



Product Service

CERTIFICATE

No. Q1N 16 03 36993 009

Holder of Certificate: TRACOE medical GmbH

Reichelsheimer Str. 1/3
55268 Nieder-Olm
GERMANY

Facility(ies):

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



Certification Mark:



Scope of Certificate:

Design and development, production, sales, distribution and servicing of tracheostomy products, laryngectomy products for tracheostomized and laryngectomized patients.

Applied Standard(s):

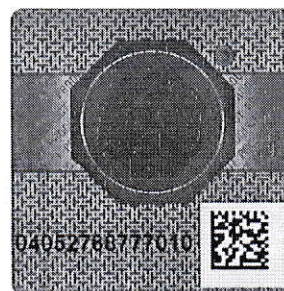
EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

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). See also notes overleaf.

Report No.: 713078485

Valid from: 2016-06-08

Valid until: 2019-05-31



Date, 2016-06-08

Stefan Preiß

Page 1 of 1

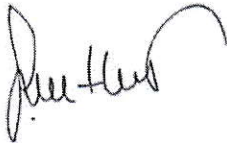
DAKkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Statement on conformity with EN ISO 13485

We, TRACOE medical GmbH, located at Reichelsheimer Straße 1/3, 55268 Nieder-Olm, Germany, hereby confirm that we are certified according to EN ISO 13485: Medical devices - Quality management systems - Requirements for regulatory purposes.

Recertification was successfully completed in May 2019. The update of the certificate is still pending. The certificate will be submitted as soon as it becomes available.

Best regards



Dr. Susanne Muther

Regulatory Affairs Specialist

TRACOE medical GmbH
Reichelsheimer Straße 9-11
55268 Nieder-Olm
Tel: 0 61 36 - 91 69 - 0 / Fax -200

SAO Y BAN CHINH
Ngày.....Tháng.....Năm.....



Nguyễn Hữu Khánh Hưng