FRANCE IVD REGULATORY MAP

A practical orientation for global RA teams entering France

START HERE: WHAT IS THE PRODUCT IN FRANCE?

1 Confirm French regulatory identity

France follows EU IVDR. Confirm the intended use, product family, and whether the item is an IVD reagent, analyzer/instrument, software/other, self-test, or near-patient test.

IVD reagent | Analyzer / instrument | Software / other | Self-test | Near-patient test

2 Choose the regulatory route

CLASS A — Lowest risk

Non-sterile Class A devices have the lightest regulatory route (self-certification).

CLASS B — Low–moderate risk

Requires involvement of a Notified Body for assessment of technical documentation.

CLASS C — Moderate–high risk

Notified Body conformity assessment is required. The applicable IVDR conformity-assessment route depends on device class and the selected Annex IX, X, or XI pathway.

CLASS D — High risk

Notified Body assessment is required; additional Class D mechanisms may apply depending on the device, including EU reference-laboratory involvement where applicable.

France uses the EU IVDR classification framework.

Non-sterile Class A = lightest route. Classes B–D require increasing Notified Body involvement. Class D = highest-risk route.

3 Build the France market-access infrastructure

IVDR / CE marking & ANSM environment

Ensure compliance with EU IVDR requirements and maintain awareness of ANSM guidance, vigilance practices, and local enforcement priorities.

EU Authorized Representative (where needed)

Use an EU Authorized Representative as required. Ensure clear roles, written mandate, and device/vigilance responsibilities are in place.

EUDAMED / importer-distributor / operator setup

Register in EUDAMED as required and set up French importer/distributor relationships and operator responsibilities with traceability.

French labeling / IFU readiness

French law requires French for end-user labeling, IFU, other Annex I Section 20 user information, the EU Declaration of Conformity, and field safety notices. Confirm commercialization readiness.

4 Build the evidence stack

Administrative
- Licences & registrations
- Device master data
- ANSM communications
- Market history

Quality / QMS
- QMS aligned to ISO 13485
- EU IVDR compliance
- Process validation
- CAPA & change control

Analytical performance
- Performance data
- Accuracy & precision
- Interference & robustness
- Stability

Clinical / scientific performance evaluation
- Clinical performance
- Scientific evaluation
- Report, risk controls, and claims

Labeling & IFU
- French labeling & IFU
- Annex I Sec. 20 info
- Symbols & warnings
- Operator instructions

RA TRAP TO AVOID

Do not hunt for a separate French classification pathway first — begin with the EU IVDR class → then localize for French language, operator setup, vigilance, and commercialization.

STRATEGIC INSIGHT

France is primarily an IVDR compliance plus French localization exercise. Lead with a robust EU dossier and execute strong French-specific readiness.

FRANCE IVD: HOW THE WORK ACTUALLY FLOWS

From EU IVDR classification to French commercialization

A Program flow

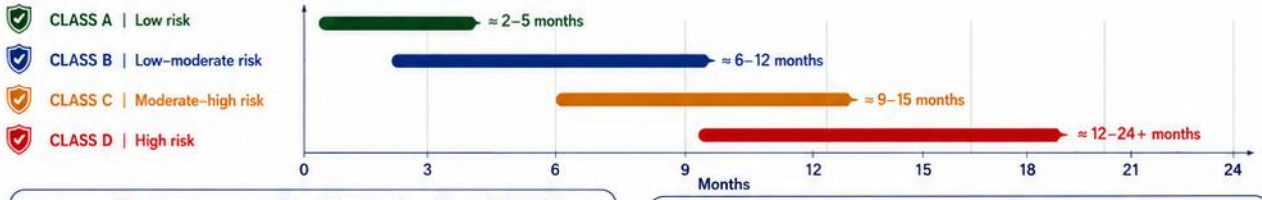
1. **Scope** — Define intended use and product family.
2. **Classify under IVDR** — Apply EU IVDR risk classification (Classes A–D).
3. **Authorized representative / economic operator setup** — Establish EU Authorized Representative if needed and ensure EU economic-operator obligations.
4. **CE / notified-body strategy** — Determine conformity-assessment route, select notified body where needed, and plan certification.
5. **Evidence & performance** — Generate and assess analytical performance, clinical/scientific performance, and overall safety/performance.
6. **French labeling & launch readiness** — Prepare French labeling/IFU, translations, UDI, and market-entry requirements.
7. **Vigilance / maintain** — Implement PMS, trend reporting, vigilance, and post-market updates.

B What gets heavier as the class rises?

Signal	CLASS A	CLASS B	CLASS C	CLASS D
Pathway intensity	Lowest ●	Low ●●	High ●●●	Very high ●●●●
Analytical performance	Basic ●	Moderate ●●	High ●●●	Very high ●●●●
Clinical / scientific support	Performance evaluation required ●	Performance evaluation required ●●	Performance evaluation required ●●●	Performance evaluation required ●●●●
QMS readiness	Basic ●	Moderate ●●	High ●●●	Very high ●●●●
Post-market surveillance	Low ●	Moderate ●●	High ●●●	Very high ●●●●

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual timing depends on notified body access, evidence quality, and translation/localization.



Planning ranges are Hopestone estimates, not ANSM or Notified Body review clocks. Actual duration depends on classification, NB capacity, evidence maturity, and translation/localization requirements.

French market entry requires CE marking under IVDR. Local labeling and language readiness are essential before launch.

D Labeling & language essentials

French-language labeling & IFU
Labels and IFU intended for use (IFU) must be in French for products supplied in France. Ensure clarity, accuracy, and readability.

Claims control
Claims must be supported by evidence and consistent with intended use and performance data.

UDI & operator information
Ensure current UDI-DI, operator (manufacturer / importer) details, and contact information.

Technical documentation control
Keep technical documentation up to date, controlled, and readily available.

KEY RESOURCES USED FOR THIS TRAINING AID

- ANSM – Dispositifs médicaux : information et guidance | ansm.sante.fr
- European Commission – Medical devices sector | ec.europa.eu/health/medical-devices-sector_en
- Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) | eur-lex.europa.eu/eli/reg/2017/746
- EUDAMED – European Database on Medical Devices | ec.europa.eu/tools/eudamed

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

STRATEGIC INSIGHT

Plan early for notified body engagement, evidence generation, French-language labeling, and market-launch readiness to avoid costly delays.

