



RUSSIA IVD REGULATORY MAP

A practical orientation for global RA teams entering Russia.

1 START HERE: WHAT IS THE PRODUCT IN RUSSIA?

Confirm the intended use, product family, and whether the item is an IVD reagent, analyzer / instrument, or software / other. Registration of IVD medical devices is overseen by Roszdravnadzor (the Federal Service for Surveillance in Healthcare).



IVD reagent



Analyzer / instrument



Software / other

2 Choose the regulatory route

CLASS 1



Low risk

State registration applies. Lower-risk IVDs with proven safety and performance. Standardized review pathway.

CLASS 2a



Lower-moderate risk

State registration applies. Greater risk than Class 1; requires more evidence and additional expert review.

CLASS 2b



Moderate-higher risk

State registration applies. Substantial risk; requires extensive testing, clinical evidence, and multi-expert assessment.

CLASS 3



Highest risk

State registration applies. Highest individual & public health risk; most rigorous review and strongest evidence requirements.



All IVDs require state registration. Higher classes face deeper expert review, broader testing, and more demanding evidence.



Foreign manufacturers must appoint an authorized representative in Russia. Documents in foreign languages require notarized Russian translation.

3 Build the Russia market-access infrastructure



Roszdravnadzor framework

Comply with Federal Law No. 323-FZ "On the Basics of Health Protection" and applicable regulations for IVD medical devices; follow Roszdravnadzor guidance and requirements.



Authorized representative / registration holder in Russia

Appoint an authorized representative (legal entity) that acts on your behalf with Roszdravnadzor and bears legal responsibility for registration and post-market obligations.



Russian localization & submission language

All submissions, labeling, IFU and certificates must be in Russian. Localize content to meet Russian regulatory and clinical practice expectations.



Product-specific testing / standards / QMS readiness

Ensure testing to Russian standards (e.g., GOST R) and conformity with QMS requirements (GMP / ISO 13485). Plan for Russian certificates and test reports.

4 Build the evidence stack



Administrative

Application documents, manufacturer data, power of attorney, quality agreements, representative details.



Quality

QMS information, manufacturing details, process validation, supplier controls, change management.



Analytical performance

Analytical and technical performance data, validation studies, precision, accuracy, linearity, sensitivity, etc.



Clinical / scientific

Clinical evaluation report, equivalence justification or trials where needed, literature, PMCF plan if applicable.



Labeling & IFU

Russian labeling and Instructions for Use (IFU) with required information, symbols and contraindications.



RA TRAP TO AVOID

Do not underestimate translation, local-representative setup, or testing strategy. Gaps in Russian-language documents, GOST R testing, or representative authority can lead to refusals, delays and costly rework.



STRATEGIC INSIGHT

Class assignment, test burden, and dossier completeness drive timing more than a simple published review clock. Strong planning and early local engagement increase predictability and first-time success.



RUSSIA IVD: HOW THE WORK ACTUALLY FLOWS

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

A Program flow



B What gets heavier as the class rises?

Signal	CLASS 1	CLASS 2a	CLASS 2b	CLASS 3
Premarket pathway	Declaration of conformity	State registration	State registration	State registration
Evidence intensity	Low ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High ● ● ● ○ ○	Very high ● ● ● ● ●
Analytical performance	Basic ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High ● ● ● ○ ○	Extensive ● ● ● ● ●
Clinical / scientific support	Not usually required ● ○ ○ ○ ○	Limited ● ● ○ ○ ○	Substantial ● ● ● ○ ○	Extensive ● ● ● ● ●
Manufacturing / QMS readiness	Basic ● ○ ○ ○ ○	Strong ● ● ○ ○ ○	Very strong ● ● ● ○ ○	Exceptionally strong ● ● ● ● ●
Post-market control	Basic reporting ● ○ ○ ○ ○	Enhanced ● ● ○ ○ ○	Intensive ● ● ● ○ ○	Very intensive ● ● ● ● ●

C Indicative route-based planning ranges

Roszdravnadzor publishes a 50-working-day registration review period after the registration process starts. Testing, expert queries, and clinical-trial timing sit outside that simple clock, so these bars are Hopestone planning estimates.



i Timelines vary by product type, testing requirements, expert queries, availability of clinical data, and site inspections.

🕒 The 50-working-day review applies after the dossier is accepted for review; it is not a total time-to-market promise.

D Labeling & language essentials

Russian-language support
Provide Russian-language versions of labels, IFU, and support materials.

Product labeling
Labels must be in Russian and include required information per IVD rules.

Instructions for use
Russian-language IFU must reflect approved intended use and warnings.

Claims control
Claims must be consistent with approved intended use and evidence.

Product identifier & documentation
Use UDI, maintain document traceability and support post-market safety monitoring.



PRIMARY RESOURCES USED FOR THIS TRAINING AID

- Roszdravnadzor State Registration of Medical Devices | <https://roszdravnadzor.gov.ru/services/registration>
- Roszdravnadzor Medical Device Safety Monitoring | <https://roszdravnadzor.gov.ru/services/monitoring>
- Roszdravnadzor Applicant Cabinet (Electronic Services / Tracking) | <https://lk.roszdravnadzor.gov.ru>
- Hopestone Capital & Consulting | <https://hopestonecapital.com>



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