Lloyd's Register
LRQA

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:	15 October 2016
Current Certificate:	15 October 2016
Certificate Expiry:	14 October 2019

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom

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 Products
Enterosgel

Schedule Issue: 01

Date of Schedule Issue: 15 October 2016

LRQA Notified Body Number 0088

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