



Russia: Registration of Medical Devices and Equipment

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July 2014

Summary

Registration of medical devices and equipment has always been a rather complex, time consuming, and expensive process. All medical devices and equipment have to go through a mandatory set of tests, even though the same tests have been performed during a process of obtaining a CE-mark or an FDA approval. Since 2002, the Russian government started to change this process through substituting tests with other types of product safety assurance, such as plant auditing, quality systems, and post market vigilance. Unfortunately, these attempts were not successful and in reality this process tightened even further since January 01, 2013.

Registration Certificate

Registration certificate for medical devices is an official document issued by the Federal Service for Control over Healthcare and Social Development (Roszdravnadzor) that confirms that this device passed all trials, and can be manufactured, imported, sold and used on in the territory of Russia.

All medical devices that are manufactured in Russia or abroad should be registered. The registration certificate will contain the name of the title holder, who can be a manufacturer, distributor, or legal representative.

If the medical device consists of modules/blocks manufactured by different producers, and doesn't constitute a trade-marked product, then each module/block should be registered individually.

The registration certificate gives the right to the manufacturing company to have a reduced VAT or 0% VAT, if the device is in the list of essential products (Government Decree January 17, 2002 N 19, http://www.rg.ru/oficial/doc/postan_rf/19_p.shtm).

On June 06, 2012 Minister of Healthcare of Russian Federation Skvortsova signed an Order N 4H "About Conformation of Nomenclature Classification of Medical Devices"
<http://www.rg.ru/2012/10/24/medizina-dok.html>

This order includes the classification according to use (Addendum 1) and class of risk (Addendum 2).

The classification of risk for all medical devices, excluding in vitro diagnostic kits that have their own classification, is the following:

- Class 1 - low risk
- Class 2a - medium risk
- Class 2b - elevated risk
- Class 3 - high risk

Tests can be done only by the laboratories listed in the Government Decree from May 06, 2011 N 352. As for clinical tests, the list of institutions that can perform this function is published on the website of Roszdravnadzor
http://www.rozdravnadzor.ru/national_foreign_medprod/clinical_trials/list

- Toxicological
- Technical
- On Electromagnetic compatibility
- Clinical

The foreign manufacturer should provide the following documents:

- The Power of attorney from manufacturer for registration/certification process (should be notarized and apostilled).
- The document of registration of the company in its country (for example: The reference from the Chamber of Commerce Industry, Annual registration FDA or Certificate of Incorporation, Business License) (should be notarized and apostilled).
- Certificate confirming correspondence of medical product to the national or international norms and describing the conditions of its production (for example: ISO 9001, 9002, 13485, 13488) (should be notarized and apostilled).
- Certificates of conformity of medical product to Directive 93/42/EEC and safety of product (for example: EC Certificate, Declaration of Conformity (only for I-IIA class), Free Sale Certificate, FDA Certificate) or document confirming the registration of medical device in the country of manufacturer or in other countries (should be notarized and apostilled).
- Test Report for safety (IEC 60601-1, IEC 60601-1-2, ISO 10993 etc.) - it might be as well would be helpful to give the complete report to lighten the technical examination at the testing laboratory (for medical electrical devices).
- Test Reports for toxicological safety / biocompatibility.
- Samples for the technical, toxicological tests.
- An application for registration or re-registration of a medical product. 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.
- Power of Attorney to the authorized representative to conduct registration. 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.

GMP (Good Manufacturing Practices) inspections are not required for the registration process, but the legislation that will introduce these inspections will be in place in the near future.

Usually the cost of registration is from \$ 10,000 to \$ 15,000 U.S. dollars depending on the range of tests needed.

It is possible to check the registration status of a medical device on the Russian version of Rospotrebnadzor website: <http://roszdravnadzor.ru/registration/mi/login>

Analogues (same potential risk class, applied by the same methods, same efficiency) of medical devices of class 1 and 2a are registered on the basis of document from the manufacturer stating that the two products are equivalent or on the basis of technical tests, safety evaluation, confirming that there are only small differences.

All others, including class 2b, 3 and 1 and 2a (without analogues) are registered on the basis of technical tests, safety evaluation, clinical and medical tests that confirm effectiveness and safety.

Registration number and date of registration of medical device must be on packaging, label, areas of use, instructions for use, advertising products, so that the end-user can see this information.

Step-by-step process

Step 1

Since August 14, 2012, the representative of the company has to file an application for the permission of Rosdravnadzor to send samples to Russia. This permission is valid for 6 months. In addition he has to provide a description of the product, signed contracts with testing laboratories, a power of attorney or a contract with the manufacturer.

