Medical Device Regulatory Requirements for Russia

Registering Medical Equipment in Russia
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Author: Ludmila Maksimova

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SUMMARY

Despite positive changes in the last several years, the registration procedure for Medical Equipment in Russia still lacks clarity and transparency. Russia still relies on product testing as a key element of the medical product approval process. Other types of product safety assurance, such as plant auditing, quality systems, and post market vigilance started to develop only recently, after the adoption of the Federal Law of the Russian Federation on Technical Regulation of July 1, 2002. Russia adheres to redundant practices of further testing of FDA-approved and CE-marked medical equipment and devices which delays entry of advanced medical technologies into the country. In addition, cultural and language barriers continue to be a significant challenge to foreign companies attempting to register medical equipment by themselves without appropriate legal advice or help from experienced distributors or consultants.

Medical Equipment Registration Structure and Stages

The Federal Service for Control over Healthcare and Social Development (Roszdravnadzor) is the main government agency responsible for registration of medical equipment, including foreign-made. The Service has a Russian-language web site containing a section devoted to registration of foreign medical equipment at http://www.roszdravnadzor.ru/registration/zarub/contact/zarub_contact.html
The site also publishes contact information for the staff of the Department of Registration of Foreign Medical Equipment and Devices who are directly involved in registration of foreign-made medical equipment. Experts of the Department do not provide consultation by phone and prefer meeting in person with authorized company representatives to discuss registration procedures and documents and solve problems whenever necessary. The business language of these meetings is Russian.

As the registration procedure is quite complicated and as the documents tend to change due to continuous changes in the regulatory requirements, the only way to accomplish registration of a medical product in Russia is through one of the following types of companies: a company incorporated in Russia and belonging to the U.S. parent company, a Russian distributor/authorized agent or a consulting company. U.S. companies are

recommended to work with reliable partners and consulting companies on medical product registration issues. Also, useful information regarding registration can be obtained at the following web site: www.pharminform.ru. It belongs to the Russian consulting company Pharminform and offers an English version.

The registration procedure includes the following stages. At first, the authorized company representative has to meet with an expert from the Department of Registration of Foreign Medical Equipment and Devices and submit documents necessary for registration. The Department will review documents, make a decision on accepting the documents for registration. The Department will further do in-depth examination of documents and decide the types (usually technical, clinical and toxicological and/or others) and the scope of tests that the medical equipment should undergo, if necessary. At the third stage the samples will be sent for testing to special centers and laboratories. In some cases, companies will execute testing of samples prior to submitting the documents. At the fourth stage, the results of the tests will be sent to the Department of Registration of Medical Equipment and Devices for final review, approval and issuing the registration certificate.

List of Documents

Below is the list of documents, which an authorized representative of a foreign company must submit to Roszdravnadzor to start the registration process:

1. **A letter from the manufacturer (see Appendum #1)**

The letter should state manufacturer's intention to apply for registration of their products and must be typed on the company's letterhead in the official language of the Manufacturer with translation into Russian.

2. **An application for registration or re-registration of a medical product (see Appendum #2)**

The application must be on the applicant's (the legal entity which is authorized to conduct registration in Russia) letterhead. The Application should contain a description of all components and parts, which come with the device or equipment. The application must be in Russian or have a Russian translation.

3. **A Power of Attorney to the authorized representative to conduct registration (see Appendum #3)**

The manufacturing company must issue a Power of Attorney to the legal entity (addressed to the head of the legal entity), which is authorized to conduct registration, and it must be notarized in the country of the origin of the manufacturer**.** It should also be translated into Russian and have an Apostil from the Russian Consulate office in the United States. The Power of Attorney must state that the manufacturer entrusts the

Applicant to conduct the registration of a medical device/equipment, sign a consultative and expert works contract and receive the registration certificate.

4. **A reference material on the medical product**

The material must contain the most detailed description of the purpose and area of application of the product. If the product is new, treatment principals and systems should be attached. It should contain information on when the product was developed, launched into production and which world markets it is supplied to. The document must be prepared in Russian or have a Russian translation.

5. **A picture of the medical device/equipment (not smaller than 130x180 millimeters)**

The picture must reflect the appearance of the device and its components.

6. **Advertising illustrative materials.** Can be provided in a foreign language.

7. **Documents on registration of the manufacturing company in the country of origin and/or third countries**

   Examples of such documents include: Certificate of registration, Patent for the right to conduct certain business activity, Certificate of incorporation or a similar document issued by a Chamber of Commerce or a government agency in the country of origin. The above documents should not be confused with the license on manufacturing.

8. **Documents on the registration of a product in the country of origin as a measurement device (if available)**

9. **National or international documents confirming the conformity of medical device/equipment to the requirements of national and international normative documents and characterizing the manufacturing process**

In other words, these documents should confirm the fact that the product was registered in the country of origin as medical device as well as prove the quality of manufacturing process. Examples of such documents include:

- ISO 9001, ISO 9002, ISO 13485, ISO 13488 certificates which should be notarized in the country of origin and have an Apostil,
- Certificates of registration of medical equipment issued by a respective government agency in the country of origin such as FDA certificates, EC Certificates (CE Mark) and Declaration of Conformity. All these certificates should be notarized in the country of origin and have an Apostil,
- Certificate of free sales,
- Electrical safety and EMC (electromagnetic compatibility) certificates,

If a medical device does not have a certificate of manufacturing, it is necessary to make a reference to the national document, which proves that such certificate is not required.

10. Manufacturer's operational manual in Russian and Manufacturer's price list on its letterhead

Documents in the items 7, 8, 9 and 10 should be originals or notarized copies, which have undergone legalization or have an Apostil obtained from the Russian Consulate office in the United States.

