

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

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

Zavod Medsintez, LLC

*Legal address: 28, Kirova Str., office 205, 620028, Ekaterinburg, Sverdlovsk region, Russia
Actual address: 15, Torgovaya Str., 624130, Novouralsk, 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 according to Annex

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: 28th August, 2020

Expires on: 30th 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

*Alex Stoichitoiu
President of IQNet*

Arkady Vladimirtsev

*Arkady Vladimirtsev,
Director General of
Russian Register*



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ANNEX 1 to IQNet Certificate

Number RU-20.1001.026

Certification scope of the management system of Zavod Medsintez, LLC

1. Product / service: 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 according to Annex.
2. The requirements of 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) ISO 13485:2016 are not applicable to the certification scope of QMS.




Alex Stoichitoiu
President of IQNet


Arkady Vladimirtsev,
Director General of
Russian Register



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