



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
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 I in sterile conditions, sterilized systems or procedure packs)

No. G1S 036993 0014 Rev. 01

Manufacturer:

TRACOE medical GmbH

Reichelsheimer Str. 1/3
55268 Nieder-Olm
GERMANY

**Product
Category(ies):**

**sterile Connecting Tubes cpm,
Speaking Valves, Compress,
Accessories for tubes and buttons:
occlusion caps and stopper**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex II. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 713167694

Valid from: 2020-03-26

Valid until: 2024-05-26

Date, 2020-03-26

Christoph Dicks
Head of Certification/Notified Body

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04 / 07 / 17