



# DENMARK MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering Denmark

## START HERE: WHAT IS THE PRODUCT IN DENMARK?

### 1 Confirm Danish regulatory identity

Confirm 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 deeper technical, clinical, and QMS scrutiny.

#### CLASS III



Highest risk

Strongest conformity assessment and highest clinical evidence expectations.

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

### 3 Build the Denmark market-access infrastructure



EU MDR /  
Danish Medicines Agency  
framework

Denmark applies the EU MDR and the Danish Medicines Agency oversees the market.



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.



Danish labeling /  
commercialization readiness

When the device is made available to the final user or patient in Denmark, labeling and IFU generally must be in Danish; safe-use information needed for software and user-facing content must also support Danish-market use.

### 4 Build the evidence stack



#### Administrative

Intended purpose, device description, classification, DoC, economic operator data, and agreements.



#### Quality / QMS

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



#### Safety / performance

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



#### Clinical evaluation

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



#### Labeling & IFU

Danish-language labeling and IFU content, warnings, claims, and instructions.



#### RA TRAP TO AVOID

Do not assume CE marking alone finishes the work; Denmark execution often turns on classification, NB scope, Danish-language readiness, EUDAMED, and economic-operator setup.



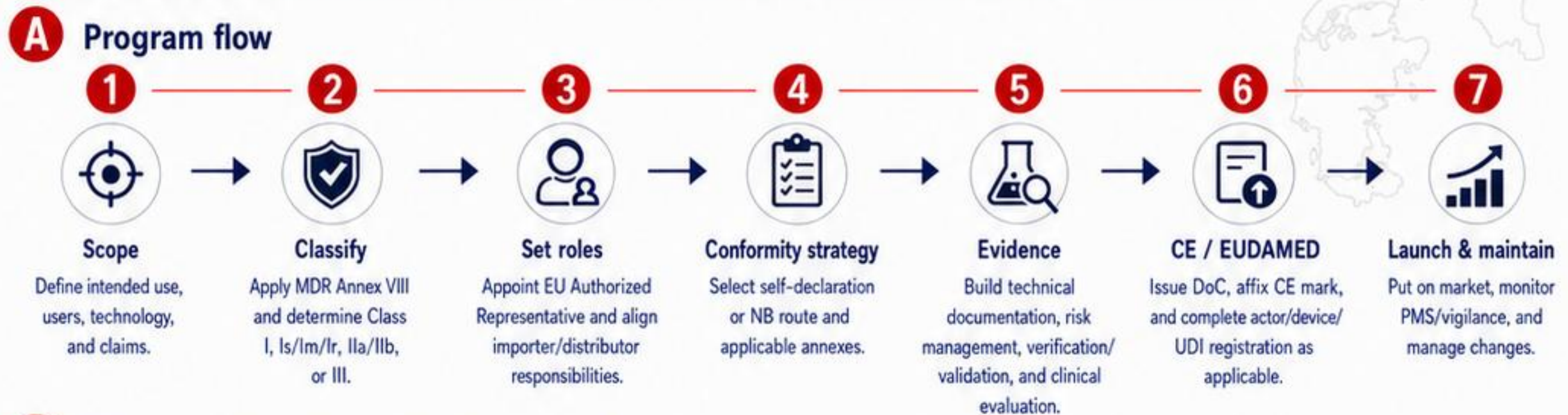
#### STRATEGIC INSIGHT:

Build the MDR route first, then localize Danish-language support and EUDAMED readiness early.



# DENMARK MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

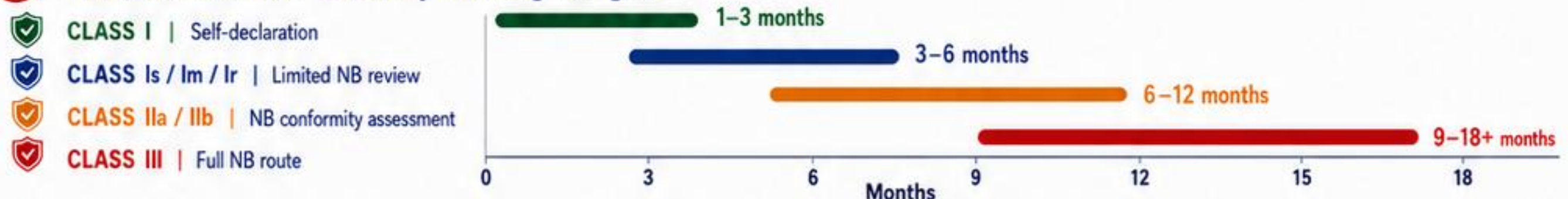
From classification to commercialization — with the decision points a newer RA professional should watch



## 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



**i** Planning ranges are Hopestone estimates, not regulator or Notified Body promises. Actual timing depends on classification, NB capacity, evidence maturity, translations, and EUDAMED readiness.

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

## D Labeling & language essentials

|                                                                                                                              |                                                                                                                   |                                                                                                                             |                                                                                |                                                                                                                    |
|------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|
| <b>Danish-language support</b><br>Labeling and IFU must generally be in Danish when made available to final user or patient. | <b>Labeling content</b><br>Meet MDR Annex I Section 23 content, CE mark, UDI, warnings, and operator information. | <b>Instructions for use</b><br>Complete IFU; eIFU may be used for professional-use situations only where legally justified. | <b>Claims control</b><br>Claims must align with intended purpose and evidence. | <b>Traceability / records</b><br>Maintain UDI and distribution traceability and support PMS/vigilance obligations. |
|------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|



### PRIMARY RESOURCES USED FOR THIS TRAINING AID

- Danish Medicines Agency – Registration and marketing of medical devices [mst.dk/virksomhed/medicinsk-udstyr/registrering-og-markedsforing](https://mst.dk/virksomhed/medicinsk-udstyr/registrering-og-markedsforing)
- Danish Medicines Agency – Language requirements [mst.dk/virksomhed/medicinsk-udstyr/sprogkrav](https://mst.dk/virksomhed/medicinsk-udstyr/sprogkrav)
- European Commission – EUDAMED information [ec.europa.eu/tools/eudamed](https://ec.europa.eu/tools/eudamed)
- EUR-Lex – Regulation (EU) 2017/745 (MDR) [eur-lex.europa.eu/eli/reg/2017/745](https://eur-lex.europa.eu/eli/reg/2017/745)
- Hopestone Capital & Consulting – [hopestonecapital.com](https://hopestonecapital.com)



### IMPORTANT

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