







object of conformity confirmation ISO 13485:2016

Certification System

Goods Works and Services Management Systems

EuroStandardRegister

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 RECORD NUMBER ON ACCREDITATION IN THE REGISTER OF ACCREDITED PERSONS: RA.RU.13HA90

CERTIFICATE OF CONFORMITY

Issue 1. QMS is certified since July 2023

№ POCC RU.C.04XЖ.CK.1107
Is given to: «BioPHARMAHOLDING»
Limited Liability Company
(«BioPHARMAHOLDING» LLC)

TIN 7734348027

Building 33, 18, Gamalei str., Moscow, 123098

THIS CERTIFICATE CERTIFIES THAT

QUALITY MANAGEMENT SYSTEM AS APPLIED TO DESIGN, DEVELOPMENT, PRODUCTION, STORAGE AND SALES OF MEDICAL DEVICES (COLLAGEN-BASED INJECTABLE AND INTRADERMAL IMPLANTS, COLLAGEN-BASED DENTAL MATERIALS, ABSORBABLE COLLAGEN AND OSTEOPLASTIC MATERIALS)

COMPLIES WITH THE REQUIREMENTS OF ISO 13485:2016

The Appendix forms is an integral part of the certificate of conformity

By virtue of: Decision of the Certification Body № 0203 dated 16 June 2025

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: 16 June 2025

Expiry date: 27 July 2026 (If the inspection control is passed)

Terms for the second inspection: Not later than 27 July 2025

S.A. KORKIN

OHCAJITNHI.

I.I. KORASTELEVA

Head of the Certification Body

Head of the Audit Team

Nº 003558

FEDERAL AGENCY OF TEGLINICAL REGULATION AND METROLOGY
Goodwill Certification System «EuroStandard-Register», Registration №POCC RU.3557.04XЖ00
Certification parent body «EuroStandard-certifica» OGRN 1097746081498
Address: 121352, Russia, Moscow, Davydkovskaya str. 3, tel. 8 (800) 100-0037



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Appendix
Is an integral part of
Certificate № POCC RU.C.04XЖ.CK.1107

Scope of Certification of the Quality Management System

Design, development, production, storage and sales of medical devices (collagen-based injectable and intradermal implants, collagen-based dental materials, absorbable collagen and osteoplastic materials) 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. 7.5.10, p. 8.3.4 ISO 13485:2016

"BioPHARMAHOLDING" Limited Liability Company,

Including:

Production site "BioPHARMAHOLDING" LLC

Building 4, building 10, building 11, building 18, building 33, 18, Gamalei str., Moscow, 123098

Production site "BioPHARMAHOLDING" LLC 4, Klara Tsetkin str., Moscow, 127299

Production site "BioPHARMAHOLDING" LLC 71, Revoluzii str., Mosalsk, Kaluga region, 249930

S.A. KORKIN

Head of the Certification Body I.I. KORASTELEVA

Head of the Audit Team

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