



BELGIUM MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering Belgium

START HERE: WHAT IS THE PRODUCT IN BELGIUM? ▶

1 Confirm Belgian regulatory identity

Confirm the intended purpose, users, claims, technology, and whether the product is a medical device under the EU MDR.
Identify device type triggers such as general device, sterile/measuring/reusable surgical, software/active/implantable.
Determine classification under MDR Annex VIII and whether a non-EU manufacturer needs an EU Authorized Representative.



General medical device



Sterile / measuring / reusable



Software / active / implantable

2 Choose the MDR regulatory route

CLASS I



Lowest risk

Self-declaration for most non-sterile Class I devices.

CLASS Is / Im / Ir



Special Class I

Limited Notified Body involvement for sterility, measuring function, or reusable surgical aspects.

CLASS IIa / IIb



Higher risk

Notified Body conformity assessment with stronger technical, clinical and QMS scrutiny.

CLASS III



Highest risk

Strongest conformity assessment and clinical-evidence expectations.

Classification is rule-based under MDR Annex VIII.
The strictest applicable rule determines the device class.

3 Build the Belgium market-access infrastructure



EU MDR / FAMHP framework

Belgium applies the EU MDR and the FAMHP is the competent authority.



EU Authorized Representative

Required for non-EU manufacturers.



EUDAMED / UDI readiness

Actor registration, UDI / device registration, certificates, and market-surveillance modules mandatory from 28 May 2026.



Language readiness

Safe-use information and IFU must support Belgian market needs in Dutch, French, and/or German depending on distribution territory and user.

4 Build the evidence stack



Administrative

Intended purpose, classification rationale, declarations (DoC), and economic-operator data and agreements.



Quality / QMS

ISO 13485 aligned QMS, design controls, supplier controls, process validation, and CAPA.



Safety / performance

Bench testing, biocompatibility, EMC / electrical safety, sterilization, software validation, usability, and risk management.



Clinical evaluation

MDR clinical evaluation with clinical evidence and PMCF / investigations where applicable.



Labeling & IFU

Safe-use information, CE / UDI content, warnings, claims, and user instructions.



RA TRAP TO AVOID

Do not treat Belgium as a separate premarket approval system after CE marking; the real execution risks are classification, NB scope, localization by region, EUDAMED readiness, and operator setup.



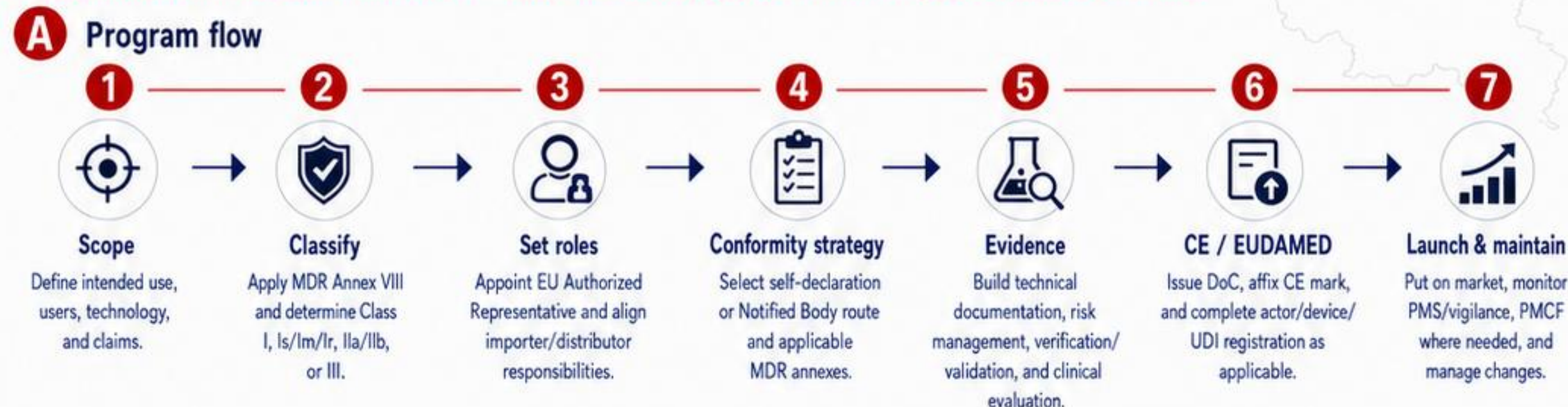
STRATEGIC INSIGHT:

Build the MDR route first, then localize Belgian distribution and language strategy early.



