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. 00

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

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. 00

Report No.: 713169106

Valid from: 2020-12-18
Valid until: 2025-12-17

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2020-12-18

Digitally signed by Gherman Irina
Date: 2022.05.25 12:40:02 EEST
Reason: MoldSign Signature
Location: Moldova

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Classification:	IIa
Device Group:	Z1202 - ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY INSTRUMENTS
Intended Purpose:	-
Classification:	IIb
Device Group:	Z120110 - LASER SURGERY INSTRUMENTS
Intended Purpose:	Laser units are intended to provide laser radiation for cutting, coagulation, vaporization and ablation of biological tissue, as well as for lithotripsy of stones during surgical procedures. Laser units do not have direct body contact.
Classification:	IIb
Device Group:	Z120290 - VARIOUS ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY INSTRUMENTS
Intended Purpose:	The KARL STORZ OR1™ control NEO and the KARL STORZ OR1™ SCB CONTROL device control allow the display and remote control of almost all parameters of the SCB devices connected to the KARL STORZ SCB® control NEO system and to the KARL STORZ OR1 SCB CONTROL and devices of other manufacturers. The system is operated via a graphical user interface, whereby the command input takes place with a maximum of two touch-sensitive LCD monitors* (touch screens). The graphical. The user interface is designed so that entries can be made with the finger without the need for any aids. The following basic functions are possible: - Remote control of the main operating functions of SCB® devices - Display of the relevant SCB® device parameters - User and application specific Presets (pre-programming) of all connected SCB® Devices.
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

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