BELGIUM IVD REGULATORY MAP

A practical orientation for global RA teams entering Belgium.

START HERE: WHAT IS THE PRODUCT IN BELGIUM?

1 Confirm intended use and product family and whether the item is an IVD reagent/test kit, analyzer/instrument, or software/other. Commercialization is governed by EU IVDR with Belgium-specific oversight by FAGG / AFMPS (Federal Agency for Medicines and Health Products).

- IVD reagent / kit
- Analyzer / instrument
- Software / other

2 Choose the regulatory route

CLASS A
Lowest risk

Self-declaration route

Non-sterile Class A IVDs are generally self-declared by the manufacturer under the EU IVDR.

CLASS B
Moderate risk

Notified-body route

Moderate risk products require conformity assessment by a Notified Body with IVDR technical documentation review.

CLASS C
Higher risk

Notified-body route

Higher risk IVDs require Notified Body assessment with stronger scrutiny of performance evaluation and clinical evidence.

CLASS D
Highest risk

Notified-body route

Highest risk IVDs require the most comprehensive evidence and, where relevant, additional control mechanisms and review by Notified Body.

3 Build the Belgium market-access infrastructure

FAGG / AFMPS + IVDR framework

CE marking under IVDR with Belgium competent-authority oversight by FAGG / AFMPS.

EU authorized representative / importer setup

For non-EU manufacturers, appoint an EU Authorized Representative and define importer/distributor obligations.

Market-language strategy

Align labels and IFU to the marketed region: Dutch, French, and/or German as appropriate in Belgium.

EUDAMED / UDI / post-market readiness

Ensure actor registration, device registration, UDI assignment, and local traceability / vigilance alignment are in place.

4 Build the evidence stack

Administrative
QMS, PMS plan, risk management, supplier controls, supporting procedures and records.

Quality
ISO 13485, process validation, CAPA, change control, internal audits, management review.

Analytical performance
Method performance, precision, accuracy, linearity, LoD/LoQ, interference, robustness.

Clinical / scientific
Clinical performance study or literature evidence, clinical performance assessment.

Labeling & IFU
Compliant labels and IFU in required language(s); symbols, claims, and limitations clearly stated.

RA TRAP TO AVOID

Do not assume a single-language strategy covers all Belgium commercialization contexts. Align route, evidence, and region-appropriate localization early.

STRATEGIC INSIGHT

Belgium follows the EU IVDR route, but language planning, EUDAMED readiness, and importer/distributor execution heavily influence smooth market access.

BELGIUM IVD: HOW THE WORK ACTUALLY FLOWS

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

A Program flow

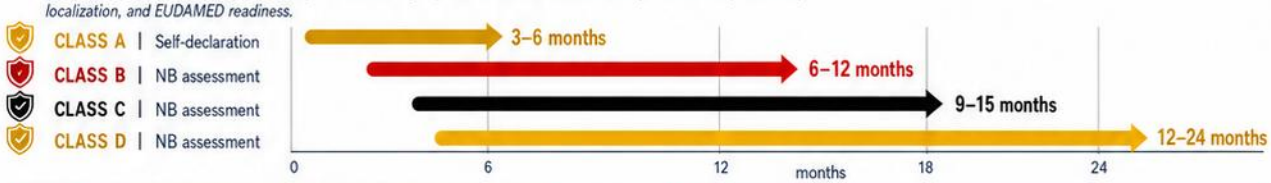
1. **Scope** — Define intended use, population and specimen type.
2. **Classify under IVDR** — A / B / C / D.
3. **Economic operator setup** — Appoint EU authorized representative (if needed).
4. **Standards / NB strategy** — Plan & complete standards mapping; select Notified Body approach.
5. **Evidence** — Compile technical documentation; risk management & performance evaluation.
6. **Register / certify** — EUDAMED actor/device registration and NB certification where needed.
7. **Launch & maintain** — CE mark, market release; PMS, vigilance, change control.

B What gets heavier as the class rises?

Signal	CLASS A	CLASS B	CLASS C	CLASS D
Premarket pathway	Self-declaration	NB assessment	NB assessment	NB assessment
Evidence intensity	Low ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High ● ● ● ○ ○	Very high ● ● ● ● ●
Analytical performance	Basic ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High ● ● ● ○ ○	Very high ● ● ● ● ●
Clinical / scientific support	Not usually required ● ○ ○ ○ ○	Limited ● ● ○ ○ ○	Substantial ● ● ● ○ ○	Extensive ● ● ● ● ●
Manufacturing / QMS readiness	Basic ● ○ ○ ○ ○	Strong ● ● ○ ○ ○	Very strong ● ● ● ○ ○	Highly robust ● ● ● ● ●
Post-market control	Basic reporting ● ○ ○ ○ ○	Enhanced ● ● ○ ○ ○	Strict ● ● ● ○ ○	Intensive ● ● ● ● ●

C Indicative route-based planning ranges

Hopestone planning ranges for timing only — actual timing depends on class, evidence maturity, notified-body availability, localization, and EUDAMED readiness.



Shorter timelines are more likely for Class A products with mature evidence and clear intended use.

Longer timelines reflect NB workload, clinical evidence generation, performance evaluation, and EUDAMED submission cycles.

D Labeling & language essentials

- **Regional language strategy** — Use Dutch, French, and German as appropriate for the regions of marketing.
- **Product labeling** — Labels must be in the language(s) of the intended market(s).
- **Instructions for use** — Provide IFU in required language(s); clear, complete, and user-friendly.
- **Claims control** — Claims must be truthful, evidence-backed, and appropriate.
- **Product identifier & documentation** — Use UDI per IVDR; ensure device traceability and retain technical records.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- FAGG / AFMPS – EUDAMED and medical devices pages: www.fagg-afmps.be
- European Commission – EUDAMED overview: ec.europa.eu/tools/eudamed
- EUR-Lex – Regulation (EU) 2017/746 (IVDR): eur-lex.europa.eu
- Hopestone Capital & Consulting: hopestonecapital.com

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