BELGIUM MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

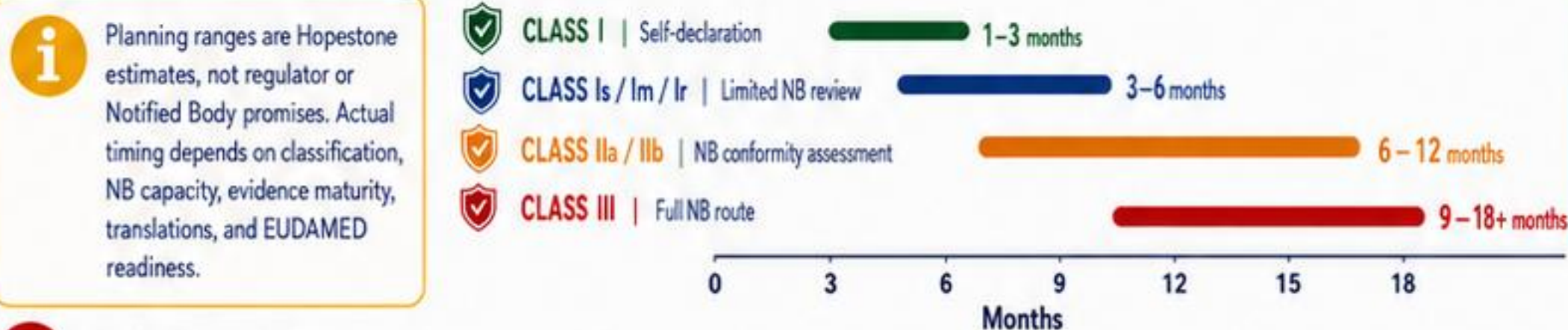
From classification to commercialization — with the decision points a newer RA professional should watch



B What gets heavier as the class rises?

Signal	CLASS I	CLASS Is / Im / Ir	CLASS IIa / IIb	CLASS III
Pathway intensity	Self-declaration ● ● ● ● ●	Limited NB involvement ● ● ● ● ●	Full NB assessment ● ● ● ● ●	Highest NB scrutiny ● ● ● ● ●
Evidence intensity	Basic ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Clinical / scientific support	Usually limited ● ● ● ● ●	Targeted ● ● ● ● ●	Significant ● ● ● ● ●	Extensive ● ● ● ● ●
Manufacturing / QMS readiness	Basic ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Post-market control	Lower ● ● ● ● ●	Moderate ● ● ● ● ●	Higher ● ● ● ● ●	Highest ● ● ● ● ●

C Indicative route-based planning ranges



L EUDAMED actor, UDI/device, certificates, and market-surveillance modules are mandatory from 28 May 2026.

D Labeling & language essentials

National language support
Use Dutch, French, and/or German according to Belgian market distribution and safe-use needs.

Labeling content
Meet MDR Annex I Section 23 content, CE mark, UDI, warnings, and operator information.

Instructions for use
Provide complete IFU; eIFU only where legally justified.

Claims control
Claims must align with intended purpose, evidence, and promotional controls.

Traceability / records
Maintain UDI and distribution traceability and support PMS/vigilance obligations.



PRIMARY RESOURCES USED FOR THIS TRAINING AID

- FAMHP** – Medical devices pages (FAMHP website)
https://www.famhp.be/en/medical_devices
- European Commission** – EUDAMED information
<https://health.ec.europa.eu/eudamed>
- EUR-Lex** – Regulation (EU) 2017/745 (MDR)
<https://eur-lex.europa.eu/eli/reg/2017/745/oj>
- Hopestone Capital & Consulting** — hopestonecapital.com



IMPORTANT

Product-specific MDR requirements, Notified Body expectations, and Belgian language obligations govern. Confirm current requirements before execution.