

REGISTRATION IN RUSSIA



Medical equipment, devices and products



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REFERENES

- Rosstandard (Russian Standard, Ltd.) is a New-York based Russia Certification Center, serving the needs of North American exporters to Russian Federation since 2000).
- This presentation has been prepared by Mr. Gregory Temkin, CEO of Rosstandard.
- This presentation is available for download in the PDF format at www.rosstandard.com/medproducts.pdf

WHY



- As in most countries, in Russia a medical product can be admitted to the domestic market only when and if it has been found in conformity with technical and medical safety regulations pertaining to this particular product.

WHO



- Assessment of conformity of medical equipment and products to existing safety standards is carried out by the Russian Health Ministry and Federal State Scientific Certification Center for Medical Products. If found in conformity, the product gets entered in the Federal Registry and the “Registration” license is issued.

WHAT



- ❑ Letter of the manufacturer;
- ❑ Power of Attorney to the authorized agent/consultant;
- ❑ Application form;
- ❑ Brief description of the medical product;
- ❑ Pictures of the product;
- ❑ Advertising materials and relevant publications;
- ❑ Existing registration documents and licenses;
- ❑ Certificate of the medical product as a measurement tool (if applicable);
- ❑ Documents certifying the conformity of the medical product to the national or international requirements;
- ❑ Operational manual

FLOW CHART



- All interaction with the Russian authorities is handled on behalf of the exporter/manufacturer of medical products by a duly authorized Russian representative.

FLOW CHART



Application documents

FEDERAL INSPECTORATE OF THE HEALTH MINISTRY:

- Accept documents
- Check documents
- File the application

FLOW CHART



Documents are submitted for examination

SCIENTIFIC CERTIFICATION CENTER FOR MEDICAL PRODUCTS:

- Examination of documents;
- Advice on registration, types and subjects for trials;
- Invoice;

FLOW CHART



Advice on registration process

FEDERAL INSPECTORATE OF THE HEALTH MINISTRY:

- Ordering tests;
- Supervision over testing;

FLOW CHART



Testing

TESTS USUALLY PERFORMED BY TEST CENTER AND LABORATORIES:

- electrical safety;
- electromagnetical compatibility;
- radiation safety;
- safety of electromagnetical and light emanations;
- toxicological tests;
- clinical studies

FLOW CHART

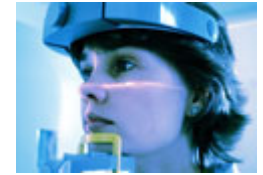


Test Results

FEDERAL INSPECTORATE OF THE HEALTH MINISTRY:

- Analyse the test reports
- Approve or deny the registration

FLOW CHART



REGISTRATION CERTIFICATE RECEIVED



VALIDITY



The term of registration is 10 years for medical devices and equipment, and 5 years for medical products



RENEWAL

Russian Health Ministry will renew or amend the Registration license if:

- ❑ License has expired;
- ❑ Manufacturer's name has changed;
- ❑ Another manufacturer is producing it;
- ❑ Product's name has changed;
- ❑ Product has been upgraded or modernized;
- ❑ Application area or usage directions have changed;
- ❑ Producer has changed specifications or regulations;
- ❑ Changes do not conform to Russian or international standards;
- ❑ New materials in the product contact with human body.

Manufacturer/exporter must inform Russian Federal Authorities of any contingencies that may require amendments in the registration papers.

Anything else?



Most likely, yes.

Once the Federal Registration has been obtained, you will need to apply for a

GOST-R Certificate of Conformity,

and a **Sanitary (Hygienic) Certificate.**



PITFALLS



Traditional **red tape and bureaucracy** that Russia has not only in full measure inherited from the Soviet Union, but augmented it significantly as well.

PITFALL #1: dossier



An incomplete dossier can cause your registration last forever.

Advice:

Make sure you know the list of necessary documents, and the documents you submit look as close to sample documents as possible.

PITFALL #2: system



Whether we like the Russian Certification system or not, it is there and we have to cope with it. They do have to protect the consumers from low-quality and unsafe products.

Advice:

Do not fight the routine in Russia. Be result-oriented and conform. Deliver enough samples. Avoid submitting on the eve of major Russian holidays. Be nice to people you have to work with.



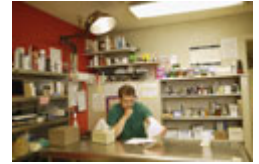
PITFALL #3: human factor

Russian Federal employees who process your papers and test your products have work hours, and they are not concerned with your urgencies. They have a long line of applicants and small salaries... You may expect from the Russian authorities as much or less compassion or concern, as from FDA or INS. Impartial meticulousness is what you may at best anticipate on contact with them.

Advice:

Find yourself a reliable US consultant with strong connections with the Russian Health Ministry, and choose well! A mistake can cost you the market. .

HOW LONG



Bad case scenario: forever.



Good case scenario: **3 months.**

HOW MUCH



Depending on the product and tests, the overall cost may range from a few thousand to several tens of thousand USD.

The costs comprise:

- Consulting fee
- Translation and authentication of translation;
- Health Ministry Experts fee
- Tests and clinical studies
- State Registration fee

OTHER HELPFUL SERVICES

Market Profile

Up-to-date medical products and medical devices market report. A comprehensive Market Profile may comprise more than 1,000 pages of in-depth market data, which optionally could be specified for each of 89 regions of the Russian Federation.

Market Profile puts the medical devices market into context, setting it against the political, economic and demographic conditions of the country, as well as exploring how it fits within the healthcare system as a whole in terms of healthcare policies and development issues.

OTHER HELPFUL SERVICES

Product Profile

Product Profile is a detailed set of information about registrations, sales, marketing results and average prices for any medical devices product, supplied with comparative data for various time periods.

Product Profile helps to monitor developments in Russian market, identify new opportunities, assess product areas, or use the data as an integral part of the marketing campaign.

OTHER HELPFUL SERVICES

Product Profile may include

- ❑ **Number of registrations for a particular product;**
- ❑ **Dates of registrations, expiry dates, expired registrations;**
- ❑ **Registrants activity by forms in 5-year or 10-year period;**
- ❑ **Wholesale and retail sales volumes;**
- ❑ **Retail sales volumes;**
- ❑ **Dynamic of changing a percentage of added value in retail trading for this Trade Name, %;**
- ❑ **Sales volumes for hospital sector in USD based on wholesale prices;**
- ❑ **Average wholesale and retail prices in USD.**

OTHER HELPFUL SERVICES

Logistical Support

- Creation and carrying out of an optimal logistic plan
- Bonded warehousing, local medical devices warehousing consulting
- Customs clearance consulting

CONCLUSION



Is Russian market lucrative? – Yes.

Is Russian market difficult? – Yes.

Is Russian market doable? – With Rosstandard,
definitely yes!