

RUSSIA



The Medical Device Approval Process in Russia





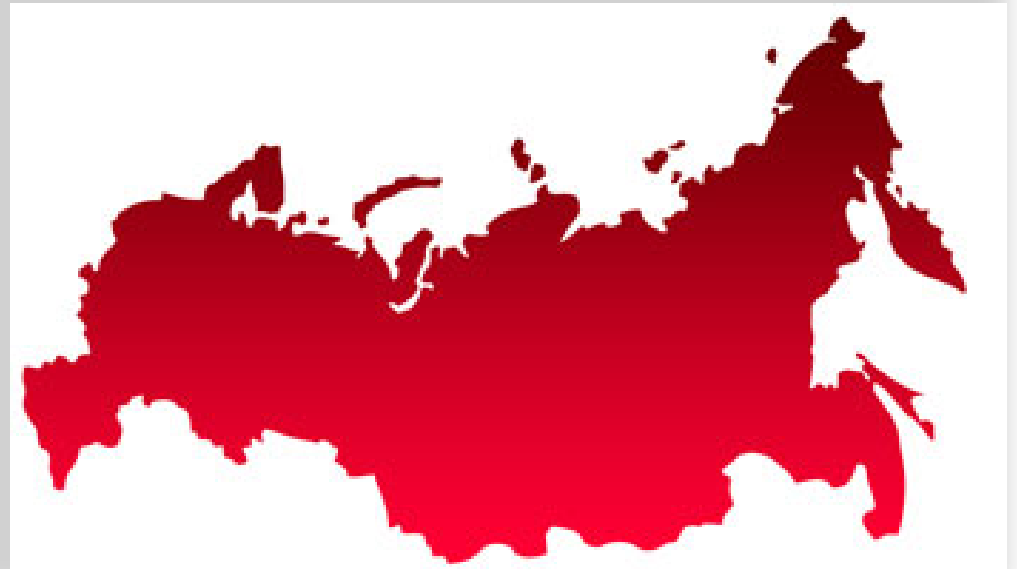
Key Points

- *Device classification in the Russian Federation*
 - *Authorized representation requirements*
 - *Testing*
- *Registration Dossier preparation and submission*
 - *Obtaining a Registration Certificate*
 - *Declaration of Conformity applications*
 - *Timelines*



Russian Market Overview

- Population: more than 142 million*
- GDP of \$2 trillion*
- Healthcare spending: 5.4% of GDP*
- Large but fragmented and complex medical device market
- Local contacts essential for successful commercialization



**Source: CIA World Factbook*

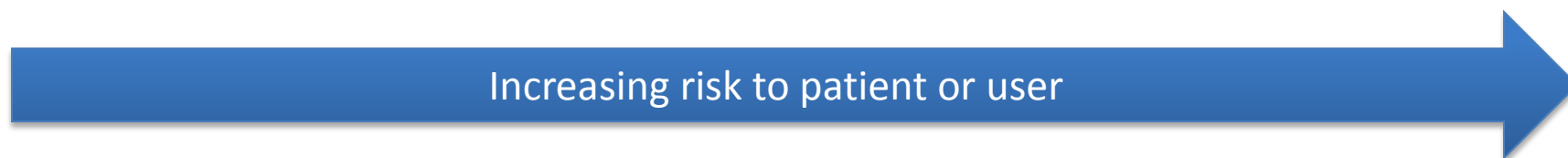
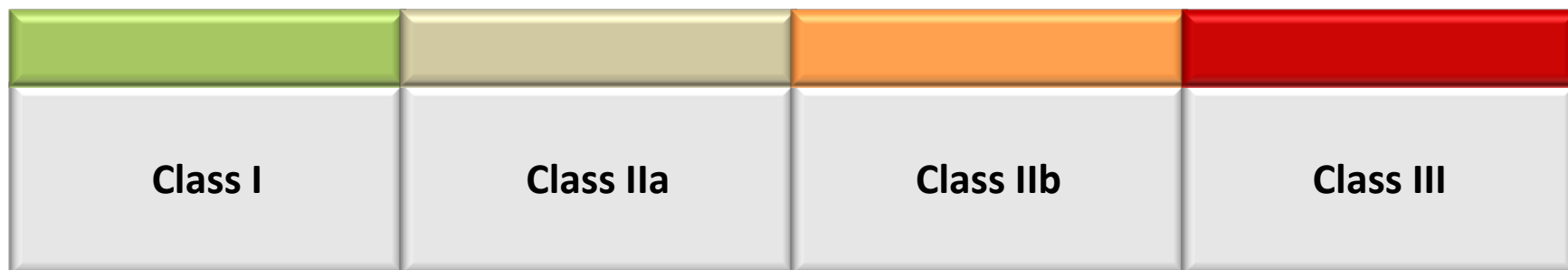


Medical Device Classification in Russia

- Russian classification system similar but not identical to European system
- Identification of equivalent devices already marketed in Russia required
- Classifications are confirmed using Roszdravnadzor Order No. 735 and GOST 51609-2000.



Device Classification, cont'd.





