



RUSSIAN FEDERATION MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering Russia



1 Confirm the Russian regulatory identity

Determine whether the product is a medical device under Russian rules and identify its risk class.

- Classify the device into Classes 1, 2a, 2b, or 3.
- Foreign manufacturers must appoint an authorized representative in Russia.



General device



Software / active



Sterile / implant / measuring

2 Choose the state-registration route

CLASS 1



Lower risk

Lighter evidence burden in some cases

Some lower-risk products may face a lighter clinical path.

CLASS 2a



Moderate risk

Full state-registration pathway

Technical and clinical expectations rise.

CLASS 2b



High risk

Heavy review

Testing and clinical evidence typically deepen.

CLASS 3



Highest risk

Most demanding route

Highest-risk devices face the strongest evidence burden.

3 Build the Russia market-access infrastructure



Authorized representative

Appoint the local representative to support registration and post-market obligations.



Application package

Prepare technical, regulatory, and operating documents plus device photos.



Testing plan

Plan technical trials, toxicology for body-contact devices, and measuring-device approval where applicable.



Clinical route

When needed, secure permission for clinical trials and use authorized medical institutions.

4 Build the evidence stack



Administrative
Application, classification, local representative documents.



Quality
Manufacturing / process controls and QMS evidence.



Technical
Testing / technical trials, EMC, biocompatibility, sterilization as applicable.



Clinical
Safety / effectiveness evidence and clinical-trial outputs where required.



Translation
Notarized Russian translations for foreign-language materials.



RA TRAP TO AVOID

Do not underestimate Russian translation, testing, and local clinical planning.



STRATEGIC INSIGHT

The critical path is usually driven by evidence generation, local representation, and state-registration logistics — not only dossier writing.



RUSSIA 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 1	CLASS 2a	CLASS 2b	CLASS 3
Pathway intensity	Low ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Evidence intensity	Low ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Technical / toxicology load	Low ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Clinical burden	Not usually required ● ● ● ● ●	Limited ● ● ● ● ●	Moderate ● ● ● ● ●	Extensive ● ● ● ● ●
Post-market obligations	Lower ● ● ● ● ●	Moderate ● ● ● ● ●	Higher ● ● ● ● ●	Highest ● ● ● ● ●

C Indicative route-based planning ranges



i Planning ranges are Hopstone estimates, not regulator promises.

D Registration & language essentials



State registration
Roszdravnadzor performs state registration; foreign devices need a Russian authorized representative.



Translation
Foreign-language dossier materials must be submitted with duly notarized Russian translations.



Testing
Technical trials are required; toxicology applies to body-contact devices; measuring devices may need type-approval testing.



Clinical trials
When required, clinical trials need Roszdravnadzor permission and approved medical institutions.

E Country-specific decision points



Clock
Roszdravnadzor performs registration within 50 working days after the decision to start registration; clinical-trial time is excluded.



Stage I
Experts first assess the dossier and the possibility of clinical work.



Stage II
Experts then evaluate the completeness and results of testing and clinical evidence.



Primary resources
roszdravnadzor.gov.ru



Confirm product-specific requirements before execution.