POLAND IVD REGULATORY MAP

A practical orientation for global RA teams entering Poland

START HERE: WHAT IS THE PRODUCT IN POLAND?

1 Confirm Polish regulatory identity

Confirm the intended use, specimen type, and whether the item is an IVD reagent, analyzer/instrument, software, or other. Classification and certification depend on the degree of risk to human health under the EU IVDR framework.

- IVD reagent
- Analyzer / instrument
- Software / other

2 Choose the regulatory route

CLASS A
Lowest risk

Self-declaration for non-sterile Class A IVDs. Demonstrate IVDR compliance and maintain technical documentation. No Notified Body involvement unless special conditions apply.

CLASS B
Low to moderate risk

Conformity assessment by a Notified Body. Evidence of safety, performance, and IVDR compliance required before placing on the market.

CLASS C
High risk

Conformity assessment by a Notified Body. Greater performance evidence expectations and clinical evaluation depth required.

CLASS D
Highest risk

Conformity assessment by a Notified Body with the strongest evidence expectations and clinical evaluation requirements.

3 Build the Poland market-access infrastructure

EU IVDR framework

Comply with Regulation (EU) 2017/746. Apply general safety and performance requirements, classification rules, technical documentation, and UDI.

EU Authorized Representative
(if manufacturer is outside the EU)

Appoint an Authorized Representative established in the EU to act on your behalf under IVDR.

EUDAMED / operator setup & Polish authority interface

Register in EUDAMED as manufacturer and SRN holder. Interface with Poland's competent authority: Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych (URPL).

Product-specific standards, QMS & importer readiness

Apply harmonized standards and manage QMS under IVDR. Prepare EU importers/ distributors and economic-operator readiness.

4 Build the evidence stack

Administrative
Technical documentation, risk management, PMS plan, SRN/EUDAMED records, declarations.

Quality
QMS per IVDR Annex IX, supplier controls, CAPA, process validation records.

Analytical performance
Performance data, accuracy, precision, reference materials, method reports.

Clinical / scientific support
Clinical performance studies or literature and clinical evaluation report per IVDR.

Labeling & IFU
Polish-language labeling and IFU, symbols per IVDR Annex I, UDI carrier, and eIFU readiness.

RA TRAP TO AVOID

Do not begin with the timeline alone. Start with classification and risk → Notified Body strategy → Polish language readiness → importer/distributor setup. The sequence is the result of those decisions.

STRATEGIC INSIGHT

Plan early for IVDR class, Notified Body capacity, Polish-language user materials, and EUDAMED/operator readiness. Early alignment prevents delays and avoids costly rework later.

POLAND IVD: HOW THE WORK ACTUALLY FLOWS

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

A Program flow

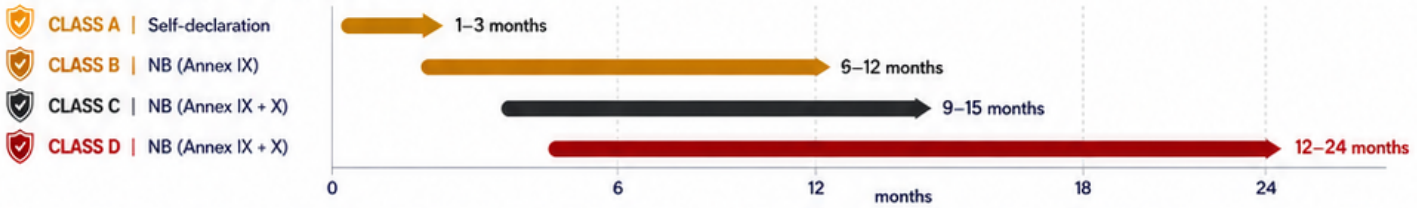
1. **Scope** — Define intended use, population and specimen type.
2. **Classify** — Class A, B, C or D per IVDR rules.
3. **AR / operator setup** — Appoint Authorized Representative (AR) and establish operator.
4. **Testing & standards** — Plan conformity assessment; test to IVDR standards.
5. **Evidence** — Compile technical documentation; risk & performance.
6. **Register / submit** — Register in EUDAMED and submit to Notified Body (if required).
7. **Launch & maintain** — Place on market; maintain PMS, vigilance and periodic reviews.

B What gets heavier as the class rises?

Signal	CLASS A	CLASS B	CLASS C	CLASS D
Premarket pathway	Self-declaration	Notified Body (Annex IX)	Notified Body (Annex IX + X)	Notified Body (Annex IX + X)
Evidence intensity	Low ●○○○○	Moderate ●●○○○	High ●●●○○	Very high ●●●●●
Analytical performance	Basic ●○○○○	Moderate ●●○○○	High ●●●○○	Comprehensive ●●●●●
Clinical / scientific support	Not usually required ●○○○○	Limited ●●○○○	Extensive ●●●●○	Extensive + pivotal ●●●●●
Manufacturing / QMS readiness	Basic ●○○○○	Adequate ●●○○○	Strong ●●●○○	Very strong ●●●●●
Post-market surveillance	Basic monitoring ●○○○○	Regular ●●○○○	Enhanced ●●●○○	Comprehensive ●●●●●

C Indicative route-based planning ranges

Illustrative Hopestone planning ranges for timing only — actual timing depends on Notified Body capacity, documentation maturity, product specifics, and your study requirements.



Self-declaration (Class A) timeline is typically shortest and depends on internal readiness and product scope.

Classes B–D depend on Notified Body workload, documentation quality, and product complexity.

D Labeling & language essentials

Polish-language support
Provide Polish versions of key materials (label, IFU, claims, etc.).

Product labeling
Labels must be in Polish; meet IVDR content and format rules.

Instructions for use
Polish IFU required; follow IVDR template and content elements.

Claims control
Claims must be truthful, verifiable, and consistent with evidence and labeling.

Product identifier & documentation
Assign UDI-DI, register in EUDAMED, and retain records per IVDR.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) — EUR-Lex
- European Commission — EUDAMED (https://ec.europa.eu/tools/eudamed)
- URPL — Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (https://www.urpl.gov.pl)
- Hopestone Capital & Consulting — hopestonecapital.com
- This template also reflects screening-level requirements from Hopestone's internal global device requirements workbook.

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

