



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 15 03 36993 006

Manufacturer:

TRACOE medical GmbH

Reichelsheimer Str. 1/3
55268 Nieder-Olm
GERMANY

Facility(ies):

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 Dilatation Tracheostomy Set with Atraumatic
Insertor

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.:

713066983

Valid from:

2015-04-27

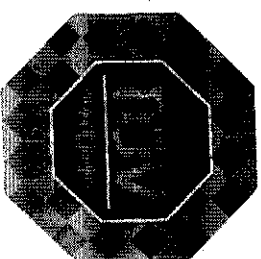
Valid until:

2020-03-15

Date, 2015-04-28

H.-H. Junker

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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