



# СЕРТИФИКАТ

Настоящим удостоверяется, что система менеджмента качества

**ООО "Завод Медсинтез",**  
включая производственные площадки, указанные в Приложении  
ул. Кирова, 28, пом. 205, Екатеринбург, Свердловская обл., 620028, Россия

была проверена и признана соответствующей требованиям стандарта

**ISO 13485:2016**

в отношении разработки, постановки на производство, подготовки производства, производства, хранения и реализации медицинских изделий: активных и неактивных изделий для инъекций, инфузий, диализа, искусственного кровообращения и гемафереза; неактивных изделий для очистки, промывания, приготовления растворов; средств защиты из нетканых материалов

№: 20.1001.026  
от 6 октября 2021 г.

Система менеджмента сертифицирована с 2017 года

Сертификат действителен до **30 августа 2023 г.**

  
Генеральный директор Ассоциации  
по сертификации "Русский Регистр"

Приложение является неотъемлемой частью сертификата. Действие сертификата распространяется только на площадки компании, указанные в настоящем сертификате. Сертификат теряет силу в случае невыполнения условий сертификации (<http://www.rusregister.ru/doc/004.00-105.pdf>).

РУССКИЙ РЕГИСТР

RUSSIAN REGISTER

10-000276







# CERTIFICATE

This is to certify that the Quality Management System of

**LLC "Zavod Medsintez"**  
including production sites in the Annex  
28, Kirova Str., office 205, 620028, Ekaterinburg, Sverdlovsk region, Russia

has been assessed and found to be in accordance  
with the requirements of

**ISO 13485:2016**

in respect of development, launching into manufacture, preparing for  
manufacture, manufacture, storage and marketing of medical devices:  
active and non-active devices for injection, infusion, dialysis, artificial  
circulation and hemapheresis; non-active devices for cleaning,  
rinsing, preparation of solutions; protective equipment  
made of nonwoven materials

No: 20.1001.026  
of 6<sup>th</sup> October, 2021

Management system certified since 2017

This certificate is valid until **30<sup>th</sup> August, 2023**

Director General of Certification  
Association "Russian Register"

The annex is an integral part of the certificate. The certificate covers only those sites of the company which are stated in this certificate. This certificate becomes invalid if conditions of certification are not fulfilled (<http://www.rusregister.ru/doc/004.00-105.pdf>).



РУССКИЙ РЕГИСТР  
RUSSIAN REGISTER

10-000277



СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА  
RUSSIAN REGISTER CERTIFICATION SYSTEM



Приложение к Сертификату  
№ 20.1001.026  
от 6 октября 2021 г.  
бланк № 10-000276

**Область сертификации системы менеджмента  
ООО "Завод Медсинтез"**

1. Продукция / услуги: разработка, постановка на производство, подготовка производства, производство, хранение и реализация медицинских изделий: активных и неактивных изделий для инъекций, инфузий, диализа, искусственного кровообращения и гемафереза; неактивных изделий для очистки, промывания, приготовления растворов; средств защиты из нетканых материалов.
2. Процессы выпуска продукции в соответствии с ISO 13485:2016:
  - 7.1. Планирование выпуска продукции
  - 7.2. Процессы, связанные с потребителем
  - 7.3. Проектирование и разработка
  - 7.4. Закупки
  - 7.5. Производство продукции и предоставление услуг
  - 7.6. Управление оборудованием для мониторинга и измерений
3. Исключения из процессов жизненного цикла продукции: 7.3.6 и 7.3.7 (в части подключения к другому изделию(ям) или наличию общего интерфейса); 7.5.1 f) (в части действий после поставки); 7.5.2 (кроме воды дистиллированной); 7.5.3; 7.5.4; 7.5.9.2; 7.5.10; 8.2.6 (в части имплантируемых МИ); 8.4f.

Генеральный директор Ассоциации  
по сертификации "Русский Регистр"



А.В. Владимирцев



СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА  
RUSSIAN REGISTER CERTIFICATION SYSTEM



**Annex to the Certificate  
№ 20.1001.026  
of 6<sup>th</sup> October, 2021  
registration form № 10-000277**

**Certification scope of management system of  
LLC "Zavod Medsintez"**

1. Product / service: development, launching into manufacture, preparing for manufacture, manufacture, storage and marketing of medical devices: active and non-active devices for injection, infusion, dialysis, artificial circulation and hemapheresis; non-active devices for cleaning, rinsing, preparation of solutions; protective equipment made of nonwoven materials.
2. Processes of product realization in compliance with ISO 13485:2016:
  - 7.1. Planning of product realization
  - 7.2. Customer-related processes
  - 7.3. Design and development
  - 7.4. Purchasing
  - 7.5. Production and service provision
  - 7.6. Control of monitoring and measuring equipment
3. Exclusions from the processes of product realization: 7.3.6 и 7.3.7 (in terms of connection with another medical device(s) or availability of a common interface); 7.5.1 f) (in terms of post-delivery activities); 7.5.2 (except of distilled water); 7.5.3; 7.5.4; 7.5.9.2; 7.5.10; 8.2.6 (in terms of implantable medical devices); 8.4f.

