



America

CERTIFICATE

No. QS6 036993 0024 Rev. 01

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

Certification Mark:



Scope of Certificate: Design and Development, Production and Distribution of Tracheostomy Tubes, Stoma Buttons, Heat/Moisture Exchangers, Compresses, Cuff Pressure Control Devices for Endotracheal Tubes and Tracheostomy Tubes, Percutaneous Dilation Tracheostomy Set, Balloon Dilation Catheter, Sterile Connecting Tubes, Cuff Pressure Monitor, Compress, Speaking Valves, Occlusion Caps and Stoppers for Tubes and Buttons

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: F001364

Effective Date: 2022-05-10

Expiry Date: 2025-04-25

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Date of Issue: 2022-05-19

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services



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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 16/2013
 - RDC ANVISA n. 23/2012
 - RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
 - PMD Act

United States

- 21 CFR Part 803
 - 21 CFR Part 806
 - 21 CFR Part 807 – Subparts A to D
 - 21 CFR Part 820

Facility(ies):

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

TRACOE medical GmbH
 Reichelsheimer Str. 9-11, 55268 Nieder-Olm, GERMANY

TRACOE medical GmbH
 Reichelsheimer Straße 8, 55268 Nieder-Olm, GERMANY

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Facility Scopes:

TRACOE medical GmbH

Reichelsheimer Str. 1/3, 55268 Nieder-Olm, GERMANY

Design and Development, Production and Distribution of Tracheostomy Tubes, Stoma Buttons, Heat/Moisture Exchangers, Compresses, Cuff Pressure Control Devices for Endotracheal Tubes and Tracheostomy Tubes, Percutaneous Dilation Tracheostomy Set, Balloon Dilation Catheter, Sterile Connecting Tubes, Cuff Pressure Monitor, Compress, Speaking Valves, Occlusion Caps and Stoppers for Tubes and Buttons
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TRACOE medical GmbH

Reichelsheimer Str. 9/11, 55268 Nieder-Olm, GERMANY

Warehousing and Distribution of Tracheostomy Tubes, Stoma Buttons, Heat/Moisture Exchangers, Compresses, Cuff Pressure Control Devices for Endotracheal Tubes and Tracheostomy Tubes, Percutaneous Dilation Tracheostomy Set, Balloon Dilation Catheter, Sterile Connecting Tubes, Cuff Pressure Monitor, Speaking Valves, Occlusion Caps and Stoppers for Tubes and Buttons
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TRACOE medical GmbH

Reichelsheimer Straße 8, 55268 Nieder-Olm, GERMANY

Production of Tracheostomy Tubes, Speaking Valves
REPs Facility ID: F001364

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