



Emergo Group assists medical device companies worldwide with classification, registration, representation and testing in the Russian Federation as shown below.

Device classification consulting

Russia's device classification scheme is similar to Europe. However, it is more difficult to ascertain the proper classification of a device. Our Moscow-based team has extensive experience with medical device classification, the first important step toward a smooth registration process.

Regulatory representation in Russia

Foreign companies are required to have a local liaison to communicate with the Russian authorities. Many companies appoint a distributor to act as their "authorized representative" and register their device with Roszdravnadzor. Doing so may give the distributor control over the device registration. Emergo Group is an independent representative, allowing you to maintain more control over your medical device approvals.

GOST-R testing in Russia

The Russian approval process is based on product testing, regardless of whether your medical device has been tested and certified to international standards. Of course, trying to coordinate this process from outside Russia is nearly impossible since face-to-face meetings are typically still required. Emergo Group can assist by meeting with officials to determine which tests will be required and coordinating the testing with authorized test facilities within the Russian Federation. Testing results are then used as a key component of the registration dossier.

Medical device registration dossier for Russia

Russia does not recognize European CE Marking, US FDA 510(k) clearance or any other approval from a national Ministry of Health. However, Russia MAY require your device to have approval in your home market. The dossier is the most important part of the registration process and our consultants will ensure that all documents are properly formatted, testing results are included and all documents and certificates are translated into Russian. We will also work with officials from Roszdravnadzor to answer questions during the registration process as needed.

Device labeling and translation into Russian

Our office in Moscow will advise you on device labeling requirements in Russia and aid in the translation of Instructions for Use (IFU), labeling and other documents as required by law.

Finding and managing medical distributors in Russia

The Russian Federation is a challenging business environment for outsiders and finding well qualified, reputable distributors can be the difference between success and failure. Our office in Moscow can help you find, evaluate and manage qualified distributors in Moscow, St. Petersburg and other cities within Russia.

* Classification of devices is very similar to the European system.

** Product testing completed within Russia is required because devices must conform with Russian GOST standards which are not harmonized with international standards, albeit very similar. The Russian GOST-R certificate is similar to a European CE Marking certificate.

^ All documents and certificates submitted as part of the registration process MUST be translated into Russian.

^^ For Class I or IIa device which has an approved equivalent in the Russian Federation, additional testing specified by Roszdravnadzor is usually not required

ROSZDRAVNADZOR – This is the Ministry of Health and the common name of "The Federal Service for Control over Healthcare and Social Development of Russian Federation." This agency oversees all medical devices and controls the registration procedure. GOSSTANDART – Known as the "Federal Agency for Technical Regulation and Metrology," this agency is responsible for GOST-R certification, ensuring that all medical equipment imported into Russia meets established Russian standards.