MANUFACTURER:	Bioline Products s.r.o.
ADRESS:	Pátkova 831, Libeň, 182 00 Prague 8, Czech Republic[1]
EUROPEAN REPRESENTATIVE:	N/A
PRODUCT NAME:	ENTEROSGEL®
VARIANTS OF THE DEVICE:	Sachets 10*15g, tube 225 g, tube 90 g
CLASSIFICATION:	class IIa, rule 5 according to Annex IX of the MDD 93/42/EEC
CONFORMITY ASSESSMENT ROUTE:	Council Directive N°. 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 MDD 93/42/EEC, Annex V and MDR (EU) 2017/745, article 120 for medical devices. All supporting documentation is retained under the premises of the manufacturer.
As found appropriate, harmonized, or international standards were applied in the design and manufacture of the device to demonstrate compliance with relevant Essential Requirements (all are listed in the Appendix 1, document Essential Requirements).

NOTIFIED BODY: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 Munich, Germany, identification number 0123
(EC) CERTIFICATE: G2 106926 0002 Rev. 00, valid till 2024-05-26
CONFIRMATION LETTER: CL 112575 0001 Rev.00, valid till 2028-12-31

START OF CE-MARKING: 2020-07-14
PLACE, DATE OF ISSUE: Prague, Czech Republic, 2021-05-19

Note: no significant changes to the product were implemented, and no new products were added to the Declaration of Conformity concerned.

Bioline Products s.r.o.
Pátkova 831, 182 00 Praha 8, Libeň
IČ: 282 53 060, DIČ: CZ28253060
zapsaná u MS v Praze, oddíl C, vložka 135523

Date of the document approval: 05.03.2025
Approved by: Boris Odrin, CEO

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

[1] address approved in the project CN_Change of Address_75962859