The Medical Device Approval Process in Russia
The medical device approval process in the Russian Federation

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
The medical device approval process in the Russian Federation

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.

- **Class I**: Low risk to patient or user
- **Class IIa**: Moderate risk to patient or user
- **Class IIb**: Higher risk to patient or user
- **Class III**: Increasing risk to patient or user
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.*
The medical device approval process in the Russian Federation

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
The medical device approval process in the Russian Federation

Declaration of Conformity: Required Documents

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

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

Ann Marie Boullie
Vice President of Business Development
Emergo Group
US office: +1.512.327.9997
EU office: +31.70.346.7299
marketing@emergogroup.com