Director General of Certification  
Association "Russian Register"



A. Vladimirtsev

СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА  
RUSSIAN REGISTER CERTIFICATION SYSTEM



Приложение к Сертификату  
№ 20.1001.026  
от 6 октября 2021 г.  
бланк № 10-000276

**Область сертификации системы менеджмента  
ООО "Завод Медсинтез" включает:**

**1. Цех № 1**

Юридический адрес: ул. Кирова, 28, пом. 205, Екатеринбург, Свердловская обл., 620028, Россия

Фактический адрес: ул. Торговая, 15, Новоуральск, Свердловская обл., 624130, Россия

**2. Цех № 2**

Юридический адрес: ул. Кирова, 28, пом. 205, Екатеринбург, Свердловская обл., 620028, Россия

Фактический адрес: ул. Торговая, 15, стр. 3, Новоуральск, Свердловская обл., 624130, Россия

**3. Цех № 11**

Юридический адрес: ул. Кирова, 28, пом. 205, Екатеринбург, Свердловская обл., 620028, Россия

Фактический адрес: ул. Подгорная, 9, Новоуральск, Свердловская обл., 624130, Россия

Генеральный директор Ассоциации  
по сертификации "Русский Регистр"



А.В. Владимирцев



СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА  
RUSSIAN REGISTER CERTIFICATION SYSTEM



**Annex to the Certificate  
№ 20.1001.026  
of 6<sup>th</sup> October, 2021  
registration form № 10-000277**

**Certification scope of management system of  
LLC "Zavod Medsintez" includes:**

**1. Workshop No. 1**

Legal address: 28, Kirova Str., office 205, 620028, Ekaterinburg, Sverdlovsk region, Russia

Actual address: 15, Torgovaya Str., 624130, Novouralsk, Sverdlovsk region, Russia

**2. Workshop No. 2**

Legal address: 28, Kirova Str., office 205, 620028, Ekaterinburg, Sverdlovsk region, Russia

Actual address: 15, Torgovaya Str., Bldg. 3, 624130, Novouralsk, Sverdlovsk region, Russia

**3. Workshop No. 11**

Legal address: 28, Kirova Str., office 205, 620028, Ekaterinburg, Sverdlovsk region, Russia

Actual address: 9, Podgornaya Str., 624130, Novouralsk, Sverdlovsk region, Russia

Director General of Certification  
Association "Russian Register"



A. Vladimirtsev



THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

*Certification Association "Russian Register" has issued an IQNet recognized certificate that the organization:*

## **LLC "Zavod Medsintez"**

*including production sites in the Annex  
28, Kirova Str., office 205, 620028, Ekaterinburg, Sverdlovsk region, Russia*

*has implemented and maintains a*

### **Quality Management System**

*for the following scope:*

development, launching into manufacture, preparing for manufacture, manufacture, storage and marketing of medical devices: active and non-active devices for injection, infusion, dialysis, artificial circulation and hemapheresis; non-active devices for cleaning, rinsing, preparation of solutions; protective equipment made of nonwoven materials

*which fulfils the requirements of the following standard:*

## ISO 13485:2016


*Issued on: 6<sup>th</sup> October, 2021*

*Expires on: 30<sup>th</sup> August, 2023*

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

**Registration Number: RU-20.1001.026**



  
*Alex Stoichitoiu*  
*President of IQNet*

  
*Arkady Vladimirtsev,*  
*Director General of*  
*Russian Register*



**IQNet Partners\*:**

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy  
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA  
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica  
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland  
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia  
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)





THE INTERNATIONAL CERTIFICATION NETWORK

**ANNEX 1 to IQNet Certificate**  
**Number RU-20.1001.026**

**Certification scope of management system of**  
**LLC "Zavod Medsintez"**

1. Product / service: development, launching into manufacture, preparing for manufacture, manufacture, storage and marketing of medical devices: active and non-active devices for injection, infusion, dialysis, artificial circulation and hemapheresis; non-active devices for cleaning, rinsing, preparation of solutions; protective equipment made of nonwoven materials.
2. Processes of product realization in compliance with ISO 13485:2016:
  - 7.1. Planning of product realization
  - 7.2. Customer-related processes
  - 7.3. Design and development
  - 7.4. Purchasing
  - 7.5. Production and service provision
  - 7.6. Control of monitoring and measuring equipment
3. Exclusions from the processes of product realization: 7.3.6 и 7.3.7 (in terms of connection with another medical device(s) or availability of a common interface); 7.5.1 f) (in terms of post-delivery activities); 7.5.2 (except of distilled water); 7.5.3; 7.5.4; 7.5.9.2; 7.5.10; 8.2.6 (in terms of implantable medical devices); 8.4f.



*Alex Stoichitoiu*  
*Alex Stoichitoiu*  
*President of IQNet*

*Arkady Vladimirtsev*  
*Arkady Vladimirtsev,*  
*Director General of*  
*Russian Register*



**IQNet Partners\*:**

- AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy  
 CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA  
 FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifointi Oy Finland INTECO Costa Rica  
 IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland  
 NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia  
 SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)





THE INTERNATIONAL CERTIFICATION NETWORK

**ANNEX 2 to IQNet Certificate**  
**Number RU-20.1001.026**

**Certification scope of management system of  
LLC "Zavod Medsintez" includes:**

**1. Workshop No. 1**

Legal address: 28, Kirova Str., office 205, 620028, Ekaterinburg, Sverdlovsk region, Russia

Actual address: 15, Torgovaya Str., 624130, Novouralsk, Sverdlovsk region, Russia

**2. Workshop No. 2**

Legal address: 28, Kirova Str., office 205, 620028, Ekaterinburg, Sverdlovsk region, Russia


Actual address: 15, Torgovaya Str., Bldg. 3, 624130, Novouralsk, Sverdlovsk region, Russia

**3. Workshop No. 11**

Legal address: 28, Kirova Str., office 205, 620028, Ekaterinburg, Sverdlovsk region, Russia

Actual address: 9, Podgornaya Str., 624130, Novouralsk, Sverdlovsk region, Russia



  
*Alex Stoichitoiu*  
President of IQNet

  
*Arkady Vladimirtsev,*  
Director General of  
Russian Register



**IQNet Partners\*:**

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy  
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA  
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica  
IRAM Argentina JQA Japan KFAQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland  
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia  
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)