

REGISTRATION OF MEDICAL DEVICES

IN THE RUSSIAN FEDERATION AND THE EAEU



About us

We operate all over the world



We bring manufacturers from any country to the Russian and the EAEU market



Domestic and foreign manufacturers



Personalized approach to non-standard products



English-speaking team



More than
200
registration
certificates for
medical devices



Saving your time and resources



Subject-matter experts

our employees work on projects for which they are the best specialists. There is a separate group of experts who register in vitro diagnostics and software



Reducing registration costs,

due to shorter registration periods and repeated tests. Extensive work experience makes it possible to "not reinvent the wheel" but use already verified forms of documents. We offer to carry out laboratory tests at the best prices from reputable partner laboratories with whom we have been working for years



Double document quality control

before crucial stages and delivery of documents to clients, documents are checked by several employees



One-stop-shop approach

we assign an employee who accompanies the client from the start of work to receive the registration certificates

Principal stages of obtaining a registration certificate

(class 1 products of potential risk and 2a not sterile)

1 STAGE

Adjustment/preparation of technical and operational documentation of the manufacturer by the requirements of the legislation of the Russian Federation (EAEU)

2 STAGE

- Selection of laboratories, complete and comprehensive support during technical, toxicological, clinical and other studies
- Creation and submission of the registration application to Roszdravnadzor
- Receiving a reference number from Roszdravnadzor

3 STAGE

- Assistance in the examination of the effectiveness, quality and safety of a medical device
- Interaction with Roszdravnadzor in case of a request for additional materials and information
- Receipt and transfer of the registration certificate to the Customer

The average duration of the state registration procedure

12-14
months



Principal stages of obtaining a registration certificate

[2a sterile products, 2b and 3 classes of potential risk]

1 STAGE

Adjustment/preparation of technical and operational documentation of the manufacturer by the requirements of the legislation of the Russian Federation (EAEU)

2 STAGE

- Selection of laboratories, complete and comprehensive support during technical, toxicological, clinical and other studies

3 STAGE

- Organization of production inspection
- Creation and submission of the registration application to Roszdravnadzor
- Receiving a reference number from Roszdravnadzor
- Assistance in the examination of the effectiveness, quality and safety of a medical device
- Interaction with Roszdravnadzor in case of a request for additional materials and information
- Receipt and transfer of the registration certificate to the Customer

The average duration of the state registration procedure

**16-18
months**



Roadmap for registration of a medical device

Class 1 products of potential risk and 2a not sterile




Action	Deadline (working days)	Executor	Expenses	
Documentation development, verification and editing of existing documents	40	Cliff Medical	40% of the cost of Cliff Medical services	
Assistance in research, technical tests	30	Laboratory	30% of the cost of Cliff Medical services + payment for technical tests	
Toxicological tests (in parallel with the technical)		Laboratory	Payment for toxicological tests (to the laboratory)	
Clinical trials	25	Clinic	Payment for clinical trials (to a medical institution)	
Certification of the application and submission of documents to the Roszdravnadzor	10	Cliff Medical, Customer	30% of the cost of Cliff Medical services + payment of state duties	
Receiving comments from the Roszdravnadzor	30			
Corrective actions and re-submission to the Roszdravnadzor	50	Cliff Medical, Customer		12-14 months The average period for obtaining a registration certificate
Obtaining the registration certificate	30	Roszdravnadzor		

Roadmap for registration of a medical device

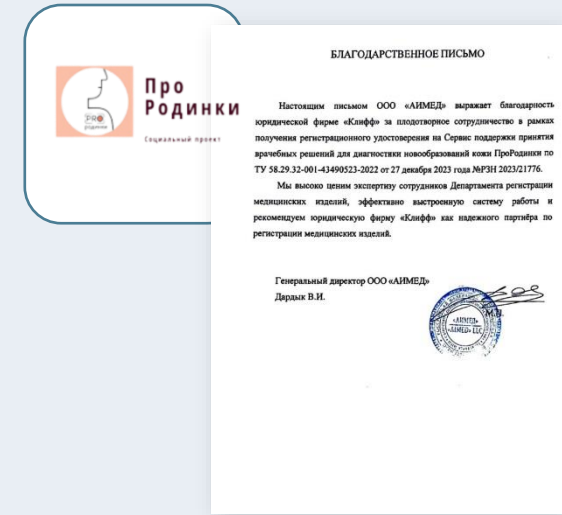
2a sterile products, 2b and 3 classes of potential risk

Action	Deadline (working days)	Executor	Expenses	
Documentation development, verification and editing of existing documents	40	Cliff Medical	40% of the cost of Cliff Medical services	
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Toxicological tests (in parallel with the technical)		Laboratory	Payment for toxicological tests (to the laboratory)	
Clinical trials	25	Clinic	Payment for clinical trials (to a medical institution)	
Certification of the application and submission of documents to the Roszdravnadzor	10	Cliff Medical, Customer	30% of the cost of Cliff Medical services + payment of state duties	
Inspection of production	90		Payment for inspection to Roszdravnadzor	
Receiving comments from the Roszdravnadzor	30			16-18 months The average period for obtaining a registration certificate
Corrective actions and re-submission to the Roszdravnadzor	50	Cliff Medical, Customer		
Obtaining the registration certificate	30	Roszdravnadzor		

