GERMANY IVD REGULATORY MAP

A practical orientation for global RA teams entering Germany

START HERE: WHAT IS THE PRODUCT IN GERMANY?

1 Confirm German regulatory identity

Germany follows EU IVDR Regulation (EU) 2017/746, with national implementation and oversight under the Medizinprodukte Durchführungsgesetz (MPDG). Confirm whether the product is an IVD reagent, analyzer/instrument, or software/other.

- IVD reagent
- Analyzer / instrument
- Software / other

2 Choose the regulatory route

CLASS A	CLASS B	CLASS C	CLASS D
Lowest risk	Moderate risk	Higher risk	Highest risk
Generally self-declared for non-sterile Class A.	Notified Body conformity assessment required.	Notified Body conformity assessment required with stronger evidence and technical-document scrutiny.	Strongest scrutiny and Notified Body assessment.

This is the EU IVDR class framework used in Germany. Route intensity rises from Class A to D.

3 Build the Germany market-access infrastructure

EU IVDR / Germany environment

CE-marked IVDR pathway (EU) 2017/746.

National implementation and oversight under the MPDG.

EU Authorized Representative (where needed)

Required for non-EU manufacturers.

EUDAMED / importer-distributor setup

Economic operator registration, SRN, UDI/device and certificates registration in EUDAMED, importer/distributor setup.

As of **28 May 2026** the Actor, UDI/Device, Notified Bodies & Certificates, and Market Surveillance modules are mandatory.

German labeling / commercialization readiness

Prepare German-language labeling and IFU for the German market and confirm launch readiness.

4 Build the evidence stack

Administrative
- Technical documentation
- PMS & vigilance plan
- Risk management
- Declaration of conformity

Quality / QMS
- ISO 13485 QMS
- Process validation
- CAPA & change control
- Supplier controls

Analytical performance
- Performance evaluation
- Method comparison
- Accuracy, precision, linearity, LOD/LOQ
- Stability

Clinical / scientific performance
- Clinical performance evaluation
- Scientific validity
- Literature & real-world evidence

Labeling & IFU
- German language
- Claims, symbols, UDI, CI
- Clear IFU for end users

RA TRAP TO AVOID

Do not begin with "What is the Germany timeline?" Begin with classification → operator setup → labeling → evidence → route. The order you choose determines your success.

STRATEGIC INSIGHT

Germany is an IVDR route plus country-specific language and implementation details. Get the class right first, then localize smartly.

GERMANY 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, user/ patient group and specimen type.
2. **Classify** — Class A–D under EU IVDR Annex VIII rules.
3. **Route selection** — Self-declare (A non-sterile) or use Notified Body route (B–D).
4. **Local setup** — Establish EU SRN, internal PRRC/EU rep if applicable.
5. **Evidence** — Compile technical documentation & performance evaluation.
6. **Submit / register** — ID with EUDAMED (actor, UDI-D) and submit to NB (B–D).
7. **Launch / maintain** — Place on the market, post-market surveillance, vigilance & updates.

B What gets heavier as the class rises?

Signal	CLASS A	CLASS B	CLASS C	CLASS D
Premarket pathway	Self-declaration (non-sterile A)	Notified Body assessment	Notified Body assessment	Notified Body assessment
Evidence intensity	Low ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High ● ● ● ○ ○	Very high ● ● ● ● ○
Analytical performance	Basic ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High ● ● ● ○ ○	Very strong ● ● ● ● ○
Clinical / scientific support	Performance evaluation required (basic) ● ○ ○ ○ ○	Performance evaluation required (moderate) ● ● ○ ○ ○	Performance evaluation required (extensive) ● ● ● ○ ○	Performance evaluation required (comprehensive) ● ● ● ● ○
Manufacturing / QMS readiness	Basic ● ○ ○ ○ ○	Strong ● ● ○ ○ ○	Very strong ● ● ● ○ ○	Very robust ● ● ● ● ○
Post-market control	Basic PMS ● ○ ○ ○ ○	Enhanced PMS ● ● ○ ○ ○	Strong PMS ● ● ● ○ ○	Intensive PMS ● ● ● ● ○

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — not official review clocks. Actual duration varies by product, Notified Body workload, quality of submission, and completeness of documentation.

Class A (self-declared) timelines are typically shorter but depend on product and internal readiness.

Notified Body routes (Classes B–D) depend on assessment scope, technical review, and site audits.

D Labeling & language essentials

German-language support
Information for users and patients should generally be available in German.

Product labeling
Labels must be in German. Include product name, UDI-DI, intended use, warnings, and symbols per IVDR.

Instructions for use
Provide in German, including safety information and performance claims.

Claims control
Claims must be truthful, verifiable, supported by evidence, and not misleading.

Product identifier & documentation
Use UDI-DI & UDI-PI (where applicable) and retain traceable records.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- Paul-Ehrlich-Institut (PEI): https://www.pei.de
- EUDAMED Overview: https://ec.europa.eu/tools/eudamed
- EUDAMED Actor Registration: https://webgate.ec.europa.eu/eudamed/#/actor/registration
- EUDAMED UDI/Device Registration: https://webgate.ec.europa.eu/eudamed/#/udi-diary
- German / EU IVDR Authority Resources: BfArM, PEI, EU IVDR guidance documents

IMPORTANT

Product-specific German and EU IVDR requirements govern.
Confirm current official sources should always be confirmed before execution.

