FAQ

information for foreign manufacturers

1. How do I register a medical device in Russia?

Registration of a medical device in accordance with the national procedure (Decree of the Government of the Russian Federation No. 1684 dated 11/30/2024) is carried out in several stages.:

- Development and registration of a set of documents for a medical device
- Organization of technical, toxicological and clinical trials
- Collecting a set of registration dossier and submitting it to Roszdravnadzor
- Roszdravnadzor verifies the completeness and reliability of the information provided as part of a set of registration dossiers
- Examination of the quality, effectiveness and safety of a medical device in Roszdravnadzor
- Making an entry in the official register of medical devices

The full list of necessary documents for registration of a medical device can be downloaded from the link. Please note that during the preparation of the documents, the expert may request additional information.

2. What is included in the cost of medical device registration support?

The cost of our work includes the following services:

- Preparation of the application based on the needs of the client and on the basis of available documents.
- Preparation of the package of documents of the registration dossier. Analysis and correction of the documents available to the client for medical devices, in the absence - development in accordance with current standards.
- Selection of accredited testing laboratories.
- Support of medical equipment testing from the conclusion of the contract to the proofreading of drafts and receipt of signed protocols.
- Drawing up an equivalence table and obtaining a clinical trial certificate.
- Recommendations on the certification and legalization of documents.
- Collecting a set of registration dossier and checking it.
- Submission of documents in electronic form to Roszdravnadzor for state registration of medical devices.
- Elimination of the comments of the state body in case of their receipt.

3. What other costs can there be in the process of registering a medical device?

- for the translation of documents and their certification

The average cost of translation from English is 700 rubles per page. We cannot calculate in advance the costs of translation and notarization of documents.

- for sample delivery and customs clearance

Tariffs for international cargo transportation depend on many criteria, and it is not possible to provide a preliminary estimated price range, just like customs clearance services provided by a broker.
- to pay for testing laboratories
The estimated cost range for each type of test is indicated in the commercial offer. The exact cost of each type of test is calculated by the testing laboratory based on the prepared set of documents for the medical device.
- for payment of state duties
The state duty is a monetary payment for services provided by the state, in our case for conducting an examination of the quality, effectiveness and safety of medical products, and registration of a medical product.

4. Is it necessary to appoint a representative in Russia during the registration process of a medical device?
To register medical devices on the territory of the Russian Federation, it is mandatory to appoint an authorized representative of the manufacturer, who is a tax resident of the Russian Federation.
We are ready to provide a service for performing the function of an authorized representative of a foreign manufacturer. We provide this both during the procedure of state registration of medical devices, and in the process of their further circulation on the Russian market after receiving the registration certificate and the start of sales.
The fee for the services of an authorized representative is paid separately for each registration entry. This is a one-time payment charged for representing your interests during the registration period of a medical device. If you plan for us to continue acting as your authorized representative in the future, these services will be paid separately on an annual basis; the cost will be negotiated individually.

5. Is it possible to change the authorized representative in Russia after completing the registration procedure for medical products?
If you want to change your authorized representative after completing the registration process, you will need to initiate a procedure for making changes to the registration dossier without verification. If RegTrend was an authorized representative during registration, then the cost of this procedure will be free for you, you will only need to pay a state fee of 2,500 rubles.

6. Are there mandatory payments after the registration of medical devices in Russia is completed?
No additional fees will be charged after the registration of the medical device is completed. If you want to make changes to your medical device after receiving registration (for example, to change the manufacturer's legal address, add a model range or variants, etc.), they will be paid for. The cost will depend on the volume and nature of the changes being made.