DENMARK IVD REGULATORY MAP

A practical orientation for global RA teams entering Denmark.

START HERE: WHAT IS THE PRODUCT IN DENMARK?

1 Confirm Danish regulatory identity

Classify the product family and whether it is a reagent / test kit, analyzer / instrument, or software / other.
Commercialization is governed by EU IVDR with Denmark-specific oversight by the Danish Medicines Agency.

- Reagent / test kit
- Analyzer / instrument
- Software / other

2 Choose the regulatory route (EU IVDR classes)

A CLASS A
Lowest risk
Self-declaration route
Manufacturer self-declares conformity with IVDR requirements and affixes the CE mark.
No Notified Body involvement.

B CLASS B
Low risk
Notified Body route
Notified Body assesses quality management system and technical documentation.
EU quality management system certification required.

C CLASS C
Moderate risk
Notified Body route
Adds in-depth review of technical documentation and performance evaluation.
Stronger scrutiny over clinical performance.

D CLASS D
Highest risk
Notified Body route
Most stringent review including clinical evaluation, performance studies and post-market performance follow-up.
Highest level of scrutiny.

3 Build the Denmark market-access infrastructure

Danish Medicines Agency / IVDR framework
CE marking under IVDR with Danish national implementation and oversight by the Danish Medicines Agency.

EU authorized representative / importer setup
For manufacturers outside the EU, appoint an EU authorized representative (AR) and define importer / distributor responsibilities in Denmark.

Danish localization & market-facing materials
Labeling and IFU in Danish when the device is made available to the final user or patient in Denmark; safe-use information must be in Danish.

EUDAMED / UDI / QMS readiness
Actor registration, device registration, UDI assignment, and quality-system readiness aligned to IVDR.

4 Build the evidence stack

Administrative
Forms, holder documentation, product registration dosier, legal authorization.

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
Danish labeling and IFU with intended use, indications, contraindications, warnings, symbols, UDI, per IVDR.

RA TRAP TO AVOID

Do not assume CE mark alone is the full launch plan. Denmark still requires country-ready language and strong execution on economic-operator obligations.

STRATEGIC INSIGHT

Denmark is an EU IVDR route plus Danish language execution. Get class, evidence, and Danish localization right early.

Training overview — verify current product-specific requirements with the Danish Medicines Agency and current EU IVDR guidance. Not legal advice.

DENMARK 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** — Class A / B / C / D per IVDR rules.
3. **Economic operator setup** — Appoint Danish authorized representative (if needed) and SRN.
4. **Standards & NB strategy** — Plan & complete testing to IVDR standards; select Notified Body (NB) early.
5. **Evidence** — Compile technical documentation; risk management per IVDR.
6. **Register / certify** — Self-declare (Class A) or NB assessment and IVDR EU declaration.
7. **Launch & maintain** — Post-market obligations: PMS, vigilance, FSCA, trend reporting.

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 ●○○○○	Extensive ●●●○○	Very extensive ●●●●●
Manufacturing / QMS readiness	Basic ●○○○○	Strong ●●○○○	Very strong ●●●●○	Highest ●●●●●
Post-market control	Basic reporting ●○○○○	Enhanced ●●○○○	Strict ●●●●○	Intensive ●●●●●

C Indicative route-based planning ranges

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

Class A (self-declaration) timelines are typically shorter but may vary by product category and test complexity.

NB assessments (Classes B–D) depend on review complexity, technical questions, and site inspections.

D Labeling & language essentials

- **Danish-language support** — All labels and IFU must be in Danish when provided to final users/patients in Denmark.
- **Product labeling** — Labels must be in Danish and meet IVDR Annex I and Danish Medicines Agency guidance.
- **Instructions for use** — IFU must be in Danish. Necessary safe-use information must be accessible in Danish.
- **Claims control** — Claims must be truthful, verifiable, and consistent with evidence and labeling.
- **Product identifier & documentation** — Use UDI-DI/UDI-PI per IVDR and retain traceable records as required.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- **Danish Medicines Agency — Language requirements:** sst.dk/en/english/medical-devices/language-requirements
- **Danish Medicines Agency — EUDAMED & devices:** sst.dk/en/english/medical-devices
- **European Commission — EUDAMED overview:** health.ec.europa.eu/medical-devices-eudamed_en
- **EUR-Lex — Regulation (EU) 2017/746 (IVDR):** eur-lex.europa.eu/eli/reg/2017/746
- **Hopestone Capital & Consulting:** hopestonecapital.com

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

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