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Zentralstelle der Länder
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bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 036993 0016 Rev. 01

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

Product Category(ies): **Tracheostomy Tubes incl. Accessories, Voice Protheses, Stoma Buttons, Heat-/Moisture-Exchangers, Compresses, Cuff Pressure Control Devices for Endotracheal Tubes and Tracheostomy Tubes, Percutaneous Dilation Tracheostomy Set with Minimal Traumatic Insertter, Balloon Dilation Catheter**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713167690

Valid from: 2020-03-16
Valid until: 2024-05-26

Date, 2020-03-10

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT