



ISO CONSULTING  
ИСОКОНСАЛТИНГ



object of conformity  
confirmation  
ISO 13485:2016

# Certification System

Works and Services, Management Systems

## InterSertTest

**MANAGEMENT SYSTEM CERTIFICATION BODY  
OF LIMITED LIABILITY COMPANY  
"ISO CONSULTING"**

PREMISES 126, 127, 128, AND 129, BLOCK 2, FLOOR 2, 3, DAVYDKOVSKAYA STR., MOSCOW, 121352  
UNIQUE NUMBER OF THE ACCREDITATION RECORD IN THE REGISTER OF ACCREDITED PERSONS: RA.RU.13HA90

### CERTIFICATE OF CONFORMITY

Issue 2. QMS is certified since January 2021

№ **POCC RU.C.04III.A.CK.2015**

Is given to: **"Research and Production Company "VINAR"  
Limited Liability Company  
("RPC "VINAR", LLC)**

TIN 5023001024

Office VIII, Building 7A, 5, Gospitalniy Val, Moscow, 105094

### THIS CERTIFICATE CERTIFIES THAT

**QUALITY MANAGEMENT SYSTEM AS APPLIED TO DESIGN, DEVELOPMENT, PRODUCTION AND SALES OF THE FOLLOWING MEDICAL DEVICES: CHEMICAL AND BIOLOGICAL STERILIZATION, DISINFECTION AND DECONTAMINATION INDICATORS; PROCESS CHALLENGE DEVICES; CHEMICAL INDICATORS FOR DISINFECTING AND STERILIZING SOLUTIONS CONCENTRATION CONTROL; WASH MONITORING AND PRE-CLEANING TESTS; PACKAGING MATERIALS FOR STERILIZATION AND WASHING; "COLD CHAIN" CONTROL INDICATORS; DISPOSABLES FOR STERILIZATION AREAS, OPERATING ROOMS AND CLEAN AREAS; ANTISEPTICS AND DISINFECTANTS**

### COMPLIES WITH THE REQUIREMENTS OF ISO 13485:2016

The Appendix forms are integral part of the Certificate of Conformity

*By virtue of: Decision of the Certification Body № 0096 dated 24 January 2024*

THIS CERTIFICATE SHALL BIND THE ORGANIZATION TO MAINTAIN THE STATE OF THE QUALITY MANAGEMENT SYSTEM IN THE WORKABLE CONDITION IN COMPLIANCE WITH THE REQUIREMENTS OF THE ABOVE STANDARD, TO CONFIRM THIS COMPLIANCE BY RESULTS OF THE ANNUAL INSPECTION CHECK-UP IN "ISO CONSULTING" LLC MANAGEMENT SYSTEM CERTIFICATION BODY WITHIN THE ENTIRE PERIOD OF THE CERTIFICATE DURATION.

**Issued 24 January 2024**

**Expiry date: 24 January 2027**  
*(If the inspection control is passed)*



*Terms for the start of the first inspection: Not later than 18 January 2025*

*Terms for the start of the second inspection: Not later than 18 January 2026*

**S.A. KORKIN**  
Head of the  
Certification Body



№ 006416

**T.V. GRICHANAYA**  
Head of the  
Audit Team

FEDERAL AGENCY OF TECHNICAL REGULATION AND METROLOGY  
Goodwill Certification System "InterSertTest", Registration №POCC RU.3570.04III.A00  
Certification parent body "EuroStandard - certifica" OGRN 1097746081498  
Address: 121170, Moscow, Kutuzovskiy prospect 36, build. 3, tel: (495) 744-2923



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### Appendix

Is an integral part of

Certificate № POCC RU.C.04III.A.CK.2015

### Scope of Certification of the Quality Management System

Design, development, production and sales of the following medical devices: chemical and biological sterilization, disinfection and decontamination indicators; process challenge devices; chemical indicators for disinfecting and sterilizing solutions concentration control; wash monitoring and pre-cleaning tests; packaging materials for sterilization and washing; "cold chain" control indicators; disposables for sterilization areas, operating rooms and clean areas; antiseptics and disinfectants except p. 7.5.3, p. 7.5.4, p. 7.5.6 in terms of the validation of the application of computer software used in production and service provision, p. 7.5.9.2, p. 7.5.10, 8.2.6 in terms of records, for implantable products, for the identification of personnel conducting any type of control or testing ISO 13485:2016

### "Research and Production Company "VINAR" Limited Liability Company,

Including:

Production site "RPC "VINAR", LLC

17/2 Kolontsova str., Mytishchi, Moscow region, 141009

Production medical devices: chemical and biological sterilization, disinfection and decontamination indicators; process challenge devices; chemical indicators for disinfecting and sterilizing solutions concentration control; wash monitoring and pre-cleaning tests; "cold chain" control indicators; disposables for sterilization areas, operating rooms and clean areas

Production site "RPC "VINAR", LLC

51b, Bolshaya Protechnaya str., Pereslavl-Zalessky, Yaroslavl region, 152020,

Production medical devices: packaging materials for sterilization and washing; antiseptics and disinfectants

S.A. KORKIN

Head of the  
Certification Body

E.V. GRICHANAYA

Head of the  
Audit Team

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