



CERTIFICATE

This is to certify that the Quality Management System of

Limited Liability Company
"Zavod Medsintez" (LLC "Zavod Medsintez")
including production sites in the Annex
28, Kirova Str., room 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: devices for injection, artificial blood circulation
and hemapheresis

No: 23.0985.026
of 20th September, 2023

Management system certified since 2017

This certificate is valid until **30th August, 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>).



СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА
RUSSIAN REGISTER CERTIFICATION SYSTEM



**Annex to the Certificate
№ 23.0985.026
of 20th September, 2023**

**Certification scope of management system of
Limited Liability Company "Zavod Medsintez"
(LLC "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 hemapheresis).
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 post-delivery activities); 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); 8.4 f 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
№ 23.0985.026
of 20th September, 2023**

**Certification scope of management system of
Limited Liability Company "Zavod Medsintez"
(LLC "Zavod Medsintez") includes:**

1. Workshop No. 1

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

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

Kinds of activity: preparation, filling, sterilization, packaging.

2. Workshop No. 2

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

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

Kinds of activity: assembly, packaging.

Director General of Certification
Association "Russian Register"



A. Vladimirtsev