



## CERTIFICATE

No. QS6 036993 0024 Rev. 04

**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, Japan MHLW / PMDA, USA FDA. 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. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6\\_036993\\_0024\\_Rev\\_04](http://www.tuvsud.com/ps-cert?q=cert:QS6_036993_0024_Rev_04)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** F001364  
**Report No.:** 713393226  
**Effective Date:** 2026-04-14  
**Expiry Date:** 2027-07-20

( Renee Walker )  
Director, US Certification Body, MHS





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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

REPs Facility ID: F001364

**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

REPs Facility ID: F001364

**TRACOE medical GmbH**

Reichelsheimer Straße 8, 55268 Nieder-Olm, GERMANY

Production of Tracheostomy Tubes, Speaking Valves

REPs Facility ID: F001364

( Renee Walker )  
Director, US Certification Body, MHS