Step 2

Then these samples have to be cleared through Customs. In addition to samples a representative should provide a contract, a letter for customs officials, and an invoice).

Step 3

The following tests have to be performed at the accredited laboratories: toxicological, technical, and tests on electromagnetic compatibility (only for electrical products).

Step 4 (parallel with Step 3)

The company should prepare a full package of documents.

Step 5

If a medical device is of class 2b, 3, 1, and 2a and it has no analogue in Russia, the first stage of quality assessment, efficiency and safety is performed. After the clinical tests in two different medical facilities are done, the second state of quality assessment, efficiency and safety is done.

Step 6

The company brings the whole package of documents to Rospotrebnadzor.



Metrological Certificate

http://www.esspb.ru/q1_controllers.html

In addition to the Registration Certificate, Approval of Weighting and Measuring Instruments, which is also called Metrological Certificate is needed for medical devices with weight or measure tools (gauges, thermometers, and various sensors). This certificate confirms that this tool has passed all technical and metrological tests, complies with the requirements of current legislation in the Russian Federation and is included in the list of approved tools. The list of all such approved tools is published on the website of Federal Agency for Technical Regulations and Metrology (Rosstandart)

http://www.fundmetrology.ru/10_tipy_si/list.aspx

If this weight or measure tool is already approved, a manufacture or its legal representative should apply to National Certification agency (VNIIS) to get the letter confirming it.

The following documents govern the process of obtaining Metrological Certificate:
Federal Law N102 “About Provision of the Unity of Measurements of June 26, 2008
<http://www.rg.ru/2008/07/02/izmereniya-dok.html>

Administrative Order N970 of June 25, 2013
<http://www.rg.ru/2013/10/16/rosstandart-reg-dok.html>

The validity of this certificate is 5 years. The costs vary and the range can be from \$ 3,000 to \$ 20,000. Usually it takes about 3 months to get this certificate and both manufacturer and importer can be the title holders.

The following documents should be supplied as well as that should be translated, notarized and apostilled, if the originals are not in Russian) should be supplied:

1. Application form (Sample is attached in the Addendum 1 of the Order N970)
The letter should state manufacturer’s intention to apply for Metrological Certificate and must be typed on the company’s letterhead in the official language of the Manufacturer with translation into Russian.
2. Technical Documentation for a weight or measure tool, including the technical work specification and methods of manufacturing.
3. Original program of metrological tests.
4. Metrological test results.
5. Description of a weight or measure tool, its HS Customs Code, instruction for use.
6. Original passport of a weight or measure tool.

7. Labels.
8. Samples, usually one, but sometimes three or the photos of a weight or measure tool



Customs Union State Registration Certificate (EurAsEC hygienic registration)

http://www.budemzdrovee.ru/sertifikat_varranty

This Certificate is needed only for medical devices that have disinfectants and dental mixtures on the basis of cast in its contents.

It replaced Hygienic Certificate on June 01, 2010 for Customs Union (now Eurasian Economic Union) between Russia, Kazakhstan and Belarus.

It is issued by the Federal Service for Supervision of Consumers Protection and Welfare (Rospotrebnadzor).

The document that provides all the necessary information about this Certificate, as well as documents that are required for it to be issued (they are same as for Registration Certificate) are published on the website of Eurasian Economic Union
http://www.eurasiancommission.org/ru/act/texnreg/depsanmer/sanmeri/Documents/Единф_ормдок-206.pdf

There is no validity period for this certificate and as in the case of Registration certificate the title holder can be a manufacturer, a distributor, or a legal representative.



ТАМОЖЕННЫЙ СОЮЗ
ДЕКЛАРАЦИЯ О СООТВЕТСТВИИ

Заявитель, ЗАО «ПО Физтех»

634012, Российская Федерация, г. Томск, пр. Кирова, д. 58, стр. 70, тел. +3822431717, факс +3822431771, ОГРН 1107017009208

и. л. Директора Чуприкова В.А.

заявляет, что Арматура промышленная трубопроводная: краны пробковмертвыходовые нагнанные муфтовые универсальные, мод. ФТ1.003, Продукция изготовлена в соответствии с ТР ТС 010/2011 «О безопасности машин и оборудования».

изготовитель: ЗАО «ПО Физтех», 634012, Российская Федерация, г. Томск, пр. Кирова, д. 58, стр. 70

Стандарты, нормативные документы: ТУ 3712-001-64115539-2013

Код ТН ВЭД ТС: 8481808190

Серийный выпуск

соответствует требованиям

ТР ТС 010/2011 "О безопасности машин и оборудования"

Декларация о соответствии принята на основании

протокола № 41403-ТО2/1-0524 от 23.07.2013 г., Испытательная лаборатория ООО "ЮтРесурс", рег. № РОСС RU.0001.21AB93 от 28.10.2011, адрес: Краснодарский край, г. Новороссийск, ул. Мира, д. 9, оф. 307.

