



Product Service

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

To whom it may concern

Munich, 2021-07-08

Order No.: 713218192

Confirmation concerning EC Certificates G1 084462 0012 Rev. 01, G1 18 04 84462 012, G2S 084462 0013 Rev. 01 and G2S 18 04 84462 013 and

We confirm that the following certificates:

G1 084462 0012 Rev. 01 (issued on 2021-05-25; valid until 2023-07-16)
G2S 084462 0013 Rev. 01 (issued on 2021-05-25; valid until 2023-07-16)

issued to the legal manufacturer of medical devices:

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

cover the Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) with the product categories (**G1 084462 0012 Rev. 01**):

- 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

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at www.tuvsud.com/imprint

Supervisory Board:
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TÜV SÜD Product Service GmbH
Foreign Affairs
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- 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
- Foot Switches Motor Control Unit
- Shaver/ Drills
- Morcellator Systems
- EM Navigation
- Active controlling systems, components of software

cover the Directive 93/42/EEC on Medical Devices (MDD), Annex V with the product categories **(G2S 084462 0013 Rev. 01)**:

- Medical equipment drape
- Suction/irrigation tubing
- ENT probe
- Adhesive bandage
- Laparoscopic cholangiography catheter
- Surgical plume evacuation system filter
- Laparoscopic access cannula seal
- Surgical instrument assist arm system, manually-adjusted
- Surgical irrigation/aspiration tubing set

With this letter we confirm that the products covered by the certificate **G1 084462 0012 Rev. 01** and **G2S 084462 0013 Rev. 01** are identical with the products covered by certificate **G1 18 04 84462 012** and **G2S 18 04 84462 013**, respectively (certificate replaced).

We further confirm that the above-mentioned devices are covered by a quality assurance system that has been established by the manufacturer and is certified by the notified body TÜV SÜD Product Service GmbH.

The above-mentioned medical devices can be labelled with CE mark (CE 0123) and placed on the market in the European Economic Area based on the existing declaration of conformity issued by the

