Regulatory affairs.
Medical Devices circulation in Russia:
The Rules and Procedure

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MD Regulation and Scope

“The basis of health protection in the Russian Federation“
Article 38. Medical devices.

**In scope**
(similar to Directives 93/42/EEC, 90/385/EEC, 98/79/EC)

**Out of scope**
Beauty products
Fitness and wellness products
Products for individual usage
Pharmaceuticals

**Medical devices are:**
any instrument, apparatus, appliances, equipment, materials and other devices used for medical purposes alone or in combination with each other as well as with other accessories required for use of these devices for their purpose, including special software and designed by the manufacturer for the prevention, diagnosis, treatment and rehabilitation of diseases, monitoring the state of the human body, for medical research, rehabilitation, replacement, changes of anatomical structure or physiological functions, prevention or termination of pregnancy, which function is not implemented by pharmacological, immunological, genetic or metabolic effects on the human body. Medical devices may be recognized as interchangeable if they are comparable in functionality, quality and technical characteristics and can replace each other.
Restrictions and bans

The circulation of NOT-REGISTERED MD in Russia are **strictly prohibited** according to Low (Federal Law No.323-FZ dated 21.11.2011)

The **CIRCULATIONS** includes the following stages:

- Import and Export
- All the kinds of Trials, Studies and Testing
- Manufacturing / Production / Packaging
- Sales
- Usage, Installation and Intended application
- Maintenance and Service
- Utilization and disposal
- Incident reports, safety corrective actions and recalls

ALL the Medical devices **MUST BE** registered in Federal Service for Surveillance in Healthcare (ROSZDRAVNADZOR). ROSZDRAVNADZOR is an **only** authorized State body to Register and to approve circulation of MD in Russia
Algorithm of Registration procedure (for the MD class IIa, IIb, III) in Russian Federation

Pre-registration procedure

Registration of medical devices (Stage I)

Preparation of docs

Registration of medical devices (Stage II)

In-country Testing of medical devices at Russian Authorized Labs:
- Technical tests
- Toxicological test
- Metrological tests (if necessary)

The Registration dossier forming in Russian (application, check-list, test reports)

The review of documents

Elimination of violations (if necessary)

Stage I
Expertise of the quality, effectiveness and safety of medical devices

Permission to conduct clinical trials

Refusal in state registration

Stage II
Expertise of the quality, effectiveness and safety of medical devices

The decision on the state registration

Refusal in state registration

In country clinical trials of medical devices at Russian Authorized Hospitals (suspension of state registration of medical devices)

Renewal of state registration

The review of documents

Request additional materials and information

Stage I
Expertise of the quality, effectiveness and safety of medical devices

Renewal of state registration

The decision on the state registration

Refusal in state registration

Stage II
Expertise of the quality, effectiveness and safety of medical devices

Request additional materials and information

Refusal in state registration
Algorithm of Registration procedure (for the MD class I) in Russian Federation

Pre-registration procedure

In-country Testing of medical devices at Russian Authorized Labs:
- Technical tests
- Toxicological test
- Metrological tests (if necessary)

In country Clinical trials of medical devices at Russian Authorized Hospitals

The Registration dossier forming in Russian (application, check-list, test reports, report of clinical trials)

Registration of medical devices (Stage II)

Renewal of state registration

The review of documents

Stage II
Expertise of the quality, effectiveness and safety of medical devices

Request additional materials and information

The decision on the state registration

Refusal in state registration
Preparation of Docs of Registration Dossier,
getting Permission for Import for testing

At the beginning the Manufacturer must decide who will be responsible for the circulation on RF market:

The Manufacturer by himself is responsible for registration process and for circulation of MD on the market.

or

to appoint an Authorized Representative in Russia, who will serve testing and registration process and will be responsible for circulation of MD on the market.

The responsible company:

1. To conclude the contract with Russian Authorized testing Labs for the testing (technical, toxicological, biocompatibility, metrological, etc.)
2. To determine with the Labs the number of samples needed for testing.
3. To apply to ROSZDRAVNADZOR for Import Permission of the samples for testing

Application must contain:

- Medical device name, specification including accessories, quantity, serial number, lot, batch number, date of production, expiry and (or) exploitation dates
- Purpose of medical device, intended use
- Applicant’s information (the Manufacturer of his Authorized Representative)
- Name and address of Russian Authorized testing Lab where the tests going to be conducted
- Copies of contracts with Russian Authorized testing Labs with the required number of samples
- Manufacturer’s Power of Attorney (if Authorized Representative appointed).

Permission for import of medical device for the purpose of registration

Refusal to Import
Responsibility

“Authorized Representative of Manufacturer” –

the company duly registered at Russian tax authority and appointed by the Manufacturer of Medical device to represent his interests in field of circulation of medical device on the Russian market and for registration procedure, including testing and expertise.

The Registration certificate can be issued to the name of:

- Manufacturer
  (in this case the Manufacturer is responsible for circulation, incident reports, including safety corrective actions and keep up to date the dossier);
  or
- Authorized representative of Manufacturer
  (in this case the Representative is responsible for circulation of MD, incident reports, including safety corrective actions and keep up to date the dossier);

The Manufacturer are free to change Authorized Representative anytime, BUT must inform ROSZDRAVNADZOR about this changing immediately and apply for according amendments in Registration Certificate.
Testing of MD in-country
(regulated by Ministry of Health Order No.2n dtd 09/01/2014)

Once samples are imported, conduct testing of the device in Russia, i.e. technical, toxicological, and/or metrological testing, depending on device. Depending on the classification and design of your device, you may be required to perform multiple device and materials tests that meet Russian standards. Also you may require to provide to testing Lab all the necessary non-standard testing tools.

