



Outgoing number [redacted] dated [redacted], 202[redacted].

COMMERCIAL OFFER for comprehensive registration of a medical device

Thank you for contacting our company!

Goszdravnadzor (CIRMI LLC) was formed to provide services in obtaining permits for manufacturers and suppliers of medical devices and products. We are trusted because they value a responsible approach to work, high-quality and timely provision of services, professionalism and a high degree of responsibility.

Check out the commercial offer for a comprehensive procedure for the state registration of a medical product with the Federal Service for Surveillance in Healthcare (Roszdravnadzor):

Name of the medical product for registration: [redacted];
Potential risk class for the use of a medical device: [redacted] ([redacted]);

The cost of our company's services for the comprehensive provision of services for the registration of the declared medical device in Roszdravnadzor is [redacted] rubles.

The cost of services is final and is fixed in the contract with our company (LLC CIRMI)

The result of the provision of services by our company is the issued registration certificate of Roszdravnadzor for medical optical printing system with the declared models (specifications).

The registration certificate is valid indefinitely throughout the Russian Federation.

The deadline for completing the work is [redacted] calendar days from the moment the project was launched. It is possible to reduce the period with operational interaction with the expert department of our company.

Payment for services for the registration of a medical device occurs in three stages:

- **Stage 1:** payment of [redacted] % of the cost of services - after the launch of the project for the registration of a medical product;
- **Stage 2:** payment of [redacted] % of the cost of services - after the formation and development on our part of the necessary design and operational documentation for a medical device (before the start of testing);
- **Stage 3:** payment of [redacted] % of the cost of services - after receiving a registration certificate for a medical device in Roszdravnadzor.

TESTING OF MEDICAL DEVICES:

When issuing a registration certificate of Roszdravnadzor for medical devices, it is necessary to confirm their quality and safety through testing.

Preliminary calculation of the cost of testing a medical device:

- Technical tests – [redacted] rubles;
- Toxicology research * – [redacted] rubles;
- Clinical researches – [redacted] rubles.

Testing of medical devices is carried out in laboratories approved by [Rosaccreditation](#) and [Roszdravnadzor](#).

** Toxicological tests for materials of a medical device are carried out in case of direct contact with the human body during the operation of the device.*

COST OF THE STATE DUTY:

When registering a medical device, the applicant pays a state fee (in accordance with Article [333.32.2](#) of the Tax Code of the Russian Federation).

- [redacted] rubles - for the examination of the quality, effectiveness and safety of medical devices;
- [redacted] rubles - for the issuance of a registration certificate of Roszdravnadzor (registration certificate form).

** The cost of the state duty is indicated in accordance with the class of potential risk of using your medical device.*

ADDITIONAL EXPENSES DURING THE PERFORMANCE OF WORK:

Based on the experience of registering medical devices with Roszdravnadzor, we report the following additional costs that may appear in the course of work:

- Notarization of documentation (and, if necessary, its translation into Russian). The cost of this procedure depends on the volume of design and operational documentation for the medical device and will be determined upon its completion.
- Delivery of samples of medical devices to testing laboratories. The cost of the service depends on the actual location of the manufacturer and the selected sample delivery service.

STAGES OF WORK OF OUR COMPANY ON REGISTRATION OF A MEDICAL DEVICE:

To understand the work process, we suggest that you familiarize yourself with the stages that will be carried out by the expert department as part of the registration of the declared medical product with the Federal Service for Surveillance in Healthcare.

** To protect your interests, each stage is duplicated in the Agreement with our company.*

STAGE 1:

Correction and development of documentation for a registered medical device:

- 1.1. Correction of the technical documentation provided by the Customer in accordance with the requirements of Roszdravnadzor and the legislation of the Russian Federation;
- 1.2. Adjustment of the operational documentation provided by the Customer in accordance with the requirements of Roszdravnadzor and the legislation of the Russian Federation;
- 1.3. Development (adjustment) of information on regulatory documentation (SND) (if necessary);
- 1.4. Preparation of a power of attorney template from the manufacturer for the representative of the Contractor;
- 1.5. Search for similar medical devices registered with Roszdravnadzor;
- 1.6. Other works related to the first stage of work.

STAGE 2:

Carrying out toxicological and technical tests of a medical device:

- 2.1. Selection of a testing laboratory for conducting toxicological tests for a medical device (if necessary);
- 2.2. Accompanying the conduct of toxicological tests for a medical device (if necessary);
- 2.3. Checking documents and making changes to them based on the results of toxicological tests for a medical device (if necessary);
- 2.4. Selection of a testing laboratory for conducting technical tests for a medical device;
- 2.5. Accompanying technical testing for a medical device;
- 2.6. Checking documents and making changes to them based on the results of technical tests for a medical device (if necessary);
- 2.7. Other works related to the second stage of work.

STAGE 3:

Conducting clinical trials of a medical device and its registration with Roszdravnadzor.

- 3.1. Formation of the primary set of registration documents and its submission to Roszdravnadzor;
- 3.2. Obtaining permission to conduct clinical trials in a medical organization;
- 3.3. Checking documents and making changes to them based on the results of clinical trials (if necessary);
- 3.4. Creating a template and updating an application for state registration of a medical device;
- 3.5. Formation of a complete set of registration documents for a medical device;
- 3.6. Submission of the generated set of registration documents to Roszdravnadzor with the assignment of an incoming application number;
- 3.7. Correction of documentation based on the results of the examination of the quality and safety of the medical device (if necessary);
- 3.8. Obtaining in Roszdravnadzor and transfer to the Customer of a registration certificate for a medical device;
- 3.9. Other works related to the third stage of work.

TOTAL COST AND DURATION OF THE PROJECT:

The cost of our company's services for the registration of a medical device is rubles;
Carrying out the necessary tests of a medical device – rubles;
State duty (paid to Roszdravnadzor) – rubles;
The final cost for the project is rubles;
Project completion time - calendar days.

The prices and terms of the quotation are valid for calendar days from the date of dispatch.

Contractor (curator) for the project - (email, phone)

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