



POLAND MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering Poland



START HERE: WHAT IS THE PRODUCT IN POLAND? ▶

1 Confirm the Polish regulatory identity

Determine whether the product is an MDR device, accessory, software, implantable, or custom-made device; define intended use, users, and claims.

Classify under MDR: Class I, IIa, IIb, or III and identify any special features such as sterile or reusable surgical instrument status.



General device



Software / digital



Sterile / implant

2 Choose the regulatory route

CLASS I



Lowest risk

Self-declaration in most cases.
Follow general safety and performance requirements.



CLASS IIa



Low-moderate risk

Notified Body (NB) review of technical documentation and QMS elements.
Design Dossier required.



CLASS IIb



Moderate-high risk

Deeper NB review including design, verification/validation, and clinical evaluation.
Higher scrutiny on benefit-risk and performance data.



CLASS III



Highest risk

Highest level of NB review. Comprehensive evidence, clinical data, and PMCF. Stringent benefit-risk requirements.

Classification and conformity assessment follow Regulation (EU) 2017/745 (MDR).
All classes require compliance with MDR general safety and performance requirements.

3 Build the Poland market-access infrastructure



EUDAMED + SRN

Register operators and device data in EUDAMED as required.



EU AR / importer

Assign EU Authorized Representative and importer roles where needed.



URPL notification

When the device first enters the EU through Poland, notify the President of URPL within 14 days.



Local PMS setup

Prepare vigilance, complaint handling, FSCAs, and distributor/importer control.

4 Build the evidence stack



Administrative
Device description, intended use, risk management, market claims, and regulatory history.



Quality / QMS
MDR-aligned QMS (ISO 13485), process control, CAPA, and management review.



Technical / V&V
Design and V&V, standards mapping, biocompatibility, usability, and software validation.



Clinical evaluation
Clinical evaluation plan, literature, clinical data, and PMCF where applicable.



Labeling / IFU
Polish-language labeling and IFU per MDR Annex I 23.1(d) and national rules.



RA TRAP TO AVOID

Do not forget Polish-language labeling/IFU requirements and the Polish notification step.



STRATEGIC INSIGHT

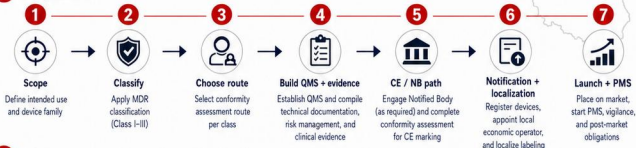
Poland is fundamentally an MDR route, but execution turns on Polish labeling discipline and URPL notification readiness.



POLAND MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

From classification to launch — where the decision points and real-world friction sit

A Program flow

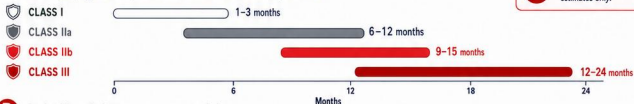


B What gets heavier as the class rises?

Signal	CLASS I	CLASS IIa	CLASS IIb	CLASS III
Pathway intensity	Low ● ● ● ●	Moderate ● ● ● ●	High ● ● ● ●	Very high ● ● ● ● ●
Evidence intensity	Basic ● ● ● ●	Moderate ● ● ● ●	High ● ● ● ●	Very high ● ● ● ● ●
Clinical evaluation / PMCF	Not usually required ● ● ● ●	Limited ● ● ● ●	Moderate ● ● ● ●	Extensive ● ● ● ● ●
QMS readiness	Basic ● ● ● ●	Moderate ● ● ● ●	High ● ● ● ●	Very high ● ● ● ● ●
Post-market control	Lower ● ● ● ●	Moderate ● ● ● ●	Higher ● ● ● ●	Highest ● ● ● ● ●

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual timing depends on product complexity, evidence quality, application completeness, audit outcomes, and Notified Body workload.



i Ranges are planning estimates only.

D Labeling & language essentials



Polish language
Devices placed on the Polish market must have labeling and IFU in Polish, or use harmonized symbols / recognized codes.



HCP exception
For devices supplied to healthcare providers, labeling or IFU may be in English by written agreement, except patient-directed information.



URPL notice
If Poland is the point of first placement in the EU, notify the President of URPL within 14 days.



Post-market
Prepare vigilance, FSCA, complaints, and local economic-operator responsibilities.

E Country-specific decision points



MDR route
CE-marked devices follow the MDR framework.



EUDAMED
Operator and device data must be managed in EUDAMED.



Clinical
Clinical evaluation remains core; investigations follow MDR rules when needed.



Primary resources
gov.pl
urpl.gov.pl
europa.eu