СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА
RUSSIAN REGISTER CERTIFICATION SYSTEM

CERTIFICATE

This is to certify that the Quality Management System of

Limited Liability Company "Zavod Medsintez"

Legal address: 28B/2, Kirova Str., room 1, office 205, 620028, Yekaterinburg, Yekaterinburg city district, Sverdlovsk region, Russia
Actual address: 15, Torgovaya Str., 624130, Novouralsk, Sverdlovsk region, Russia; 15, Bldg. 3, Torgovaya Str., 624130, Novouralsk, Sverdlovsk region, Russia; 11, Podgornaya Str., 624130, Novouralsk, Sverdlovsk region, Russia; 3/1, Podgornaya Str., 624130, Novouralsk, 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: devices for injection, artificial blood circulation and hamapheresis

No: 26.0743.026
Certificate Issue date: **20.07.2026**
Revision number: **1**
Certificate expiry date: **29.08.2029**

Issue number: **4**
Original date of the first certification cycle: **30.08.2017**
Previous certificate expiry date: **29.08.2026**

A. Vladimirtsev
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).

Register of certificates
https://rusregister.ru/

NABCB
QM 082

Certification Association "Russian Register": 101 Rimskogo-Korsakova Ave., 190121, Saint Petersburg, Russia

10-000643

RUSSIAN REGISTER РУССКИЙ РЕГИСТР

СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА
RUSSIAN REGISTER CERTIFICATION SYSTEM

Annex to the Certificate
№ 26.0743.026
of 20.07.2026
registration form № 10-000643

Certification scope of management system of Limited Liability Company "Zavod Medsintez"

1. Kinds of activity: development, launching into manufacture, preparing for manufacture, manufacture, storage and marketing of medical devices: devices for injection, artificial blood circulation and hamapheresis.
2. The requirements of p. 7.3.6 и 7.3.7 (in terms of connection with another medical device or availability of a common interface); 7.5.1.f (in terms of actions after delivery); 7.5.2; 7.5.3; 7.5.4; 7.5.9.2; 7.5.10; 8.2.6 (in terms of implantable medical devices); 8.4f ISO 13485:2016 are not applicable to the certification scope of QMS.

Director General of Certification
Association "Russian Register" A. Vladimirtsev

СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА
RUSSIAN REGISTER CERTIFICATION SYSTEM

Annex to the Certificate
№ 26.0743.026
of 20.07.2026
registration form № 10-000643

Certification scope of management system of Limited Liability Company "Zavod Medsintez" includes:

1. **Workshop No. 1**
   Legal address: 28B/2, Kirova Str., room 1, office 205, 620028, Yekaterinburg, Yekaterinburg city district, Sverdlovsk region, Russia
   Actual address: 15, Torgovaya Str., 624130, Novouralsk, Sverdlovsk region, Russia
   Kinds of activity: preparation, filling, sterilization, packaging.
2. **Workshop No. 2**
   Legal address: 28B/2, Kirova Str., room 1, office 205, 620028, Yekaterinburg, Yekaterinburg city district, Sverdlovsk region, Russia
   Actual address: 15, Bldg. 3, Torgovaya Str., 624130, Novouralsk, Sverdlovsk region, Russia
   Kinds of activity: assembly, packaging.
3. **Microbiological laboratory**
   Legal address: 28B/2, Kirova Str., room 1, office 205, 620028, Yekaterinburg, Yekaterinburg city district, Sverdlovsk region, Russia
   Actual address: 11, Podgornaya Str., 624130, Novouralsk, Sverdlovsk region, Russia
   Kinds of activity: quality control.
4. **Warehouse**
   Legal address: 28B/2, Kirova Str., room 1, office 205, 620028, Yekaterinburg, Yekaterinburg city district, Sverdlovsk region, Russia
   Actual address: 3/1, Podgornaya Str., 624130, Novouralsk, Sverdlovsk region, Russia
   Kinds of activity: storage.

Director General of Certification
Association "Russian Register" A. Vladimirtsev