Дополнительная информация

Условия хранения продукции в соответствии с ГОСТ 15150-69. Срок хранения (службы, годности) указан в прилагаемой к продукции товаросопроводительной и/или эксплуатационной документации.

Декларация о соответствии действительна с даты регистрации по 23.07.2018

включительно.



В.А. Чуприков

(инициалы и фамилия руководителя организации-заявителя или физического лица, зарегистрированного в качестве индивидуального предпринимателя)

Сведения о регистрации декларации о соответствии:

Регистрационный номер декларации о соответствии: ТС № RU Д-РУ.А.116.В.12030

Дата регистрации декларации о соответствии: 24.07.2013

Declaration of conformity GOST-R (mandatory)

<http://www.fiztech.ru/about/news/88-poluchena-deklaratsiya-o-sootvetstvii-trehhodovih-kranov-zao-po-fizteh-.html>

It is the last document to get for medical devices. Manufacturer, supplier, or a legal representative, who is registered on the territory of the Russian Federation can sign this document.

The signed declaration is registered by the certification body, accredited by Federal Agency for Technical Regulations and Metrology (Rosstandart) that checks the documentation submitted in support of the declaration. It is valid up to 5 years.

The sample form is in the Gosstandard Decree N12, from March 17, 1998.

Trade Events

Zdravookhraneniye'2014, the 24rd International Exhibition for Health Care, Medical Engineering and Pharmaceuticals
December 8 -12, 2014
Moscow, Exhibition center "Expocenter"
<http://www.zdravo-expo.ru/en/>

Resources & Contacts

The following are the key government standards organizations in Russia.
Federal Agency for Technical Regulations and Metrology (Rosstandart)
9, Leninsky Prospect
Moscow, 119991
Tel: +7 (499) 236 0300
Fax: 7 +(499) 236 6231
E-mail: info@gost.ru
<http://www.gost.ru/wps/portal/pages.en.Main>

Federal Service for Control over Healthcare and Social Development (Roszdravnadzor)
Slavyanskaya sq. 4, building 1
Moscow, 109074
Tel.: +7 (495) 698 4538
E-mail: info@roszdravnadzor.ru
<http://www.roszdravnadzor.ru>

Federal Service for Supervision of Consumers Protection and Welfare (Rospotrebnadzor)
Vadkovskiy pereulok, house 18, stroenie 5 and 7
Moscow, 127994
Tel.: +7 (499) 973 2690

E-mail: depart@gsen.ru
<http://www.rospotrebnadzor.ru/>

VNIIS
3/10, bld. 1, Elektrichesky per.,
Moscow 123557, Russia
E-mail: vniis@vniis.ru
<http://www.vniis.ru/about/contacts>

Federal Service on Accreditation (Rosakkreditastia)
ul. Vavilova, 7
Moscow, 117997
Tel: +7 (495) 539 26 70
E-mail: info@fsa.gov.ru
<http://fsa.gov.ru/>

Consult Business Group - consulting company assisting in registration
127015 Moscow
ul Butyrksaya, 77, Business center "Diagonal House", 8 floor
www.c-b-g.ru/en/
tel.: + 7 495 797 4963
fax: + 7 495 730 2482
e-mail: info@c-b-g.ru
www.c-b-g.ru

OOO CCME - consulting company assisting in registration
127422 Moscow, ul. Timiryazevskaya, house 1, building 2
Tel (499) 641-55-25, (499) 641-55-27, (499) 641-55-23.
e-mail: amashkov@list.ru, certifik@inbox.ru
www.ccme.ru

STM Group, LLC - consulting company assisting in registration
117587 Moscow,
Varshavskoe shosse, house 125, building 1, section 9
Tel/Fax: +7 495 981 44 84
www.group-stm.ru

For More Information

The U.S. Commercial Service in Moscow can be contacted via e-mail at: Miguel Hernandez Miguel.Hernandez@trade.gov; Phone+7-495-728-5580; or visit our website: <http://export.gov/russia>. For a more comprehensive report on doing business in Russia, download the latest Russia Country Commercial Guide at <http://export.gov/russia/marketresearchonrussia/index.asp>

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Comments and Suggestions: We welcome your comments and suggestions regarding this market research. You can e-mail us your comments/suggestions to: Customer.Care@trade.gov. Please include the name of the applicable market research in your e-mail. We greatly appreciate your feedback.

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