The term for registration certificates for medical equipment, devices, instruments, plants, and medical furniture is 10 years, while for medical supplies, including reagents and disposable items, 5 years. Re-registration is necessary in the following cases:

- Expiration of the registration certificate;
- Change of the manufacturer's name;
- Change of the product name;
- Change of the manufacturer of the registered product.

As follows from the above discussion, the registration procedures are quite complicated and there are many gray areas, factors that can be generally characterized as trade barriers. However, many U.S. companies directly, or through their authorized representatives, have established good working relations with the Federal Service for Control over Healthcare and Social Development and have successfully overcome difficulties, which they encounter when registering or re-registering medical products in Russia. If a U.S. company does not have a representative office in Russia with qualified registration personnel, assistance from a consultant or an authorized distributor is crucial.

Registration of medical equipment usually takes from 4-6 months up to a year and there is no easy method for estimating the entire cost. There are no formal published lists of registration fees for different types of equipment available from the Ministry of Health and Social Development list. Rather, the Ministry advises that representatives of the company request an in-person meeting with an expert from the Department of Registration of Imported Medical Equipment within the Ministry of Health. Ideally, the Department of Registration of Imported Medical Equipment should be contacted directly by an authorized representative of the U.S. company in Russia or their certification consultant.

Total costs for completing the process can vary widely after the additional costs for the tests and the commissions charged by the consultant are added to the costs of the registration certificate. Drawing on the experience of other U.S. companies whom we have supported, the final price is usually several thousand dollars, ranging $3,000 - $4,000 for medical supplies or disposable items up to $10,000 and more for high-end

technical equipment. These are only ballpark estimates and provided as general information. The actual costs need to be confirmed every time on a case-by-case basis.

Though, in rare cases, it is the distributor who covers most or all of the costs of registration, the actual registration should only be done in the name of the manufacturer and who then becomes the owner of the certificate. This gives the manufacturer more flexibility in those cases where a change of distributor occurs before the validity of the certificate expires.

The registration certificate is the first and most important document to facilitate the import of medical equipment as it authorizes the free circulation and use of the device on the country's territory. However, in order to be able to clear medical equipment through customs in addition to registration, the equipment must be accompanied by one or two of the following documents (depending on the type of the equipment): the "GOST-R" quality and safety certification and sanitary and epidemiological assessments. These two certifications can only be issued after the registration certificate is obtained. GOST R certificate is issued by a certification organ or testing center accredited by Gosstandart (Federal Agency for Technical Regulations and Metrology) for a term of one year (for a shipment or several shipments under one contract) or three years (if experts of Gosstandart visit and assess a foreign producer's manufacturing facility in the country of origin). Sanitary epidemiological conclusion is issued by Federal Service for Control over Consumer Rights and Well-Being of the Population (Rospotrebnadzor) for a term of one year (if the conclusion is obtained prior to registration) or five years (if the conclusion is obtained after the registration). Usually both certificates are issued in the name of the distributor who bears the costs.

Since obtaining the GOST R certificate of quality and safety and sanitary epidemiological conclusion is a complicated and time-consuming procedure U.S. companies are recommended to obtain them through an authorized distributor or consultant. Consultants are always able to provide these two certificates as a part of a package deal along with the registration certificate since many documents necessary for obtaining all the aforementioned documents overlap.

U.S. Commercial Service offices in Russia offer U.S. exporters a number of services aimed at generating export sales, including identifying distributors and arranging meetings with prospective buyers during business visits to Russia. For more information on our services, please visit our web site at www.buyusa.gov/russia/en or contact us directly:

Ludmila Maksimova, Commercial Specialist
U.S. Commercial Service – Embassy Moscow
Tel: 7-095-737-5037 Fax: 7-095-737-5033
E-mail: Ludmila.Maksimova@mail.doc.gov

Addendum # 1

Manufacturer's Letter

Hereby _____
Company's name and country
Would like to advise you of its wish to register (re-register) the following medical product (device, equipment) in the Russian Federation
_____
Name of the product

This medical product (device/equipment) is registered in the country of the Manufacturer (in other countries)
_____
Registration no., date and authority

This medical product is registered as a means of measuring in the country of the Manufacturer (in other countries)
_____
Registration no., date and authority

Addendum # 2

Application for registration/re-registration of a medical product in the Russian Federation

1. Name of the Company-Applicant , country, postal address, telephone, fax.
2. Name of the Company-Manufacturer of the medical product, country, postal address, telephone, fax.
3. Name of the medical product with the full list of accessories used with it (full possible specification).
4. Function and purpose of the medical product.
5. Changes that have occurred since the moment of registration in the Russian Federation (in case of re-registration).

Addendum # 3

Date
Signature and stamp of the applicant

On the Company's letterhead

POWER OF ATTORNEY

Herewith, _____, having its registered office at _____ in the person of _____ authorized the Power of Attorney to _____, with registered office at _____ Moscow, Russia, in the person of General Director _____, to register, re-register and certify all range of medical devices on the territory of the Russian Federation.

We authorized _____, to carry out the following actions in the name of our company:

- to represent interests of our company in all necessary state bodies and other organizations for testing and registration of medical devices;
- to carry out the negotiations relating to testing and registration of medical devices ;
- to submit all necessary documents to state bodies and institutions
- to sign the appropriate contracts, applications, any other documents, including financial documentation
- to seal all necessary documents in the name of our company;
- to introduce amendments and addendum inserts into documents, to give explanations, to submit additional information;
- to make payments of all official fees;
- to obtain all necessary documents.

This Power of Attorney is valid for three (3) years.

The Power of Attorney is given with the right to transferring.

Issued date:
_____