SWEDEN IVD REGULATORY MAP

A practical orientation for global RA teams entering Sweden

START HERE: WHAT IS THE PRODUCT IN SWEDEN?

1 Confirm regulatory identity

Confirm the intended use, product family, and whether the item is an IVD reagent, analyzer/instrument, or software/other.
CE-marked IVDs follow EU/EEA IVDR rules.
Swedish national language requirements apply.

IVD reagent | Analyzer / instrument | Software / other

2 Choose the regulatory route

CLASS A	CLASS B	CLASS C	CLASS D
Low risk	Moderate risk	High risk	Highest risk
Self-declaration route	**Notified Body assessment required**	**Notified Body assessment required**	**Notified Body assessment required**
Self-declaration under IVDR for the lightest-route products, such as non-sterile Class A.	Products with moderate risk require conformity assessment by a Notified Body under IVDR.	Products with high risk require Notified Body assessment with stronger performance-evaluation expectations.	Highest-risk products require Notified Body assessment with the highest scrutiny under IVDR; additional requirements may include EU reference-laboratory involvement where applicable.

3 Build the Sweden market-access infrastructure

CE mark + EU declaration + technical documentation
Apply the CE mark under IVDR with an EU Declaration of Conformity and complete technical documentation in place.

EU Authorized Representative (if outside EU/EEA)
Appoint an EU Authorized Representative if the manufacturer is established outside the EU/EEA.

EUDAMED / actor-SRN / UDI-device registration / importer-distributor readiness
Register economic operator and devices in EUDAMED. Ensure UDI assignment and maintain importer/distributor readiness.

Swedish language readiness
Safe-use information must be available in Swedish, including labeling, IFU, and user-interface/control-panel information; no general professional-user exception, although derogation may be possible.

4 Build the evidence stack

Administrative foundation
Company registration, IVDR product classification, CE declaration, Notified Body certificate, and regulatory files.

Quality / QMS evidence
IVDR-compliant QMS (e.g., ISO 13485:2016), process controls, CAPA, supplier management, audits, and record retention.

Analytical performance
Performance studies, precision, trueness, linearity, reportable range, reproducibility, and stability.

Clinical / scientific support
Clinical evidence and performance evaluation plan (PEP) execution as applicable to risk classification and state of the art.

Labeling & IFU package
Labels and IFU in Swedish, symbols per EU guidance, claims substantiation, and version control.

RA TRAP TO AVOID

Do not assume English labeling or software UI is acceptable for professional users in Sweden. Swedish safe-use information is generally expected.

STRATEGIC INSIGHT

Sweden is largely an IVDR market with a strong national-language overlay. Plan Swedish localization early for labeling, IFU, and UI to avoid delays and rework.

SWEDEN IVD: HOW THE WORK ACTUALLY FLOWS

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

A Program flow

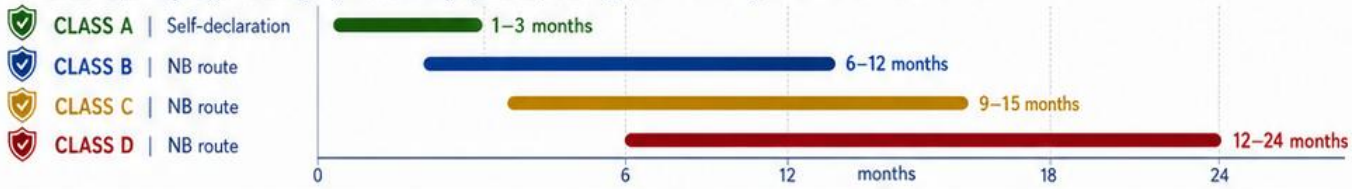
1. **Scope** — Scope the product; define intended use.
2. **Classify** — Classify under IVDR (Class A–D) per the Rules.
3. **Authorized Rep** — Appoint / confirm EU Authorized Representative if needed.
4. **Technical package** — Prepare technical documentation and performance-evaluation package.
5. **Conformity assessment** — Complete conformity assessment (self-declaration for eligible Class A, NB route for B/C/D).
6. **EUDAMED & localization** — Complete EUDAMED operator/UDI and Swedish localization steps.
7. **Launch & maintain** — Launch and maintain with PMS, vigilance, and change control.

B What gets heavier as the class rises?

Signal	CLASS A	CLASS B	CLASS C	CLASS D
Regulatory pathway	Self-declaration (eligible A)	NB route	NB route	NB route
Evidence intensity	Low ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High ● ● ● ○ ○	Very high ● ● ● ● ●
Analytical performance	Basic ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High / comprehensive ● ● ● ○ ○	Comprehensive ● ● ● ● ●
Clinical / scientific support	Not usually required ● ○ ○ ○ ○	Limited ● ● ○ ○ ○	Extensive ● ● ● ○ ○	Extensive ● ● ● ● ●
Quality / QMS readiness	Basic ● ○ ○ ○ ○	Strong ● ● ● ○ ○	Very strong ● ● ● ● ○	Very strong ● ● ● ● ●
Post-market control	Basic reporting ● ○ ○ ○ ○	Enhanced ● ● ● ○ ○	Strict / intensive ● ● ● ● ○	Strict / intensive ● ● ● ● ●

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual timing depends on product type, evidence maturity, and Swedish localization readiness.



Self-declaration for eligible Class A timelines are typically shorter but may vary by product type and risk profile.

Notified Body route (Classes B–D) timelines depend on NB availability, evidence maturity, and Swedish localization readiness.

D Labeling & language essentials

- **Swedish-language labeling & IFU** — Provide Swedish versions of labels, IFU, symbols, and safe-use information.
- **Software / UI text** — Ensure user interfaces, alerts, and electronic instructions are in Swedish where applicable.
- **Claims control** — Claims must align with intended purpose and CE-marking scope under IVDR.
- **Product documentation & UDI** — Maintain product-specific documentation and UDI traceability in line with IVDR and EUDAMED.
- **Vigilance & field actions** — Be prepared for vigilance reporting and field safety corrective actions when needed.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- **Läkemedelsverket (Swedish Medical Products Agency):** IVD – Information for manufacturers
  https://www.lakemedelsverket.se/en/medicinteknik/ivd
- Läkemedelsverket: Language requirements for medical devices and IVD
  https://www.lakemedelsverket.se/en/medical-devices/language-requirements
- **European Commission: IVDR (EU) 2017/746**
  https://health.ec.europa.eu/medical-devices-sector/new-regulations/ivdr_en
- **European Commission: EUDAMED – IVD module and guidance**
  https://health.ec.europa.eu/eudamed_en

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

