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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 15 03 36993 008**

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

M.S.D.N: 0302422840-C.T.T.N.H.H
CÔNG TY TNHH THƯƠNG MẠI - DỊCH VỤ - Y TẾ ĐỊNH GIANG
Q.BÌNH THẠNH - T.P HỒ CHÍ MINH

Nguyễn Hữu Khánh Hưng

| | |
|---|---|
| **Manufacturer:** | **TRACOE medical GmbH**<br>Reichelsheimer Str. 1/3<br>55268 Nieder-Olm<br>GERMANY |
| **Facility(ies):** | TRACOE medical GmbH<br>Reichelsheimer Str. 1/3, 55268 Nieder-Olm, GERMANY |
| **Product Category(ies):** | **sterile Connecting Tubes cpm,**<br>**Speaking Valves,**<br>**Accessories for tubes and buttons:**<br>**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.:** 713056983

**Valid from:** 2015-04-27
**Valid until:** 2020-03-15

TÜV SÜD 672546

**Date,** 2015-04-28

Hans-Heiner Junker


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




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TÜV