Authorized Representation in Russia

- Foreign medical device companies with no operations in Russia must appoint an authorized representative known as a **Declarant**.
- Your Declarant assumes responsibility for your device registration in Russia and meets with Russian regulatory officials on your behalf.
- Your Declarant manages your registration process with Roszdravnadzor as well as inspection and vigilance issues.





Product Testing Requirements

- Medical device registration in Russia is based on product testing that must be performed *in Russia*.
- Test results obtained in other markets are typically not accepted by Roszdravnadzor
- Russian GOST standards are not harmonized with other international standards





Product Testing, cont'd.

- You must obtain permission from Roszdravnadzor for importation of testing samples
- Quality, safety and efficacy testing of your device is carried out by Authorized Expertise Centers and Hospitals in Russia.
- Results of these tests are a crucial component of your registration application.





Registration Dossier Preparation and Submission

- Once product test results are finalized, you must prepare a Registration Dossier and submit it to Roszdravnadzor for review.
- Russian regulators may require proof of registration in your home market.
- Roszdravnadzor does not recognize CE Marking, US FDA 510(k) clearance or any other registration from a foreign regulator.





Registration Dossier, cont'd.

- All documents in your Registration Dossier must be submitted in Russian.
- Roszdravnadzor may require additional testing upon review of your Registration Dossier (more often for Class IIb and III devices)





Approval and Registration Certification

- *If your device is approved by Russian authorities, Roszdravnadzor will issue a **Registration Certificate** for your product.*
- *Your Registration Certificate will not expire unless you make changes to your device, claims or packaging.*



Declaration of Conformity Certification

- You must apply for Declaration of Conformity certification (formerly known as GOST-R certification) after receiving your Registration Certificate.
- Declaration of Conformity certificates are issued by the Federal Agency for Technical Regulation and Metrology (Rosstandart)
 - Maintains list of products requiring certification in Russia
 - Authorizes testing labs to perform required testing of medical devices



Declaration of Conformity: Required Documents

Your application For Declaration of Conformity certification should include documents such as:

Certificate of Registration	ISO 13485 or 9001 certification
Brochure of device technical details in Russian	Declaration of conformity with list of product codes and names
Instructions for Use in Russian	Product labeling, pictures and/or samples
Protocols and test reports from accredited laboratories	Safety Certificates from international authorities



Declaration of Conformity, cont'd.

Declaration of Conformity certificates are valid for either one or three years depending on the type of registration for your device.

2013				
	Январь	Февраль	Март	Апрель
Пн	7 14 21 28	4 11 18 25	4 11 18 25	1 8 15 22 29
Вт	1 8 15 22 29	5 12 19 26	5 12 19 26	2 9 16 23 30
Ср	2 9 16 23 30	6 13 20 27	6 13 20 27	3 10 17 24
Чт	3 10 17 24 31	7 14 21 28	7 14 21 28	4 11 18 25
Пт	4 11 18 25	1 8 15 22	1 8 15 22 29	5 12 19 26
Сб	5 12 19 26	2 9 16 23	2 9 16 23 30	6 13 20 27
Вс	6 13 20 27	3 10 17 24	3 10 17 24 31	7 14 21 28
	Май	Июнь	Июль	Август
Пн	6 13 20 27	3 10 17 24	1 8 15 22 29	5 12 19 26
Вт	7 14 21 28	4 11 18 25	2 9 16 23 30	6 13 20 27
Ср	1 8 15 22 29	5 12 19 26	3 10 17 24 31	7 14 21 28
Чт	2 9 16 23 30	6 13 20 27	4 11 18 25	1 8 15 22 29
Пт	3 10 17 24 31	7 14 21 28	5 12 19 26	2 9 16 23 30
Сб	4 11 18 25	1 8 15 22 29	6 13 20 27	3 10 17 24 31
Вс	5 12 19 26	2 9 16 23 30	7 14 21 28	4 11 18 25
	Сентябрь	Октябрь	Ноябрь	Декабрь
Пн	30 2 9 16 23	7 14 21 28	4 11 18 25	30 2 9 16 23
Вт	31 3 10 17 24	1 8 15 22 29	5 12 19 26	31 3 10 17 24
Ср	4 11 18 25	2 9 16 23 30	6 13 20 27	4 11 18 25
Чт	5 12 19 26	3 10 17 24 31	7 14 21 28	5 12 19 26
Пт	6 13 20 27	4 11 18 25	1 8 15 22 29	6 13 20 27
Сб	7 14 21 28	5 12 19 26	2 9 16 23 30	7 14 21 28
Вс	1 8 15 22 29	6 13 20 27	3 10 17 24	1 8 15 22 29

Final Approval and Listing

- If approved, your device will be listed on Roszdravnadzor's website:
<http://www.roszdravnadzor.ru/>
- Declaration of Conformity symbol, registration number and date should be placed on your device.
- Be prepared to present applicable certifications upon importation.





Additional Resources

Russian medical device regulations:

<http://www.emergogroup.com/resources/regulations-russia>

Emergo Group QA/RA blog coverage of Russia:

<http://www.emergogroup.com/blog/term/russia>

Emergo Group consulting services for the Russian market:

<http://www.emergogroup.com/services/russia>

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