ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 084462 0012 Rev. 01

Manufacturer:

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
GERMANY

Product Category(ies):

- Light Sources
- Light Carrier (adaptable)
- Optics (Telescopes) with channel
- Optics (Telescopes) without channel
- Fiberscopes with channel
- Fiberscopes without channel
- Semiflexible endoscopes with channel
- Semiflexible endoscopes without channel
- Rigid Videoscopes with channel
- Rigid Videoscopes without channel
- Flexible Videoscopes with channel
- Flexible Videoscopes without channel
- Sheaths
- Trocars
- Instruments with movable jaws
- Instruments without movable jaws
- Working Elements/ Working Inserts
- Cannulas
- HF Instruments with movable jaws
- HF Instruments without movable jaws/ HF Electrodes
- HF Suction/ Irrigation Instruments
- HF Generators
- HF Foot Switches
- HF Working Elements
- Nonactive implants for ENT
- Nonactive bone implants for arthroscopic procedures
- Insufflators with Accessories
- Tubing Sets Insufflators
- Laser Devices
- Foot Switch Laser
- Laser Fibers
- Lithotripsy Devices
- Foot Switches Lithotripsy Devices
- Lithotripsy Probes
- Pumps
- Suction/ Irrigation Instruments
- Foot Switches with Pumps
- Tubing Sets Pumps
- Motor Control Unit
- Handpieces/ Motors

Digitally signed by Cucerenco Olesea
Date: 2021.12.09 16:07:20 EET
Reason: MoldSign Signature
Location: Moldova

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

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

TÜV®

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Product Category(ies):

- Foot Switches Motor Control Unit
- Shaver/ Drills
- Morcellator Systems
- EM Navigation
- Active controlling systems, components of software

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 084462 0012 Rev. 01

Report No.: 713202293

Valid from: 2021-05-25
Valid until: 2023-07-16

Date, 2021-05-25

Christoph Dicks
Head of Certification/Notified Body

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