low to moderate risk

Notified Body route

Requires a Notified Body conformity assessment and CE marking under EU IVDR.

CLASS C
High risk

Notified Body route

Requires a Notified Body conformity assessment with stronger performance evaluation and expectations.

CLASS D
Highest risk

Notified Body route

Highest-risk devices with the strongest evidence and oversight expectations before CE marking.

3 Build the Spain market-access infrastructure

EU IVDR / AEMPS environment

Comply with EU IVDR requirements and Spanish competent authority oversight by AEMPS for vigilance, market surveillance, and local inspections.

EU Authorized Representative (if outside EU)

Appoint an EU Authorized Representative for non-EU manufacturers to act as your single point of contact.

EUDAMED / operator setup and Spanish interface

Register in EUDAMED, obtain SRN, and designate an economic operator. Ensure a smooth interface with Spanish authorities and market surveillance.

Product-specific standards, QMS, and importer/ distributor readiness

Align with relevant standards, a QMS (e.g., ISO 13485), and prepare import/distribution arrangements in Spain.

4 Build the evidence stack

Administrative
Technical documentation, UDF, certificates, economic operator details, registration evidence, and correspondence logs.

Quality
QMS design controls, supplier management, risk management, and process validation.

Analytical performance
Performance, method comparison, accuracy, precision, reference materials, stability.

Clinical / scientific support
Clinical evaluation, literature, PMS plan, risk-benefit analysis, PMCF strategy, and scientific rationale.

Labeling & IFU
Spanish-language labeling and IFU, intended use, contraindications, warnings, and symbols per IVDR.

RA TRAP TO AVOID

Do not assume CE marking alone is the full Spain market-entry plan. Language, operator setup, and documentation strategy matter as much as compliance. Get local readiness right from the start.

STRATEGIC INSIGHT

Integrate IVDR class strategy, Notified Body timing, Spanish-language materials, and local commercialization readiness early to prevent delays, rework, and market-access friction.

Training overview — verify current product-specific requirements with AEMPS and your local AR.
Not legal advice.

SPAIN IVD: HOW THE WORK ACTUALLY FLOWS

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

A Program flow

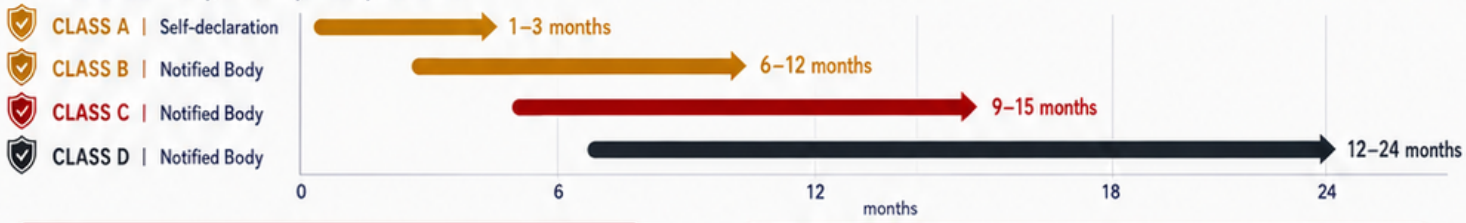
1. **Scope** — Define intended use, population and specimen type.
2. **Classify** — Per IVDR Annex VIII and MDCG 2021-24. Document rationale.
3. **AR / operator setup** — Appoint Authorized Representative (if non-EU) and legal manufacturer.
4. **Testing & performance evaluation** — Plan and conduct analytical, clinical (as applicable) and performance studies.
5. **Conformity assessment** — Engage a Notified Body and complete technical documentation review and assessment.
6. **Register / commercialize** — Register in EUDAMED; obtain CE mark and become available on the EU market.
7. **Launch & maintain** — Post-market surveillance, vigilance, trend reporting, and continual performance monitoring.

B What gets heavier as the class rises?

Signal	CLASS A	CLASS B	CLASS C	CLASS D
Premarket pathway	Self-declaration	Notified Body	Notified Body	Notified Body
Evidence intensity	Low ●○○○○	Moderate ●●○○○	High ●●●○○	Very high ●●●●●
Analytical performance	Basic ●○○○○	Moderate ●●○○○	High ●●●○○	Very high ●●●●●
Clinical / scientific support	Not usually required ●○○○○	Limited ●●○○○	Extensive ●●●●○	Extensive ●●●●●
Manufacturing / QMS readiness	Basic ●○○○○	Established ●●○○○	Strong ●●●●○	Very strong ●●●●●
Post-market surveillance	Basic ●○○○○	Enhanced ●●○○○	Intensive ●●●●○	Very intensive ●●●●●

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual timing depends on product type, clinical needs, Notified Body capacity, documentation maturity, and other product-specific factors.



Self-declaration (Class A) timelines are typically shorter but vary by product type and clinical claims.

Notified Body (Classes B–D) timelines depend on review complexity, documentation maturity, and product specifics.

D Labeling & language essentials

Spanish-language support — Provide Spanish versions of key materials (label, IFU, claims).

Product labeling — Labels must be in Spanish (Español); meet IVDR Annex I and EU labeling requirements.

Instructions for use — Spanish IFU required; follow IVDR template and include all mandatory elements.

Claims control — Claims must be truthful, verifiable, and consistent with evidence and labeling.

Product identifier & documentation — Use UDI per IVDR and retain technical documentation and records per Annex II.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- EUR-Lex: Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) – Official Journal of the EU
- European Commission – EUDAMED: https://ec.europa.eu/tools/eudamed
- AEMPS (Agencia Española de Medicamentos y Productos Sanitarios): https://www.aemps.gob.es
- IVDR MDCG Guidance Documents (e.g., MDCG 2021-24 Classification, MDCG 2021-6 Clinical Evaluation)

IMPORTANT: Product-specific requirements, standards, and recent regulatory changes govern. Confirm current requirements before execution.

