

CERTIFICATION BODY  
CERTIFICATION ASSOCIATION "RUSSIAN REGISTER"  
ACCREDITATION CERTIFICATE OF THE FEDERAL  
ACCREDITATION SERVICE № POCC RU.0001.21ГA45



# 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

**GOST ISO 13485-2017**

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: 23.0984.026  
of 20<sup>th</sup> September, 2023

Management system certified since 2017

This certificate is valid until 30<sup>th</sup> August, 2026



A. Vladimirtsev  
Head of Certification Body



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  
№ 23.0984.026  
of 20<sup>th</sup> 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 GOST ISO 13485-2017 are not applicable to the certification scope of QMS.

Head of Certification Body



A. Vladimirtsev

СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА  
RUSSIAN REGISTER CERTIFICATION SYSTEM



Annex to the Certificate  
№ 23.0984.026  
of 20<sup>th</sup> 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.

Head of Certification Body



A. Vladimirtsev