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for the medical device industry

Importing medical devices into the Russian Federation

Approval of medical devices is mandatory in the Russian Federation. Manufacturers or distributors must have medical devices approved before they can place them on the Russian market.

In the first and most important step, medical devices are registered by Federal Service for Surveillance in Healthcare (Roszdravnadzor). In this step, the devices generally undergo technical testing for safety and biocompatibility, followed by clinical evaluation.

Since the Russian Federation and the European Union have not signed a mutual recognition agreement regarding one another's conformity assessments, medical devices exported to the Russian Federation must be assessed for conformity with Russian standards and requirements.

All medical devices are included in the Russian product classification system and assigned to a certain product code. This code is cited on the registration certificate. Depending on the respective product code, medical devices are either exempted from or subject to 10% or 18% value added tax (VAT).

Registration can be applied for in either the manufacturer's or the distributor's name. If the documents are issued in the distributor's name, all registration certificates will have to be revised if the manufacturer decides to work with another contractual partner. As this is costly and time-consuming, we recommend applying for the documents to be issued in the manufacturer's name.

In this case, distributors obtain a notarized copy of the registration certificate permitting the import and marketing of the devices in the Russian Federation without difficulties.

In the second step, a declaration of conformity issued by an accredited Russian certification body must be obtained for the medical device. This declaration can only be issued in the name of a company located in the Russian Federation.

The registration certificate and the declaration of conformity are mandatory elements of the export documentation required for the Russian customs authorities and distribution.

Registration is effected by the Federal Service for Surveillance in Healthcare (Roszdravnadzor)

Before medical devices can be registered, they must first pass several tests. The responsible authority will issue a special permit to import samples of the medical device into the Russian Federation for testing. After completion of technical and biocompatibility testing, a product-specific registration dossier must be compiled and submitted to Roszdravnadzor.

The dossier must include the following documents:

- a. Application for registration
- b. Medical device information sheet
- c. Extract from the commercial register (company registration certificate)

- d. Certificate as per ISO 13485
- e. Evidence of home market approval (e.g. EC certificate, 510(k) clearance, etc.)
- f. Declaration of conformity if EC approval
- g. Technical documentation
- h. Instructions for use
- i. Product photos, product labels
- j. Technical, toxicological and, where applicable, clinical test reports

The submission will be forwarded for review from Roszdravnadzor to one of the expert organisations. After the evaluation of the technical documentation and the test results a decision is made on whether and to which extent clinical tests have to be conducted. The responsible authority issues a special permit to conduct clinical trials. Following the completion of clinical testing, the clinical documentation must be submitted to the authority. Independent experts will evaluate the documentation and inform Roszdravnadzor of their results. If the medical device is considered safe and effective, the Russian authority issues a registration certificate and enters the device in the government register for medical devices.

The registration certificate is issued without an expiration date. However, all registration certificates with unlimited validity, which were issued before December 31, 2012, must be reissued. The previous deadline for reissuing of these certificates has been cancelled by Roszdravnadzor and extended to January 1, 2021.

Registrations are available in a public database in Russian on the authority's website at:
<http://www.rozdravnadzor.ru/services/misearch>

From GOST-R certificate to declaration of conformity

The second part of the approval of medical devices in the Russian Federation comprises the issue of a declaration of conformity. On November 13, 2010, the Russian government passed its Resolution N° 906, making a declaration of conformity mandatory for almost all medical devices. Given this, the obligation to obtain a GOST-R certificate for medical devices no longer exists.

In contrast to GOST-R certificates, declarations of conformity can only be issued to companies located in Russia (generally a distributor or a branch of the manufacturer located in the Russian Federation).

The declaration of conformity confirms that the medical device complies with all applicable technical requirements and standards. The applicant applies to the Russian certification body for a declaration of conformity. The certification body reviews the test reports and contractual agreement(s) between the manufacturer and the Russian local company to verify that they are complete and correct, and if so, it issues the declaration of conformity. By issuing the declaration of conformity, the certification body confirms that the medical device complies with the Russian GOST-R standards cited in the declaration. The declaration of conformity is signed by the applicant and registered with the certification body.

After completion of the declaration of conformity, the GOST-R certification mark must be affixed to the medical device without citing the certification body.



Active medical devices require an additional declaration of conformity according to TR CU 20/2011 from the Eurasian Customs Union. The devices should be tested for electromagnetic compatibility and finally labeled with the Eurasian conformity symbol "EAC".



Voluntary GOST-R certificate

When applying for a declaration of conformity, the importers of medical devices may also apply for a voluntary GOST-R certificate for marketing reasons.

The certificate helps manufacturers to promote their products on the Russian market and demonstrates compliance with the product-specific GOST-R standards.

The voluntary GOST-R certificate has a one- or three-year period of validity. The voluntary GOST-R certification mark consists of the three letters "PTC" (which stand for "Russian standard") and the addition "Voluntary certification".



Documentation to be submitted to TÜV SÜD to obtain approval for the Russian Federation

- a. Advertising material, brochures in German, English, or Russian
- b. Medical device information sheet and detailed list of all components and accessories included in the consignment in Russian
- c. Extract from the commercial register (notarized and apostilled) in German or English
- d. Power of attorney issued by the manufacturer authorizing TÜV SÜD to act on its behalf in the approval process (notarized and apostilled) in German or English
- e. Certificate in accordance with ISO 13485 (notarized and apostilled) in German or English
- f. Evidence of home market approval (e.g. EC certificate according to 93/42/EEC, 98/79/EC or 90/385/EEC for European market or 510(k) clearance for US market, etc.; notarized and apostilled) in German or English
- g. Instructions for use in Russian
- h. Technical test reports (e.g. in accordance with IEC 60601-1, IEC 60601-1-2, and, where appropriate, for biocompatibility tests in accordance with ISO 10993, etc.) in English
- i. Technical documentation

There are many good reasons for choosing TÜV SÜD as your partner!

- We offer reliable and flexible assistance and act promptly.
- We have long-standing experience with the approval of medical devices in the Russian Federation.
- We have detailed knowledge of all criteria that must be fulfilled to obtain approval of your medical devices in the Russian Federation.
- We and our experts, native Russian speakers, accompany your project from start to finish.

Your contact partner at TÜV SÜD Product Service can provide further information.

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