



FRANCE MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering France

1 Confirm EU / French regulatory identity

Confirm intended purpose, technology, and target users.
Determine classification under the EU MDR (Annex VIII rules) and apply French national execution via ANSM.
Identify whether the device is software, active, implantable, sterile, measuring, or reusable surgical.



General device



Sterile / measuring / reusable



Software / active / implantable

2 Choose the regulatory route

CLASS I



Low risk

Most Class I devices self-declare CE compliance.
Class Is, Im, Ir require limited Notified Body involvement.

CLASS IIa



Low-moderate risk

Requires Notified Body conformity assessment.
Greater evidence and documentation expectations.

CLASS IIb



Moderate-high risk

Requires Notified Body conformity assessment.
Stronger clinical evidence and technical documentation.

CLASS III



Highest risk

Requires Notified Body conformity assessment.
Most stringent evidence, clinical evaluation, and post-market obligations.

Under the EU MDR, Classes IIa, IIb, and III require increasing levels of Notified Body involvement.
National rules via the ANSM apply to market access, vigilance, and local obligations.

3 Build the French market-access infrastructure



EU MDR + ANSM context

EU MDR sets the framework; ANSM executes national requirements for market access, vigilance, and local obligations.



EU Authorized Representative

Required for manufacturers established outside the EU.
Select and document your EU AR.



EUDAMED / UDI / importer-distributor setup

Register in EUDAMED (actors & devices), assign UDI-DI, and establish importer/distributor arrangements in France.



French language & vigilance readiness

All labeling and IFU must be in French. Prepare vigilance, FSN/FSCA, and PMS to meet ANSM expectations.

4 Build the evidence stack



Administrative

Device description, intended use, classification rationale, ANSM registrations, and local contacts.



Quality / QMS

ISO 13485-aligned QMS with CAPA, supplier control, traceability, and risk management.



Technical verification

Safety, performance, EMC, biocompatibility, sterility, and software verification as applicable.



Clinical evaluation / software / usability

Clinical evaluation per MDR, usability engineering, and software validation (if applicable).



Labeling / IFU

French-language labeling & IFU, symbols (MDR), UDI, and performance claims.



RA TRAP TO AVOID

Do not wait until the end to localize French-language materials. Late translations can delay ANSM market access and launch.



STRATEGIC INSIGHT

France is an MDR route plus strong localization country — align the CE path early, then build French labeling, IFU, FSN, and vigilance readiness into the project plan.



FRANCE MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

From MDR classification to French market execution — with the issues a newer RA professional should watch



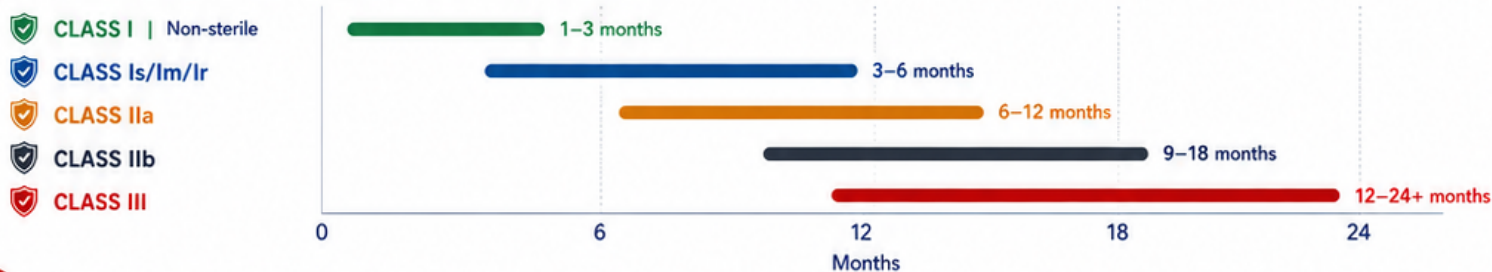
A Program flow



B What gets heavier as the class rises?

Signal	CLASS I	CLASS Is/Im/Ir	CLASS IIa	CLASS IIb	CLASS III
Pathway intensity	Low ● ● ● ● ●	Low-moderate ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Evidence intensity	Basic ● ● ● ● ●	Basic-moderate ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Clinical support	Usually not required ● ● ● ● ●	Limited ● ● ● ● ●	Moderate ● ● ● ● ●	Strong ● ● ● ● ●	Extensive ● ● ● ● ●
QMS readiness	Basic ● ● ● ● ●	Basic-moderate ● ● ● ● ●	Moderate ● ● ● ● ●	Strong ● ● ● ● ●	Very strong ● ● ● ● ●
Post-market surveillance	Basic ● ● ● ● ●	Basic-moderate ● ● ● ● ●	Moderate ● ● ● ● ●	Strong ● ● ● ● ●	Very strong ● ● ● ● ●

C Indicative route-based planning ranges *Hopstone planning ranges only.*



D Labeling & language essentials

French-language labeling and IFU
All labeling and IFU must be in French. Translations must be accurate, complete, and validated.

Implant / patient information
Implant-patient information and implant card must be provided in French.

French-language FSNs
All Field Safety Notices (FSNs) must be issued in French.

Claims control
Claims must be truthful, verifiable, supported by evidence, and in French.

ANSM / materiovigilance awareness
Follow ANSM vigilance requirements and materiovigilance reporting obligations.

EUDAMED / UDI readiness
Ensure UDI assignment and registration in EUDAMED (where applicable) are completed.

From 22 April 2026, French law requires end-user/patient labeling, IFU, other Annex I section 23 information, implant-patient information, the EU declaration of conformity naming the marketed device, and field safety notices in French.



PRIMARY RESOURCES USED FOR THIS TRAINING AID

- Regulation (EU) 2017/745 (MDR) <https://eur-lex.europa.eu/eli/reg/2017/745>
- European Commission – Medical devices sector https://health.ec.europa.eu/medical-devices-sector_en
- EUDAMED Overview <https://ec.europa.eu/tools/eudamed>
- ANSM – Agence nationale de sécurité du médicament et des produits de santé <https://ansm.sante.fr>
- Légifrance – Article R5211-3 (Public Health Code) <https://www.legifrance.gouv.fr>



IMPORTANT

French legal language requirements and product-specific MDR rules govern. Confirm classification, evidence, labeling, and submission obligations before execution.