Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 061967 0003 Rev. 00

Manufacturer	**Bioengineering Laboratories S.r.l.** Via Antonio Vivaldi 32/A 22063 Cantù (CO) ITALY
Facility(ies):	Bioengineering Laboratories S.r.l. Via Antonio Vivaldi 32/A, 22063 Cantù (CO), ITALY Bioengineering Laboratories S.r.l. Str. Provinciale per Dubino 10, 23014 Delebio (SO), ITALY
Product Category(ies):	**Sheaths for endoscopes**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:	ITA1422210
Valid from:	2020-01-30
Valid until:	2024-05-26

Date, 2020-01-31

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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A4 / 07.17