



Certificate

No. Q5 036993 0023 Rev. 03

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

Certification Mark:



Scope of Certificate: **Design and development, production, sales and distribution of tracheostomy products, laryngectomy products for tracheostomized and laryngectomized patients and catheter for dilation of the airway**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 036993 0023 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_036993_0023_Rev_03)

Report No.: 713331668

Valid from: 2024-09-03

Valid until: 2027-09-02

Date, 2024-07-26



Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **TRACOE medical GmbH**
Reichelsheimer Str. 1/3, 55268 Nieder-Olm, GERMANY

See Scope of Certificate

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

Distribution of tracheostomy products, laryngectomy products for
tracheostomized and laryngectomized patients and catheter for
dilation of the airway

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

Production of tracheostomy products

-/-