NETHERLANDS IVD REGULATORY MAP

A practical orientation for global RA teams entering the Netherlands.

START HERE: WHAT IS THE PRODUCT IN THE NETHERLANDS?

1 Confirm regulatory identity

Confirm the 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 Netherlands-specific oversight by IGJ (Health and Youth Care Inspectorate); actor registration is handled through CIBG/Farmatec.

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

2 Choose the regulatory route

CLASS A	CLASS B	CLASS C	CLASS D
Low risk	Low to moderate risk	High risk	Highest risk
Self-declaration route	**Notified Body route**	**Notified Body route**	**Notified Body route**
Lowest potential risk. Manufacturer performs conformity assesement and issues EU Declaration of Conformity for Class A IVDs.	Moderate potential risk; requires Notified Body assessment of technical documentation and QMS before CE marking.	Higher potential risk to health; requires in-depth Notified Body review including clinical evaluation and QMS.	Highest potential risk to health. Extensive clinical evidence and Notified Body scrutiny are required before CE marking.

3 Build the Netherlands market-access infrastructure

IGJ / CIBG / IVDR framework
CE marking under IVDR. Supervision by IGJ (Health and Youth Care Inspectorate). Economic-operator registration flow through CIBG/Farmatec in the EUDAMED context.

EU authorized representative / importer setup
For non-EU manufacturers, appoint an EU Authorized Representative. Align importer and distributor roles and responsibilities in the Netherlands.

Dutch localization strategy
Labels and IFU in Dutch. For professional-use-only devices, English labeling/IFU may be acceptable when only professionals use the product.

EUDAMED / UDI / post-market readiness
Ensure SRN, actor and device registration in EUDAMED. Implement UDI, PMS, vigilance, and traceability to meet IVDR post-market obligations.

4 Build the evidence stack

Administrative
Forms, holder documents, product registration dossier, legal authorization, agent agreement.

Quality
QMS, design controls, supplier management, risk management, process validation.

Analytical performance
Performance, method comparison, accuracy, precision, reference materials, stability.

Clinical / scientific
Clinical evaluation report, literature support, PMCF planning, safety & performance data.

Labeling & IFU
Dutch labeling and IFU (or English for professional-use-only when applicable), contraindications, warnings, claims, symbols per IVDR.

RA TRAP TO AVOID

Do not assume English is always acceptable in the Netherlands. Patient-facing use needs Dutch labeling/IFU, while professional-only use may permit English. Align language strategy with intended users and local expectations.

STRATEGIC INSIGHT

The Netherlands follows the EU IVDR route, but language use, EUDAMED registration, and clean economic-operator setup drive launch efficiency and long-term compliance.

NETHERLANDS 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** — Classify A / B / C / D per IVDR rules (Annex VIII).
3. **Economic operator setup** — Register manufacturer/ importer in EUDAMED (SRN) and establish EU responsibilities.
4. **Standards & NB strategy** — Plan conformity route, select Notified Body (NB), and define tech doc structure.
5. **Evidence** — Generate analytical & clinical performance evidence per IVDR requirements.
6. **Register / Certify** — NB assessment, CE certificate, and EUDAMED registration for the device.
7. **Launch & maintain** — Place on the market. Vigilance, PMS, PSUR, and updates.

B What gets heavier as the class rises?

Signal	CLASS A	CLASS B	CLASS C	CLASS D
Regulatory pathway	Self-declaration	NB assessment	NB assessment	NB assessment
Evidence intensity	Low ●○○○○	Moderate ●●○○○	High ●●●○○	Very high ●●●●●
Clinical evidence	Basic ●○○○○	Moderate ●●○○○	High ●●●○○	Extensive ●●●●●
Technical documentation	Basic ●○○○○	Moderate ●●○○○	Strong ●●●○○	Very strong ●●●●●
Quality system / QMS readiness	Basic ●○○○○	Good ●●○○○	Robust ●●●○○	Comprehensive ●●●●●
Post-market obligations	Basic vigilance ●○○○○	Enhanced vigilance ●●○○○	Extensive PMS ●●●○○	Comprehensive PMS ●●●●●

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual timing depends on product class, evidence needs, Notified Body (NB) capacity, language/localization, and EUDAMED readiness.

Shorter timelines typically apply to lower-risk Class A devices with well-established technology and minimal clinical data.

Timelines increase with class, clinical evidence complexity, NB workload, and EUDAMED processing times.

D Labeling & language essentials

Dutch-language support
Dutch labels and IFU are generally required for devices supplied in the Netherlands.

Product labeling
Labels must be in Dutch. English may be acceptable for professional-use-only IVDs.

Instructions for use
IFU must be in Dutch. English may be acceptable for professional-use-only IVDs.

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

Product identifier & documentation
Assign UDI and maintain traceable technical documentation and records per IVDR.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- IGJ labeling / language page: www.igj.nl/onderwerpen/medische-hulpmiddelen/etikettering-en-gebruiksaanwijzing
- IGJ actor registration in EUDAMED: www.igj.nl/onderwerpen/medische-hulpmiddelen/eudamed-registratie
- European Commission EUDAMED overview: ec.europa.eu/health/eudamed_en
- EUR-Lex Regulation (EU) 2017/746 (IVDR): eur-lex.europa.eu/eli/reg/2017/746/oj
- Hopestone Capital & Consulting: hopestonecapital.com

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