EC Certificate
Directive 93/42/EEC, Annex II excluding (4)
Full Quality Assurance System

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-207.15.04

Berlin Cert
Prüf- und Zertifizierstelle für Medizinprodukte GmbH

hereby certifies that

MGB Endoskopische Geräte GmbH Berlin

Schwarzschildstraße 6, 12489 Berlin

has implemented and uses a quality assurance system for the following scope of application:

Design, production and final inspection of surgical products (see Appendix)

The audit in accordance with Annex II of MDD 93/42/EEC (report no. A-17-131-SZ) provided confirmation that the requirements of Annex II of MDD 93/42/EEC have been fulfilled. The Manufacturer has to be inspected periodically by the notified body according the requirements of Annex II, Article 5 of MDD 93/42/EEC. The manufacturer is allowed to use this certification in his process for the declaration of conformity.

The manufacturer is allowed to place the CE-mark on the above mentioned products in combination with the identification No. **0633**.

issued on:	**2017-12-22**
valid from:	**2017-12-28**
valid to:	**2022-12-21**

Prüf- und Zertifizierstelle für Medizinprodukte GmbH BERLIN

Dr. N. Eschweiler
Signature of authorized representative

Digitally signed by Grabazei Alexandru
Date: 2020.03.24 11:18:38 EET
Reason: MoldSign Signature
Location: Moldova

Appendix to certificate Z-17-131-S-R II-E

from 2017-12-22

product/product category	UMDNS	Classification		
		I s/m	II a	II b
Endoscopes and accessories		☐	☒	☐
HF-surgical devices Aristo HF35, HF4000L, HF4000B, HF2000B, HF800B	11-490	☐	☐	☒
Insufflators Fencer, ML-G, ML-GX and accessories (tubes, cannulas, others)	12-144	☐	☒	☐
sterile products for single use		☐	☒	☐
Trocars and accessories (trocar sleeves, trocar stop)	14-154	☐	☒	☐
HF-surgical devices - accessories GRP-handpieces	11-494	☐	☐	☒
Accessories for suction and irrigation systems (sheaths, inserts, cannulas, tubes, handles, adapter, connection parts)	17-676	☐	☒	☐

Prüf- und Zertifizierstelle Medizinprodukte GmbH

Dr. N. Eschweiler
Signature of authorized representative