

EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE

**In accordance with the requirements of the Medical Devices
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK
Statutory Instrument 2002 No. 618**

This is to certify that the Quality Management System of:

**Bioline Products s.r.o
Krakovska 1338/10
Prague 110 00
Czech Republic**

has been assessed against the requirements of Annex V of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ 00000434
Original Approval: 13 September 2018
Current Certificate: 30 September 2019
Certificate Expiry: 12 September 2021
LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited

**EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE
CERTIFICATE LRQ 00000434 SCHEDULE**

**In accordance with the requirements of the Medical Devices
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK
Statutory Instrument 2002 No. 618**

**Bioline Products s.r.o
Krakovska 1338/10
Prague 110 00
Czech Republic**

Class IIa Medical Device

Enterogel- An oral adsorbent for the symptomatic treatment of acute diarrhoea and chronic diarrhoea associated with Irritable Bowel Syndrome.

Entersogel 225 g Tubes
Enterogel 90g Tubes
Enteosgel 15g Sachets

Sub-contract Manufacturers:

TNC SILMA LLC; 50, Shipilovskaya str., section 1, building 2, 115573 Moscow
Naturfyt-Bio s.r.o., Za Podjezdem 501/26, 790 01 Jesenik, Czechia

Schedule Issue: 04

Date of Schedule Issue: 30 September 2019

LRQA Notified Body Number 0088



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EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE CERTIFICATE LRQ 00000434 SUPPLEMENT

Bioline Products s.r.o
Krakovska 1338/10
Prague 110 00
Czech Republic

LRQA hereby confirms that the change(s) detailed below have been reviewed

This supplement is only valid in association with the EC Certificate detailed above.

Supplement Number:	Supplement Date:	Details of amendment:
0	09 September 2019	Schedule no. 3 : Approval of new sub-contract manufacturer: TNC SILMA LLC; 50, Shipilovskaya str., section 1, building 2, 115573 Moscow (Job no. 3063256)
1	30 September 2019	Schedule no. 4 : Approval of new production location for sub-contract manufacturer: Naturfyt-Bio s.r.o., Za Podjezdem 501/26, 790 01 Jesenik, Czechia (Job no. 3136110)

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