AUSTRIA IVD REGULATORY MAP

A practical orientation for global RA teams entering Austria.

1 START HERE: WHAT IS THE PRODUCT IN AUSTRIA?

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 the EU IVDR with Austria-specific oversight by BASG (Austrian Federal Office for Safety in Health Care / Austrian Medicines and Medical Devices Agency).

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

2 Choose the regulatory route

CLASS A
Lowest risk

Self-declaration route

Non-sterile Class A is generally self-declared under IVDR; sterile Class A involves notified-body review for sterility aspects.

CLASS B
Moderate risk

Notified Body route

Notified Body (NB) conformity assessment is required under the IVDR.

CLASS C
Higher risk

Notified Body route

Stronger technical documentation and performance-evaluation scrutiny by the Notified Body are required.

CLASS D
Highest risk

Notified Body route

Highest evidence burden; additional controls and EU reference-laboratory mechanisms may apply where relevant.

3 Build the Austria market-access infrastructure

BASG / IVDR framework

CE marking under the IVDR. Austrian oversight through BASG and related national processes (including vigilance and market surveillance).

EU authorized representative / importer setup

If the manufacturer is outside the EU, appoint an EU Authorized Representative and align importer/distributor roles for Austria.

German localization & market-facing materials

Prepare German-ready labeling, Instructions for Use (IFU), and market-facing documentation for the Austrian market.

EUDAMED / UDI / QMS readiness

Ensure EUDAMED actor registration, device registration, UDI, quality-system readiness, and importer/distributor traceability.

4 Build the evidence stack

Administrative
Administrative dossier, legal manufacturer responsibilities, CE declaration, and market placement documents.

Quality
QMS per IVDR Annex IX, supplier controls, change management, and process validation.

Analytical performance
Demonstrate accuracy, precision, detection performance, and interference studies.

Clinical / scientific
Scientific validity and clinical performance / performance evaluation to support intended use and claims.

Labeling & IFU
German-ready labels, IFU, claims, symbols, UDI, and traceability information aligned with IVDR.

RA TRAP TO AVOID

Do not ask only for "Austria timeline." Start with product identity → IVDR classification → EU/AR/importer setup → language strategy → evidence path.
The timeline is the result of those decisions.

STRATEGIC INSIGHT

Austria is an EU IVDR route with local execution details. Get the class right, localize smartly, and prepare EUDAMED/UDI readiness early to avoid delays.

AUSTRIA IVD: HOW THE WORK ACTUALLY FLOWS

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

A Program flow

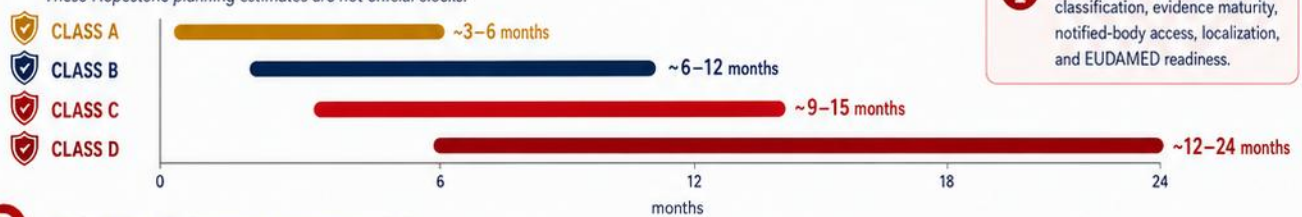
1. **Scope** — Define intended use, analyte/specimen context, and target users.
2. **Classify** — Assign EU IVDR class A/B/C/D.
3. **Economic operator setup** — Confirm manufacturer, EU authorized representative if needed, importer/distributor roles.
4. **Standards / NB strategy** — Align standards, determine notified-body involvement, and UDI/EUDAMED preparation.
5. **Evidence** — Compile technical documentation and performance evaluation.
6. **Register / certify** — Complete EUDAMED actor and device registration and NB certification where applicable.
7. **Launch & maintain** — CE mark, place on market, post-market surveillance, vigilance, and change control.

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	Lowest	Moderate	High	Very high
Analytical performance	Basic	Moderate	High	Very high
Clinical / scientific support	Performance evaluation required across classes; intensity rises with risk.			
Manufacturing / QMS readiness	Basic	Moderate	High	Very high
Post-market control	Lower	Moderate	Higher	Highest

C Indicative route-based planning ranges

These Hopestone planning estimates are not official clocks.



Actual timing depends on classification, evidence maturity, notified-body access, localization, and EUDAMED readiness.

D Labeling & language essentials

- **German-language support** — Provide German-ready labels and IFU with clear, safe-use information.
- **Product labeling** — Labels must be German-ready, accurate, durable, and include all required elements.
- **Instructions for use** — German IFU required; follow IVDR Annex I template and content requirements.
- **Claims control** — Claims must be truthful, specific, and supported by evidence.
- **Product identifier & documentation** — Use UDI and maintain device records for traceability and market access.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- BASG medical devices / EUDAMED pages: basg.gv.at/medizinprodukte
- European Commission EUDAMED overview: ec.europa.eu/tools/eudamed
- EUR-Lex Regulation (EU) 2017/746 (IVDR): eur-lex.europa.eu/eli/reg/2017/746
- hopestonecapital.com

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

