ORIGINAL

MANUFACTURER:	Bioline Products s.r.o.
ADRESS:	Krakovská 1338/10, 110 00 Praha, Czech Republic
EUROPEAN REPRESENTATIVE:	N/A
PRODUCT NAME:	ENTEROSGEL®
VARIANTS OF THE DEVICE:	Sachets 10*15g, tube 225 g, tube 90 g
CLASSIFICATION:	class IIa, rule V according to Annex IX of the MDD 93/42/EEC
CONFORMITY ASSESSMENT ROUTE:	Council Directive Nº. 93/42/EEC on Medical Devices (MDD 93/42/EEC), Annex V

We herewith declare exclusively under our sole responsibility that the above-mentioned products meet the provisions of the council directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED:

Reference	Title of the harmonised/international standard or other guidance or regulation	Level of compliance
MDD 93/42/EEC, Annex V	Medical Device Directive 93/42/EEC, Annex V	Full
MDR (EU) 2017/745	Medical Devices Regulation 2017/745	Only article 120
Ph. Eur. 10	European Pharmacopoeia	Only: Articles 2.6.12, 2.6.13, 5.1.4
Russian State Pharmacopoeia 14	Russian State Pharmacopoeia	Only: OFS.1.2.1.0004.15, OFS 1.2.1.0009.15, OFS.1.4.2.0007.15, OFS.1.2.4.0002.18
Packaging and Transport		
ISTA 2A:2011 (ASTM D4332, ASTM D642, ASTM D999, ASTM D5276)	Standard Practice for Performance Testing of Shipping Containers and Systems	Full
EN ISO 2233:2001	Packaging - Complete, filled transport packages and unit loads - Conditioning for testing	Full
EN ISO 2247: 2002	Packaging - Complete, filled transport packages and unit loads - Vibration tests at fixed low frequency	Full

EN ISO 22248:1992	Packaging - Complete, filled transport packages – Vertical impact test by dropping	Full
ISO 21948:2001	Coated abrasive sheets – Plain sheets	Full
ASTM F1886/F1886M-16	Standard Test Method For Determining Integrity Of Seals For Flexible Packaging By Visual Inspection	Full
ASTM F88/F88M-15	Standard Test Method For Seal Strength Of Flexible Barrier Materials	Full
EN 868-5:2018	Packaging for terminally sterilized medical devices – Part 5: Sealable pouches and reels of porous materials and plastic film construction – Requirements and test methods	Full
Information to be supplied by the manufacturer		
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices	Full
EN ISO 15223-1:2016	Medical devices. Symbols to be used with medical device labels, labelling, and information to be supplied. General requirements.	Full
Biological Evaluation		
EN ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	Full
EN ISO 10993-3:2014	Biological evaluation of medical devices. Tests for genotoxicity, carcinogenicity and reproductive toxicity	Full
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	Full
EN ISO 10993-11:2018	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	Full
EN ISO 10993-10:2013	Biological evaluation of medical devices. Tests for irritation and skin sensitization	Full
Risk Management		
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices	Full
ISO/TR 24971:2020	Medical devices – Guidance on the risk application of ISO 14971	Full
Quality Management System		
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes	Excluded/not applicable: ▪ 7.3 ▪ 7.5.3

		▪ 7.5.4 ▪ 7.5.5 ▪ 7.5.7 ▪ 7.5.10
EN ISO 9001:2015	Quality management systems – Requirements	Full
Usability Engineering		
EN ISO 62366-1:2015	Medical devices – Application of usability engineering to medical devices.	Full
EN ISO 14001:2015	Environmental management systems – Requirements with guidance for use	Full
Stability Testing		
ICH Q1A (R2) 2003	Stability testing of new drug substances and drug products	Full
Clean Rooms		
EN ISO 14644:2015 -1,2,3	Classification of air cleanliness in cleanrooms and associated controlled environments	Full

NOTIFIED BODY: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 Munich, Germany, identification number 0123
(EC) CERTIFICATE: G2 106926 0002 Rev. 00, valid to 2024-05-26
START OF CE-MARKING: 2020-07-14
PLACE, DATE OF ISSUE: Prague, Czech Republic, 2021-05-19

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Approved by: Boris Odrin, CEO

Signature: ----------
Boris Odrin, CEO

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