The possibilities of Russian Scientific and Research Institute for Medical Engineering and its role in Conformity Assessment for Medical Devices

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Medical Device
means any

• instrument,
• apparatus,
• appliance,
• software,
• implant,
• reagent,
• material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

➤ diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
➤ diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
➤ providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

In the territory of the Russian Federation, only medical devices **registered** by the Regulatory Authorities authorized by the Government of the Russian Federation are allowed **to be handled on the market**.
Handling of Medical Devices in the national territory

In accordance with item 3 article 38 323 Federal Law

Handling of medical devices consists of the following:

- technical tests,
- toxicological research,
- clinical trials,
- quality control safety and performance of medical devices,
- medical devices registration,
- production,
- import,
- export,
- conformity assessment,
- state/authority control,
- storage,
- delivery,
- selling,
- assembling,
- adjustment,
- application,
- technical maintenance provided by the manufacturer’s operational and technical documentation
- repair,
- recycling disposal destruction
LIABILITY FOR MEDICAL DEVICES HANDLING

The civil and criminal liability for inappropriate activities in the medical devices lifecycle is regulated by the following regulatory legal acts:


• The Criminal Code of the Russian Federation of 13.06.1996 №63-FL (ст.235.1, 238.1, 327.2).
The Member-States of the Eurasian Economic Union are the Republic of Armenia, the Republic of Belarus, the Republic of Kazakhstan, the Kyrgyz Republic and the Russian Federation with a total population of 183.8 mln people.

The EAEU provides for free movement of goods, services, capital and labor, pursues coordinated, harmonized and single policy in the sectors determined by the Treaty and international agreements within the Union.

Medical Devices registered in the Russian Federation receives Registration Certificate and the mark (ПУ).

Medical Devices with the mark ПУ are admitted all over the EAEU.
The Institute was founded by decree of Ministry of Health, May 5, 1999.

In 2005 the institute became a part of Federal Service on Surveillance in Healthcare of Russian Federation «ROSZDRAVNADZOR».

The main goal of the Institute is to provide efficient health care system by supplying high quality and safe medical devices:

- By improving the expertise and testing activity of the Institute
- By implementing a new scientific research methods in the process of lifecycle medical device control
The strategic directions of the Institute activities

Medical devices (MD) quality and safety expertise for the purposes of registration and state control

Assistance with national registration of MD

Scientific and education related activities

Technical tests, toxicological studies, metrology services

Informational and analytical support in MD security monitoring
When ROSSTANDARD issues a standard based on an ISO standard, it adds the prefix “ГОСТ” and adjusts the year accordingly.

In the Russian Federation our example standards are:


Our Testing Centre offers tests performed with accordance to more than 300 ISO standards that is the biggest numbers of tests of Medical Devices provided in the Russian Federation.
The role of Russian Scientific and Research Institute of Medical Engineering in Conformity assessment

The systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by Regulatory Authority that is Roszdravnadzor, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance for Medical Devices.

Russian Scientific and Research Institute for Medical Engineering engaged in determining whether the relevant requirements in technical regulations or standards are fulfilled.
Russian Scientific and Research Institute of Medical Engineering
Российский научно-исследовательский и испытательный институт медицинской техники
Федеральной службы по надзору в сфере здравоохранения

Федеральная служба по надзору в сфере здравоохранения сообщает, что в соответствии с пунктами 26-27 Правил государственной регистрации медицинских изделий, утвержденных постановлением Правительства Российской Федерации от 27.12.2012 № 1416, приказом Минздрава России от 16.05.2013 № 300н «Об утверждении требований к медицинским организациям, проводящим клинические испытания медицинских изделий, и порядке установления соответствия медицинских организаций этим требованиям» и приказом Росздравнадзора от 05.06.2016 № 532 Федеральное государственное бюджетное учреждение «Всероссийский научно-исследовательский и испытательный институт медицинской техники» Федеральной службы по надзору в сфере здравоохранения включено в Перечень медицинских организаций, проводящих клинические испытания медицинских изделий.

Одновременно сообщаем, что сведения о Федеральном государственном бюджетном учреждении «Всероссийский научно-исследовательский и испытательный институт медицинской техники» Федеральной службы по надзору в сфере здравоохранения размещены на официальном сайте Росздравнадзора в информационно-телекоммуникационной сети «Интернет».

М.А. Мурашко
Russian Scientific and Research Institute of Medical Engineering

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**CERTIFICATE**

**CISQ/IQNet** has issued an IQNet recognized certificate that the organization: Federal State Budget Institution «Russian Scientific and Research Institute for Medical Engineering» of Federal Service for Supervision in the sphere of public health has implemented and maintains a Quality Management System for the following scope: Examination of medical devices, technical testing and toxicochemical studies of medical devices which fulfills the requirements of the following standard:

**ISO 9001:2015**

Issued on: **2018-09-05**
Expires on: **2020-08-03**

This attestation is directly linked to the IQNet Partner’s original certificate and shall not be used as a stand-alone document.

Registration Number: **IT - 112096**

Alex Stoichita
President of IQNet

Ing. Claudio Proveniti
President of CISQ

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** samenstvo**

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OUR TESTING CENTRE

Medical materials and tools testing lab

General engineering testing lab

Mobile Medical complexes testing lab

Testing lab for MD used in functional diagnostic and physiotherapy

Software as a MD testing lab

Metrology lab

Laboratory for testing MD used in radiation therapy

Electromagnetic compatibility testing lab
OUR TESTING CENTRE

- Testing lab for MD used in Medical laboratory research
- Toxicology lab (biocompatibility tests)
- Microbiology lab
Mobile laboratory used for on-site inspections and testing of Medical Devices

- Electrical medical devices
- Non-electrical medical devices
- Software as medical devices
- In vitro medical devices

- Life-supporting MD (except implants);
- MD for in vitro diagnostic (including pre-analytical preparation);
- MD used in radiation therapy;
- MD used to monitor patient condition;
- MD used in physiotherapy;
- MD used in surgery;
- MD used in dentistry;
- MD used for illuminating;
- MD with a patient positioning support

- Non-electrical hospital equipment

- Software for Programmable medical devices;
- Medical software systems;
- Software for processing medical images;
- Software for processing the results of clinical diagnostic examinations

- In vitro reagents;
- Consumable materials.
✓ Providing advice on national system registration of Medical Devices
✓ Technical tests of Medical Devices for the purpose of national registration
✓ Standard technical tests performed per Sponsors requests
✓ Metrology services
✓ Toxicology Studies for the purpose of National registration
✓ Standard toxicology studies performed per Sponsors requests
✓ Completion of technical and operational documentation
✓ Coordination of technical specification
✓ Coordination of technical specification changes and related notices
✓ Scientific Research and Development
Thank you !

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