



GERMANY MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering Germany

1 Confirm EU / German regulatory identity

Confirm intended purpose, user, and technology, and whether the product is software, active, implantable, sterile, measuring, or a reusable surgical instrument.

Confirm risk-based classification under the EU MDR using Annex VIII rules and all applicable classification provisions.



General device



Sterile / measuring / reusable



Software / active / implantable

2 Choose the regulatory route

CLASS I



Low risk

- Self-declaration by manufacturer (Annex II & III)
- Classes Is, Im, Ir require limited Notified Body involvement (Annex IX, Chapters I–III)

CLASS IIa



Low–moderate risk

- Conformity assessment with Notified Body
- Annex IX, Chapters I & III

CLASS IIb



Moderate–high risk

- Conformity assessment with Notified Body
- Annex IX, Chapters I & III

CLASS III



Highest risk

- Conformity assessment with Notified Body
- Annex IX, Chapters I & III

The EU MDR classification drives the route. Most Class I devices self-declare. Classes Is, Im, and Ir have limited Notified Body involvement. Classes IIa–III require increasing Notified Body assessment.

3 Build the German market-access infrastructure



EU MDR + BfArM context

EU MDR is the legal basis. BfArM is the competent authority for vigilance, market surveillance coordination, and registration of operators.



EU Authorized Representative (EC REP)

If manufacturer is outside the EU, appoint an EC REP before placing the device on the EU market.



EUDAMED / UDI / importer-distributor setup

Obtain Basic UDI-DI and UDI-PI and register in EUDAMED. Appoint EU importer(s) and establish distribution and QMS responsibilities.



German vigilance & local execution

Report per MDR vigilance requirements (EU via EUDAMED). Follow BfArM/PEI guidance, field safety actions, and German language rules.

4 Build the evidence stack



Administrative

CE technical file, declarations, EUDAMED registrations, EC REP, importer agreements, MSA documentation.



Quality / QMS

QMS per ISO 13485 aligned with MDR Annex IX Chapters I & III; risk management per ISO 14971.



Analytical / technical verification

Design outputs, testing, performance verification, EMC, biocompatibility, sterilization validation, software verification.



Clinical evaluation / usability / software

Clinical evaluation per MDR; usability per IEC 62366-1; software lifecycle per IEC 62304 (as applicable).



Labeling / IFU

German language labeling and IFU per MDR Annex I 23.1, using harmonized symbols.



RA TRAP TO AVOID

Do not assume Germany has a separate routine premarket license outside the EU MDR conformity route. Focus on MDR class, economic operators, language, and post-market execution.



STRATEGIC INSIGHT

Get the MDR class and Notified Body path right first, then localize for Germany — especially language, importer/distributor readiness, and vigilance responsibilities.



GERMANY MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

From MDR classification to German market execution — with the issues a newer RA professional should watch

A Program flow

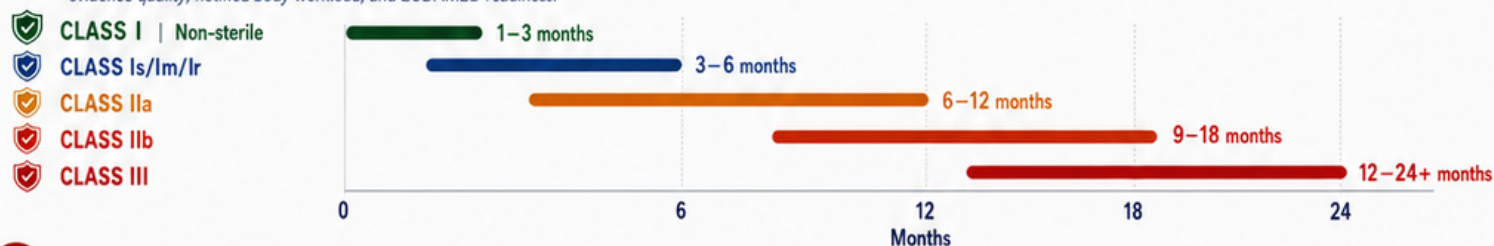


B What gets heavier as the class rises?

Signal	CLASS I	CLASS Is/Im/Ir	CLASS IIa	CLASS IIb	CLASS III
Pathway intensity	Low ● ○ ○ ○ ○	Low–mod ● ● ○ ○ ○	Moderate ● ● ● ○ ○	High ● ● ● ● ○	Very high ● ● ● ● ●
Evidence intensity	Low ● ○ ○ ○ ○	Low–mod ● ● ○ ○ ○	Moderate ● ● ● ○ ○	High ● ● ● ● ○	Very high ● ● ● ● ●
Clinical support	Not usually ○ ○ ○ ○ ○	Limited ● ○ ○ ○ ○	Moderate ● ● ● ○ ○	Strong ● ● ● ● ○	Extensive ● ● ● ● ●
QMS readiness	Basic ● ○ ○ ○ ○	Basic–mod ● ● ○ ○ ○	Moderate–high ● ● ● ○ ○	High ● ● ● ● ○	Very high ● ● ● ● ●
Post-market surveillance	Basic ● ○ ○ ○ ○	Basic–mod ● ● ○ ○ ○	Moderate ● ● ● ○ ○	High ● ● ● ● ○	Very high ● ● ● ● ●

C Indicative route-based planning ranges

Illustrative ranges for timing only — actual timing depends on device complexity, evidence quality, notified body workload, and EUDAMED readiness.



D Germany language & local execution essentials

German labeling / IFU readiness User-facing information is generally expected in German, assess professional-use exceptions case-by-case.	BfArM authority context BfArM is the competent authority for medical devices in Germany.	EUDAMED and UDI readiness Ensure UDI assignment, carrier on device/label, and actor / device registrations in EUDAMED.	Importer / distributor and economic-operator obligations Confirm roles, contracts, and obligations for importer, distributor, and AR obligations.	Claims control / GSPR alignment Claims must be truthful, evidence-based, and aligned with GSPR.	Vigilance and FSCA readiness Establish PMS, vigilance, trend reporting, and FSCA processes up front.
---	--	--	---	---	--

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- Regulation (EU) 2017/745 (MDR) — Official text
- European Commission — Medical Devices Sector: https://health.ec.europa.eu/medical-devices_en
- EUDAMED — Overview: <https://ec.europa.eu/tools/eudamed>
- BfArM — Medical Devices / Competent Authorities: https://www.bfarm.de/EN/Medical-devices/_node.html
- German MDR implementation context & guidance (BfArM communications and Q&A)



IMPORTANT

Product-specific MDR rules, national execution obligations, and current guidance govern.

Confirm classification, conformity route, evidence expectations, and registrations before execution.