



EUROPEAN IVD REGULATORY GUIDE

A practical orientation for global RA teams entering the EU IVD market

START HERE: WHAT IS THE PRODUCT IN THE EU?

1 Confirm EU regulatory identity

Confirm the intended use, product family, and whether the item is an IVD reagent, analyzer/instrument, or software/other. Classification and obligations depend on the level of risk to human health and the IVDR framework.



IVD REAGENT



ANALYZER / INSTRUMENT



SOFTWARE / OTHER



2 Determine IVDR classification (Annex VIII)

CLASS A



Lowest risk

Self-declaration
(no Notified Body)

CLASS B



Low-moderate risk

Notified Body
conformity assessment
is required.

CLASS C



Moderate-high risk

Notified Body
conformity assessment
is required.

CLASS D



Highest risk

Notified Body
conformity assessment
is required.

As class increases from A to D, the level of Notified Body involvement and regulatory scrutiny increases. Class D = highest-risk route.

3 Establish EU market-access foundation



Actor & UDI/Device Registration
Register the manufacturer and devices in EUDAMED (Actor, UDI/Device modules). UDI is mandatory.



EU Authorized Representative (if outside EU)
Required for manufacturers established outside the EU.



Quality Management System (QMS)
QMS must be certified to ISO 13485 by a notified body for Classes B, C and D.



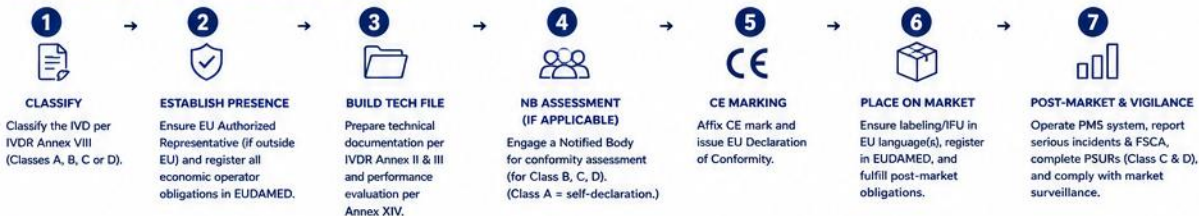
Clinical / Performance Evidence
Generate and document performance evaluation in accordance with IVDR requirements.

KEY RESOURCES

- IVDR (EU) 2017/746: eur-lex.europa.eu/eli/reg/2017/746
- EUDAMED: <https://webgate.ec.europa.eu/eudamed>
- European Commission – IVDR: ec.europa.eu/health/ivdr

- NANDO (Notified Bodies): <https://ec.europa.eu/tools/ecdem/nando/>
- MDCG (Medical Device Coordination Group): <https://health.ec.europa.eu/mdcg>
- Official Journal of the EU (OJ): <https://eur-lex.europa.eu/>

HOW THE WORK ACTUALLY FLOWS IN THE EU



B WHAT GETS HEAVIER AS THE CLASS RISES?

Signal	CLASS A (Self-declaration)	CLASS B (NB Assessment)	CLASS C (NB Assessment)	CLASS D (NB Assessment)
Premarket pathway	Self-declaration ● ○ ○	NB assessment ● ● ○ ○	NB Assessment ● ● ● ○	NB Assessment ● ● ● ●
Evidence intensity	Lower ● ○ ○	Moderate ● ● ○ ○	High ● ● ● ○	Very high ● ● ● ●
Analytical performance	Basic ● ○ ○	Moderate ● ● ○ ○	High ● ● ● ○	Very high ● ● ● ●
Clinical / scientific support	Not usually required ● ○ ○	Limited ● ● ○ ○	Moderate ● ● ● ○	Extensive ● ● ● ●
Manufacturing / QMS readiness	Basic ● ○ ○	Moderate ● ● ○ ○	High ● ● ● ○	Very high ● ● ● ●
Post-market surveillance	Lower ● ○ ○	Moderate ● ● ○ ○	Higher ● ● ● ○	Highest ● ● ● ●

C INDICATIVE ROUTE-BASED PLANNING RANGES*

	CLASS A	Self-declaration (no NB)	2 – 6 weeks
	CLASS B	NB assessment	6 – 12 months
	CLASS C	NB assessment	9 – 15 months
	CLASS D	NB assessment	12 – 24+ months

*Planning ranges are Hopestone estimates, not ANSM or Notified Body review clocks. Actual duration depends on classification, NB capacity, evidence maturity and EUDAMED readiness.

D LABELING & LANGUAGE ESSENTIALS



French labeling / IFU readiness
French is required for labeling, IFU and certain user information.



Instructions for use
IFU must be in French and follow IVDR Annex I Section 20 requirements.



EUDAMED & UDI
EI UDI & device registration in EUDAMED are mandatory.

E PRIMARY OFFICIAL RESOURCES

- IVDR (EU) 2017/746**
<https://eur-lex.europa.eu/eli/reg/2017/746>
- EUDAMED**
<https://webgate.ec.europa.eu/eudamed>
- European Commission – IVDR**
<https://health.ec.europa.eu/ivdr-regulation>
- NANDO (Notified Bodies)**
<https://ec.europa.eu/tools/ecdem/nando/>
- MDCG (Medical Device Coordination Group)**
<https://health.ec.europa.eu/mdcg>



RA TRAP TO AVOID

Placing a Class B–D device on the EU market without the appropriate Notified Body conformity assessment and EUDAMED registration. This is a compliance violation.



STRATEGIC INSIGHT

Invest early in evidence generation, QMS maturity, and EUDAMED readiness. The biggest drivers of timeline are evidence complexity and NB capacity.



DISCLAIMER

This guide is for training and planning purposes only. Regulatory requirements may change. Always verify with official sources and your regulatory specialist.