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	CLASS B	CLASS C	CLASS D
Lowest risk	Low–moderate risk	Moderate–high risk	Highest risk
Self-declaration (no Notified Body)	Notified Body conformity assessment is required.	Notified Body conformity assessment is required.	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

1 CLASSIFY
Classify the IVD per IVDR Annex VIII (Classes A, B, C or D).

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2 ESTABLISH PRESENCE
Ensure EU Authorized Representative (if outside EU) and register all economic operator obligations in EUDAMED.

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3 BUILD TECH FILE
Prepare technical documentation per IVDR Annex II & III and performance evaluation per Annex XIV.

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4 NB ASSESSMENT (IF APPLICABLE)
Engage a Notified Body for conformity assessment (for Class B, C, D). (Class A = self-declaration.)

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5 CE MARKING
Affix CE mark and issue EU Declaration of Conformity.

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6 PLACE ON MARKET
Ensure labeling/IFU in EU language(s), register in EUDAMED, and fulfill post-market obligations.

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7 POST-MARKET & VIGILANCE
Operate PMS system, report serious incidents & FSCA, complete PSURs (Class C & D), and comply with market surveillance.

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.

STRATEGIG 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.

