



AUSTRIA MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering Austria

START HERE: WHAT IS THE PRODUCT IN AUSTRIA? ▶

1 Confirm Austrian regulatory identity

Confirm the intended purpose, user, claims, and technology, and whether the product is a medical device under the EU MDR.

Identify device type triggers such as general medical device, sterile / measuring / reusable surgical, and 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 by manufacturer for most non-sterile Class I devices.

CLASS Is / Im / Ir



Special Class I

Limited Notified Body involvement for devices with sterility, measuring function, or reusable surgical aspects.

CLASS IIa / IIb



Higher risk

Notified Body conformity assessment with stronger 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 Austria market-access infrastructure



MDR / BASG framework

Austria applies the EU MDR. The BASG (Federal Office for Safety in Health Care) is the competent authority and national medical-device law overlays the MDR.



EU Authorized Representative

Required for non-EU manufacturers. Define the mandate, ensure agreement in place, and maintain compliance and communication with authorities.



EUDAMED / UDI readiness

Actor registration, UDI / device registration, certificates, and market-surveillance modules mandatory from 28 May 2026.



German labeling / launch readiness

German safe-use information required for final users / patients; for devices intended exclusively for professional users, English may be allowed for some information, but localization planning is essential.

4 Build the evidence stack



Administrative

Intended purpose, classification rationale, declarations (DoC), and economic-operator data and agreements.



Quality / QMS

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



Safety / performance

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



Clinical evaluation

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



Labeling & IFU

German safe-use information, CE / UDI content, warnings, claims, and instructions.



RA TRAP TO AVOID

Do not treat Austria as a separate national premarket approval system after CE marking; the main execution risks are classification, Notified Body scope, localization, EUDAMED readiness, and operator setup.



STRATEGIC INSIGHT:

Build the MDR route first, then localize for Austria early. German safe-use information and EUDAMED readiness can materially affect launch timing.



AUSTRIA MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

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

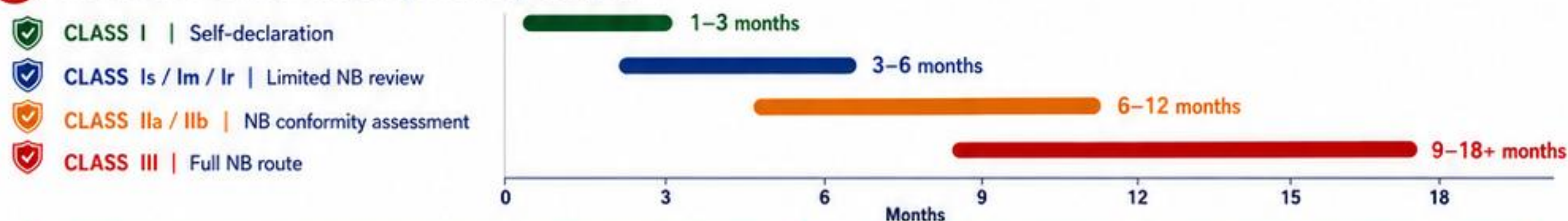
A Program flow



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



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



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

D Labeling & language essentials



German-language support
Safe-use information for final users / patients generally needs German.



Labeling content
Meet MDR Annex I Section 23 content, CE mark, UDI, warnings, and operator information.



Instructions for use
Provide complete IFU; eIFU may be possible only where legally justified.



Claims control
Claims must align with intended purpose, evidence, and promotional controls.



Traceability / records
Maintain UDI and distribution traceability and support PMS/vigilance obligations.



PRIMARY RESOURCES USED FOR THIS TRAINING AID

- BASG – Medical devices pages (BASG / Medizinprodukte)
- BASG – EUDAMED information page
- EUR-Lex – Regulation (EU) 2017/745 (MDR)
- European Commission – EUDAMED information
- Hoystone Capital & Consulting — hopestonecapital.com



IMPORTANT

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