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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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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 036993 0025 Rev. 01

Manufacturer:

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

SRN Manufacturer - DE-MF-000006938

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, 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:G10 036993 0025 Rev. 01

Report No.:	713267436
Preceding Certificate No.:	G10 036993 0025 Rev. 00
Valid from:	2024-04-17
Valid until:	2027-03-29
Date of Initial Issuance:	2022-03-29

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-04-17

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 IIa
Device Group:	R010601 - CIAGLIA TRACHEOSTOMY KITS R010604 - SELDINGER TRACHEOSTOMY KITS
Intended Purpose:	-
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	2022-03-29	713181269	-
01	2024-04-17	713267436	Supplemented: Device(s)/group of device(s) added

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