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 I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 084462 0071 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. As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. 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:G11 084462 0071 Rev. 00

Report No.: 713169106

Valid from: 2020-12-17
Valid until: 2025-12-16

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2020-12-17

Digitally signed by Cucerenco Olesea
Date: 2021.08.18 09:26:29 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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Classification:	I
Device Properties:	MDS 1006 - Reusable surgical instruments
Device Group:	MDN 1208 - Non-active non-implantable instruments
Classification:	I
Device Properties:	MDS 1005.1 - Ethylen oxyde sterilization MDS 1005.2 - Sterilisation by irradiation
Device Group:	MDN 1208 - Non-active non-implantable instruments
Classification:	I
Device Properties:	MDS 1005.1 - Ethylen oxyde sterilization MDS 1005.2 - Sterilisation by irradiation
Device Group:	MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

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