Manufacturer (or his Authorized representative) should provide to Testing Labs the following docs translated into Russian:
- List of standards applied
- User’s Manual (Operator’s Manual)
- **Technical documentation** (Extract from Technical File: Description of the device, Intended of Use, Specification of the device; Part list with accessories; Description of control philosophy/logic, usually accompanied by block diagram and schemes ; Risk analysis including software; final testing instructions or final quality procedure with list of equipment needed; Sterilization and disinfection procedure; Info about transportation, utilization; Warnings; Photo of the device with accessories and labeling etc.)
- Copies of Foreign test reports (if available)
- Copies of Declaration of Conformity, FDA or CE certificates (if available)
- Photo of the MD with accessories and Advertising brochure

**What is “Technical documentation” —**
documents governing the design of medical products, establishing technical requirements and containing data for its development, production, testing, use, operation, maintenance, repair, recycling or disposal. This document demonstrates compliance with essential requirements.
Application for Registration of MD

After Technical / Toxicological tests, the Manufacturer or his Representative should complete the dossier (technical file), by adding the test reports protocols from the Russian Authorized Laboratory. Then apply for the Registration to ROSZDRAVNADZOR

The Application Form
The List of Docs (Check-list)
The Steps and Timeline
The Definitions
The Government Duties

Approved by Resolution of Russian Federation Government  
No.1416 dtd.27/12/12
List of Docs to provide to ROSZDRAVNADZOR
for Registration of MD

1. Application signed & stamped. Application form:
   http://www.roszdravnadzor.ru/pages/print_form/registration
2. Manufacturer’s Power of Attorney for Authorized Representative;
3. Information on regulations on the MD / List of standards and rules applied;
4. Technical documents on the MD;
5. Operating documents on the MD / User’s manual / Operation manual;
6. Photos / pictures of the MD with all accessories (min. size 18 cm × 24 cm);
7. Technical test report from Russian Authorized Lab;
8. Toxicological test report from Russian Authorized Lab (for MD which is administered by contact with a human body);
9. Metrological test reports for the purpose of approval of the type of measuring tools (with respect to medical devices classified as measuring tools);
10. Check List;
11. Clinical evaluation reports or clinical trials from foreign countries (if available);
12. Draft program of clinical trials (if available)

All the docs should be in Russian or should be duly legalized and notary translated into Russian
Clinical Trials of Medical Devices
(regulated by Ministry of Health Order No.300n dated 16/05/2013)

Permissions to conduct clinical trials to be issued by Roszdravnadzor to Manufacturer after REVIEW of DOCs and documentary EXPERTISE of the quality, effectiveness and safety of MD
In some cases the conclusion about the ethical validity of the Ethics Council of the Russian Ministry of Health is needed for clinical trials

After getting Permission, the Manufacturer or his Authorized Representative should choose Russian Authorized Hospital to launch Clinical trials and approve the Plan of Clinical trials with Hospital.
List of Authorized hospitals:
http://www.roszdravnadzor.ru/services/clinicaltrials

Clinical trials are conducted in the form of:
1. Trials involving human subjects (patients)
2. Clinical evaluation and analysis of clinical data, including foreign clinical data & review
Testing of medical devices involving human are conducted in the following cases:

- a new type of medical device
- the use of new, complex and (or) unique and (or) special methods of prevention, diagnosis and treatment of diseases and conditions, as well as the use of new and complex medical technologies
- if during the analysis and evaluation of clinical data the efficacy and safety of a medical device are not confirmed

In other cases, clinical trials of medical devices are conducted in the form of analysis and evaluation of clinical data.

After finishing Clinical trials the Manufacturer of his Representative should provide the results to ROSZDRAVNADZOR for the 2\textsuperscript{nd} (final) stage of registration.
Functions of Roszdravnadzor’s Subordinate Expert Organizations

- Expertise of quality, efficiency and safety of medical devices:
  - for the purposes of registration of medical devices
  - within the framework of control measures

- Conducting technical testing of medical devices

- Toxicological studies

- Monitoring the quality, effectiveness and safety of medical devices
**Introduction of Russian Federal State Institute for Research and Testing of MD, Roszdravnadzor’s subordinate organization ([www.vniiimt.org](http://www.vniiimt.org))**

We provide the following tests of MD for registration purposes:

| Tests of active therapeutic MD to administer or exchange energy | Tests of MD intended for monitoring of vital physiological parameters |
| Tests of active MD intended for diagnosis or monitoring | Tests of IVD devices and reagents |
| Tests of active MD intended to image in vivo distribution of radiopharmaceuticals | Tests of invasive surgical MD, instruments & disposables (long-term or short term use) |
| Toxicological studies of MD (sterile & non-sterile) | Testing of MD software |
| Tests of Active MD intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology | Tests of implantable or long term invasive devices |
| Tests of the most range of non-active MD and not-invasive MD | Tests of specific disinfecting, cleaning and rinsing MD |
| Tests of MD in contact with injured skin | Tests of MD invasive in body orifices |
| Tests of MD incorporating a medicinal substance | Tests of active MD intended to administer and/or remove medicines, body liquids or other substances to or from the body |
|  | Metrological tests |
Thank you for your attention!

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