

## 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**

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

Enterosgel 225 g Tubes  
Enterosgel 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	<b>Schedule no. 3</b> : 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	<b>Schedule no. 4</b> : 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)

Certificate No: LRQ 00000434

Original Approval: 13 September 2018

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