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 042460 0016 Rev. 00

Manufacturer:

CM Instrumente GmbH
Gänsäcker 56
78532 Tuttlingen
GERMANY

SRN Manufacturer - DE-MF-000005588

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G11 042460 0016 Rev. 00

Report No.: 713280215

Valid from: 2024-10-11
Valid until: 2029-10-10

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-10-11

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification:	Class I
Device Group:	A01 - NEEDLES G02 - GASTROINTESTINAL TUBES AND SETS G03 - GASTROINTESTINAL ENDOSCOPY DEVICES L01 - SHARP INSTRUMENTS, REUSABLE L02 - SUTURE INSTRUMENTS, REUSABLE L03 - GENERAL SURGERY INSTRUMENTS, REUSABLE L04 - ABDOMINAL SURGERY INSTRUMENTS, REUSABLE L05 - OBSTETRICS AND GYNECOLOGY INSTRUMENTS, REUSABLE L06 - UROLOGY INSTRUMENTS, REUSABLE L07 - CARDIOVASCULAR SURGERY INSTRUMENTS, REUSABLE L08 - THORACIC SURGERY INSTRUMENTS, REUSABLE L09 - ORTHOPAEDIC AND TRAUMATOLOGICAL SURGERY INSTRUMENTS, REUSABLE L11 - NEUROSURGERY AND SPINAL SURGERY INSTRUMENTS, REUSABLE L14 - ENT INSTRUMENTS, REUSABLE L15 - ODONTOSTOMATOLOGY INSTRUMENTS, REUSABLE L17 - OPHTHALMOLOGY INSTRUMENTS, REUSABLE L24 - DERMATOLOGICAL SURGERY INSTRUMENTS, REUSABLE L26 - SURGICAL SCREWDRIVERS, REUSABLE L99 - SURGICAL INSTRUMENTS, REUSABLE - OTHER P09 - ORTHOPAEDIC PROSTHESES, OSTEOSYNTHESIS DEVICES, DEVICES FOR TENDON AND LIGAMENT SYNTHESIS Q01 - DENTAL DEVICES Q02 - OPHTHALMIC DEVICES V03 - MEASUREMENT DEVICES Z12 - INSTRUMENTS FOR FUNCTIONAL EXPLORATIONS AND THERAPEUTIC INTERVENTIONS
Device Properties:	MDS 1006 - Reusable surgical instruments
The validity of this certificate depends on conditions and/or is limited to the following:	./.

Revision History:

Rev.	Dated	Report	Description
00	2024-10-11	713280215	Initial issuance

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