We solve the most difficult tasks

	<p>IN VIVO</p> <p>Registration of a unique non-analogue medical device - a stair-climbing electric wheelchair</p>	<p>Complexity of the case:</p> <p>the absence of a registered analogue</p>	<p>Achievements:</p> <ul style="list-style-type: none">• Conduction of clinical trials with the participation of patients• The product was registered (RZN 2022/17643 dated 30.06.2022)	<p>12 months</p>
	<p>IN VITRO</p> <p>Registration "from scratch" of a set of reagents for the isolation of nucleic acids from human clinical material</p>	<p>Complexity of the case:</p> <ul style="list-style-type: none">• absence of any documents, work "from scratch" with the manufacturer• field tests (technical, clinical)	<p>Achievements:</p> <p>the registration certificate was received WITHOUT comments from Roszdravnadzor (RZN 2022/16678 dated 14.03.2022)</p>	<p>16 months</p>
	<p>Software</p> <p>Registration of software with artificial intelligence – a medical decision support system for the diagnosis of skin tumours</p>	<p>Complexity of the case:</p> <ul style="list-style-type: none">• Development of documents "from scratch" with the manufacturer• The need for a large number of datasets for clinical trials• High potential risk class	<p>Achievements:</p> <ul style="list-style-type: none">• Close work with NMRC of Oncology named after N. N. Blokhin and VNIIMT of Roszdravnadzor• Registration certificate has been received (RZN 2023/21776 dated 27.12.2023)	<p>16 months</p>

Some of the appreciation letters



Our achievements

Some of the appreciation letters

UNION EXPRESS

БЛАГОДАРСТВЕННОЕ ПИСЬМО

Настоящим письмом ООО «ЮНИОН ЭКСПРЕСС» выражает благодарность юридической фирме «Клифф» за плодотворное сотрудничество в рамках регистрации системы короночного стопа HyperLight с лекарственным покрытием Ceramium; катетера сосудистого проводникового удлинительного HyperJet; катетера дилатационного с гидрофильным покрытием для чрескостной трансангиальной коронарной ангиопластики (ЧТКА) Hyperolve®; катетера аспирационного тромболитического HyperBST

Эффективная модель работы и компетентность сотрудников позволила быстро, в рамках оговоренных сроков, получить регистрационные удостоверения № РИИ 2024/22865 от 05.06.2024, № РИИ 2024/22829 от 05.06.2024, № РИИ 2024/22897 от 11.06.2024, № РИИ 2024/22920 от 14.06.2024.

Мы высоко ценим компетентность сотрудников Департамента регистрации медицинских изделий и рекомендуем юридическую фирму «Клифф» как надежного партнера.

Генеральный директор
ООО «ЮНИОН ЭКСПРЕСС»
Антона К. Р.

ООО «МедикБук»

Президенту юридической фирмы «Клифф»
Ступлякено К. Г.

Уважаемый Кирилл Григорьевич!

ООО «МедикБук» выражает Вам и Вашей компании благодарность за результативную работу и высокий профессионализм в области регистрации медицинских изделий.

В рамках сотрудничества было зарегистрировано в Росздравнадзоре программное обеспечение в качестве медицинского изделия (РУ № РИИ 2022/17344 от 03.06.2022 г.). Компетентность, структурность и ответственность Вашей команды помогли справиться со всеми сложностями на пути к цели и завершить процесс в короткий срок и с нужным результатом.

Надеемся на дальнейшее развитие наших деловых отношений и с уверенностью рекомендуем юридическую фирму «Клифф» как надежного и долгосрочного партнера.

Директор
ООО «МедикБук»
Пенских А. А.

SIFARY

LETTER OF APPRECIATION

This letter, Changzhou Sifary Medical Technology Co., Ltd., China, expresses sincere gratitude to the Cliff law firm for the fruitful cooperation on the registration of intracanal digital imaging sensor Nanopix and hand-held dental X-ray system HyperLight in the Russian Federation.

The effective work model, professionalism and comprehensive team work made it possible to get the Registration Certificate RZN 2024/23900 dated April 08, 2024 (Nanopix) and RZN 2024/23125 dated April 11, 2024 (HyperLight) in a due and timely manner.

We appreciate an excellent level of expertise of Medical Devices' Registration Department's staff and highly recommend the Cliff Law Firm as a reliable and trustworthy business partner.

Chief Marketing Manager
Date: 24.04.2024

AB Superior Implant Technology

LETTER OF APPRECIATION

By this letter, A.D. Dental Devices Ltd., Israel, expresses sincere gratitude to the Cliff law firm for the fruitful cooperation on the registration of the dental implants in the Russian Federation.

