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

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 036993 0028 Rev. 00

Manufacturer: **TRACOE medical GmbH**
Reichelsheimer Str. 1/3
55268 Nieder-Olm
GERMANY

SRN Manufacturer - DE-MF-000006938

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective 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.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class III or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

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:G15 036993 0028 Rev. 00

Report No.: 713372978
713387498

Preceding Certificate No.: G10 036993 0025 Rev. 03

Valid from: 2025-11-26
Valid until: 2027-03-28

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-11-26

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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Certificate No. G15 036993 0028 Rev. 00

Classification:	Class I
Device Group:	R01 - INTUBATION DEVICES
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class IIa
Device Group:	MDN 1201 - Non-active non-implantable devices for anaesthesia, emergency and intensive care
Classification:	Class IIb
Device Group:	R010501 - TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, UNCUFFED R010502 - TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, CUFFED R010503 - TRACHEOSTOMY INNER CANNULAS
Intended Purpose:	TRACOE twist plus spare inner cannulas are indicated for use only in combination with TRACOE twist plus tracheostomy tube. They may be used up to 29 days. The product is intended to be used only in combination with TRACOE twist plus outer cannulas of the corresponding size. For the application refer to the instructions for use for the TRACOE twist plus tracheostomy tubes. For information on Clinical Benefit, Patient Population, Clinical Use, Intended User and Indications for Use please refer to the instructions for use of the respective TRACOE twist plus tracheostomy tube. TRACOE twist plus tracheostomy tubes are indicated for providing tracheal access for airway management. They may be used up to 29 days.
The validity of this certificate depends on conditions and/or is limited to the following:	-

Revision History:

Rev.	Dated	Report	Description
00	2025-11-26	713372978 713387498	Initial issuance

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