

ISO CONSULTING

Goodwill certification  
system  
ESR  
Euro Standard Register

RA/RU.13HA90

ISO  
17021  
CERTIFICATION OF  
MANAGEMENT  
SYSTEMS

Compliance  
confirmation object  
GOST ISO 13485-  
2017

## Certification System

For Products, Works and Services, Management Systems

# EuroStandardRegister

**AUTHORITY FOR CERTIFICATION OF MANAGEMENT SYSTEMS OF  
ISO CONSULTING LIMITED LIABILITY COMPANY**

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

## CERTIFICATE OF COMPLIANCE

Issue 1. QMS is certified since July 2023

**No. POCC RU.C.04XЖ.CK.1028 (ROSS RU.C.04HZH.CK.1028)**

**Issued to: BioPHARMAHOLDING Limited Liability Company  
(BioPHARMAHOLDING, LLC)**

TIN 7734348027

123098 Bldg. 33, 18 Gamalei Str., Moscow,

### THIS CERTIFICATE SHALL AUTHENTICATE:

**THE QUALITY MANAGEMENT SYSTEM, AS APPLICABLE TO THE DESIGNING, DEVELOPMENT, MANUFACTURE, STORAGE  
AND MARKETING OF MEDICAL DEVICES (COLLAGEN-BASED INJECTION AND INTRADERMAL IMPLANTS, COLLAGEN-  
BASED DENTAL MATERIALS, ABSORBABLE AND OSTEOPLASTIC COLLAGEN MATERIALS)**

### COMPLIES WITH THE REQUIREMENTS OF GOST (State Standard) ISO 13485-2017 (ISO 13485:2016)

The Enclosure is an integral part of the Certificate of Compliance

**Justification:** Certification Authority's Decision No. 0140 dated July 12, 2024

THIS CERTIFICATE SHALL BIND THE ORGANISATION TO MAINTAIN THE STATE OF QUALITY MANAGEMENT SYSTEM PROCESSES IN THE GOOD  
WORKING ORDER IN ACCORDANCE WITH THE REQUIREMENTS OF THE STANDARD MENTIONED ABOVE. CONFIRM SUCH COMPLIANCE BY THE  
RESULTS OF PASSING ANNUAL INSPECTION CONTROL AT ISO CONSULTING CERTIFICATION AUTHORITY INTERNATIONAL CENTRE  
THROUGHOUT THE CERTIFICATE VALIDITY PERIOD

**Date of issue:** 12.07.2024

**Valid until:** 27.07.2026

(Upon inspection control undergoing)

**ISO** The period of undergoing the first inspection control: on or before 27.07.2024  
**86147** The period of undergoing the second inspection control: on or before 27.07.2025

**S.A. KORKIN**

**I.I. KORASTELEVA**

**Head of**

**Head of**

**Certification Authority**

**Audit Team**

<Signed>

<Signed>

**Seal:**

ISO CONSULTING LIMITED LIABILITY COMPANY

PSRN 1187746520334 \* TIN 9731003074

ISO CONSULTING CA IC

**No. 003367**

FEDERAL AGENCY FOR TECHNICAL REGULATION AND METROLOGY

EuroStandardRegister Voluntary Registration System, Registration No. POCC RU.3357/04XЖ00 (ROSS RU.3557.04HZH00)

EuroStandard-Certifica Parent Certification Body. PSRN 1097746081498

Address: Bldg. 3, 36 Kutuzovsky Ave., Moscow, 121170 Phone (495)744-2923

## 1. THE CERTIFICATE SHALL BIND ITS HOLDER TO:

- Ensure the certificate object's compliance with the requirements of documents, pursuant to which it has been certificated;
- Create conditions for the inspection control conduct by the Certification Authority according to the rules accepted within the EuroStandardRegister System;
- Apply the mark of compliance according to the rules established within the EuroStandardRegister System;
- Suspend (terminate) the application of the mark of compliance in case of certificate effect suspension (cancellation);
- Advice Certification Authority, as has issued the certificate, in a timely manner of changes occurred for the certificate holder.

## 2. CERTIFICATE WITHOUT CONFIRMATION OF SCHEDULED INSPECTION REVIEWS SHALL BE CONSIDERED INVALID.

Confirmation of conducting scheduled inspection reviews		
Inspection number	1	2
Scheduled review date	12.07.2024	
Signature by the Head of the Certification Authority	<Signed>	
Official seal of the Certification Authority here	<u>Seal:</u> ISO CONSULTING LIMITED LIABILITY COMPANY PSRN 1187746520334 * TIN 9731003074 ISO CONSULTING CA IC	L.S.

Goodwill certification system

ESR

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## Certification System

For Products, Works and Services, Management Systems

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**The Enclosure**

**is an integral part of Certificate**

**No. POCC RU.C.04XЖ.CK.1028 (ROSS  
RU.C.04HZH.CK.1028)**

### Area of Quality Management System Certification

Designing, development, manufacture, storage and marketing of medical devices (collagen-based injection and intradermal implants, collagen-based dental materials, absorbable and osteoplastic collagen materials), with the exception of p. 7.5.3, p. 7.5.4, p. 7.5.6 with regard to the validation of applying computer software used in the manufacture and servicing, p. 7.5.10, p. 8.3.4 of GOST ISO 13485-2017 (ISO 13485:2016)

### Limited Liability Company BioPHARMAHOLDING

Including:

BioPHARMAHOLDING, LLC manufacturing site

Bldg. 4, Bldg. 10, Bldg. 11, Bldg. 18, Bldg. 33, 18 Gamalei Str., Moscow, 123098

BioPHARMAHOLDING, LLC manufacturing site

71 Revolutsii Str., Mosalsk, Kaluga Region, 249930, Russia

**S.A. KORKIN**  
**Head of**  
**Certification Authority**

<Signed>

Seal:

ISO CONSULTING LIMITED LIABILITY COMPANY  
PSRN 1187746520334 \* TIN 9731003074  
ISO CONSULTING CA IC

**I.I. KORASTELEVA**  
**Head of**  
**Audit Team**

<Signed>

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