СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА
RUSSIAN REGISTER CERTIFICATION SYSTEM

CERTIFICATE

RUSSIAN REGISTER РУССКИЙ РЕГИСТР

This is to certify that the Quality Management System of

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 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 according to Annex

No: 20.1001.026
of 28th August, 2020

Management system certified since 2017

This certificate is valid until **30th August, 2023**

Director General of Certification
Association "Russian Register"

Specification of the certification scope is provided in Annex. This certificate becomes invalid if conditions of certification are not fulfilled (http://www.rusregister.ru/doc/004.00-105.pdf). This Certificate is the property of Certification Association "Russian Register".

10-000208

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

СИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА
RUSSIAN REGISTER CERTIFICATION SYSTEM

Annex to the Certificate
№ 20.1001.026
of 28th August, 2020
registration form № 10-000208

Certification scope of management system of Zavod Medsintez, LLC

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 according to Annex.
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 (with regard to connection with another medical device(s) or availability of a common interface); 7.5.1 f) (with regard to 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 (with regard to implantable medical devices)

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