The effective work model, professionalism and comprehensive teamwork made it possible to get the Registration Certificate RZN 2024/22358 dated April 06, 2024, in a due and timely manner.

We appreciate the excellent level of expertise of Medical Devices' Registration Department's staff and highly recommend the Cliff Law Firm as a reliable and trustworthy business partner.

General Manager,
Date: 24.04.2024

Общество с ограниченной ответственностью
«БЬЮТИ МАРКЕТ»

Президенту юридической фирмы «Клифф»
Ступлякено К. Г.

Уважаемый Кирилл Григорьевич!

ООО «БЬЮТИ МАРКЕТ» выражает Вам и Вашей компании благодарность за результативную работу и высокий профессионализм в области регистрации медицинских изделий.

В рамках сотрудничества был зарегистрирован в Росздравнадзоре филлер интрадермальный на основе гиалуроновой кислоты (РУ № РИИ 2023/19791 от 13.03.2023 г.).

Компетентность, структурность и ответственность Вашей команды помогли справиться со всеми сложностями на протяжении пути к цели и завершить процесс с положительным результатом.

Надеемся на развитие наших деловых отношений и с уверенностью рекомендуем юридическую фирму «Клифф» как надежного и долгосрочного партнера.

Генеральный директор
ООО «БЬЮТИ МАРКЕТ»
16 марта 2023 г.

lasertech

Общество с ограниченной ответственностью
«ЛАЗЕРТЕЧ»

РЕКОМЕНДАТЕЛЬНОЕ ПИСЬМО

Настоящим письмом организация ООО «ЛАЗЕРТЕЧ» сообщает, что за длительный срок сотрудничества с ООО «Клифф-Эксперт» данная организация сумела зарекомендовать себя как честной и профессиональный исполнитель.

Главной отличительной особенностью работы ООО «Клифф-Эксперт» является высокая организованность и оперативность мастеров компании, готовность быстро реагировать на возникающие сложности.

Исходя из вышесказанного, фирма ООО «ЛАЗЕРТЕЧ» готова бы отметить высокой компетенции ООО «Клифф-Эксперт», надежность на результат и работу и поздравляем команду.

Эффективная модель работы и компетентность сотрудников позволила быстро, в рамках оговоренных сроков, получить регистрационные удостоверения № РИИ 2023/20416 (Аппарат механический лазерный "Лазер") и РИИ 2023/20926 (Аппарат механический лазерный "Лазер")

Мы высоко ценим компетентность сотрудников Департамента регистрации медицинских изделий и рекомендуем фирму ООО «Клифф-Эксперт» как надежного партнера.

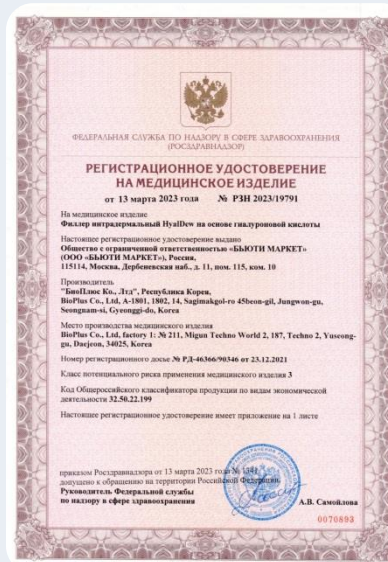
Директор
ООО «ЛАЗЕРТЕЧ»
А. А. Пешков

Some of the registration certificates

Risk class - 3



Medical decision support system



Intradermal filler



Intradermal filler



Surgical suture



A set of reagents



Saturable polymer microspheres

Some of the registration certificates

Risk class - 3



Vascular catheter



Aspiration catheter



Coronary stent system



Dilatation catheter

Some of the registration certificates

Risk class – 2b



Surgical ultrasound system



Dental implants



X-ray machine



Laser diode device



Laser device



Surgical radiofrequency system

Some of the registration certificates

Risk class – 2b



Dermatocosmetological laser device



Dental implants



Orthodontic mini screws

Some of the registration certificates

Risk class – 2a



Air purifier and disinfectant



Digital intraoral sensor



A set of reagents

Some of the registration certificates

Risk class – 2a



Electrotherapy, electrical stimulation and electrophoresis device



Oxygen concentrator



Dental needles



Chemical indicators



Dental needles



Low-frequency magnetic therapy device

Some of the registration certificates

Risk class – 2a



Endodontic instrument



Contact lenses



Reagent for the analyser



Reagent for the analyser



Hardware and software complex



Magnetic therapy device

Some of the registration certificates

Risk class – 1



Orbital laboratory shaker



Chemical indicators



Functional bed



Chairs with sanitary equipment



Microscope slide



Standing support

Some of the registration certificates

Risk class – 1



Disposable medical clothing



Moulding spoon



Dental instruments



Pen injection device



Wheelchair



Orthopedic medical products

Contact us and make sure of the impeccable quality of our services



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