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
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 084462 0072 Rev. 02

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

SRN Manufacturer: DE-MF-000005723

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
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:G10 084462 0072 Rev. 02

Report No.: 713249165

Preceding Certificate No.: G10 084462 0072 Rev. 01

Valid from: 2022-09-22
Valid until: 2025-12-17

Date of Initial Issuance: 2020-12-18

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-09-22

Digitally signed by Gherman Irina
Date: 2023.03.20 10:34:40 EET
Reason: MoldSign Signature
Location: Moldova

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No. G10 084462 0072 Rev. 02

Classification:	IIa
Device Group:	Z120202 - MOTORISED INSTRUMENTS FOR ENDOSCOPIC SURGERY
Intended Purpose:	./.

Classification:	IIa
Device Group:	Z120207 - GENITOURINARY ENDOSCOPY INSTRUMENTS
Intended Purpose:	./.

Classification:	IIa
Device Group:	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
Intended Purpose:	./.

Classification:	IIb
Device Group:	Z120203 - ENDOSCOPIC LITHOTRIPSY INSTRUMENTS
Intended Purpose:	Laser units are used to provide laser radiation for cutting, coagulation, vaporization and ablation of biological tissue, as well as for lithotripsy of stones during surgical interventions. Laser units do not come into contact with the body.

Classification:	IIb
Device Group:	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
Intended Purpose:	KARL STORZ CR1TM SCB CONTROL equipment control is used to centrally display and enable remote control of the parameters of both the SCB equipment and the designated equipment from other manufacturers which is connected to the KARL STORZ CR1 SCB CONTROL during diagnostic and therapeutic interventions. The equipment control can be operated via sterile input on touch-sensitive LCD monitors (touchscreens) and has no direct contact with the patient. The KARL STORZ CR1 SCB CONTROL hardware is used to provide a computer System in order to enable use of the KARL STORZ CR1 SCB CONTROL software. The KARL STORZ CR1 SCB CONTROL hardware has no direct contact with the patient. The KARL STORZ SCB software is used to display and enable central and sterile remote control of the parameters of both the SCB equipment connected to the KARL STORZ SCB control and the equipment from other manufacturers intended for this purpose. The KARL STORZ SCB software has no direct contact with the patient. The SCB PC card is used as a master node (administration) in the KARL STORZ SCB bus and thus enables the KARL STORZ CR1 SCB control software to control and visualize the SCB equipment. Furthermore, the SCB PC card is used as an independent watchdog for the SCB Security Task. The SCB PC card has no direct contact with the patient.

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No. G10 084462 0072 Rev. 02

Classification:	IIb
Device Group:	Z120203 - ENDOSCOPIC LITHOTRIPSY INSTRUMENTS
Intended Purpose:	CALCUSPLIT probes are intended to guide pneumatic puise energy tor lithotripsy to the caiculus. Probes are surgically invasive and meant tor short term use.
Classification:	IIb
Device Group:	Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY
Intended Purpose:	Insuffiators with heating are intended to dehiver and heat C02 for insuiflation (creating and maintaining a cavity) or replacement of ambient air in aparoscopy, thoracoscopy, transanal endoscopy and endoscopic vessel harvesting. Insuffiators are non-invasive and meant tor short-term use.
Classification:	IIb
Device Group:	Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY
Intended Purpose:	Suction/irrigation pumps are intended to irrigate irrigation fluid into organs, joints and on fields of intervention, as weil as to suction off irrigation and body fluids, secretions, tissue and gases. Suctionhirrigation pumps do not have body contact.
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

Revision History:

Rev.	Dated	Report
00	2020-12-18	713169106
01	2022-04-14	713224270

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