

# 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 16 11 82800 026



Product Service

**Manufacturer:**

**Guangdong Transtek  
Medical Electronics Co., Ltd**

Zone A, No. 105  
Dongli Road, Torch Development District  
528437 Zhongshan, Guangdong  
PEOPLE'S REPUBLIC OF CHINA



**EC-Representative:**

**MDSS GmbH**

Schiffgraben 41  
30175 Hannover  
GERMANY

**Product  
Category(ies):**

**Blood Pressure Monitor**

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.:**

7484054319

**Valid from:**

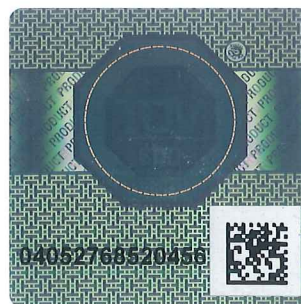
2017-03-02

**Valid until:**

2020-08-12

**Date,** 2017-03-02

Stefan Preiß



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

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Product Service

**Facility(ies):**

Guangdong Transtek Medical Electronics Co., Ltd  
Zone A, No. 105, Dongli Road, Torch Development District,  
528437 Zhongshan, Guangdong, PEOPLE'S REPUBLIC OF  
CHINA

Guangdong Transtek Medical Electronics Co., Ltd.  
Zone B, No. 105, Dongli Road, Torch Development District,  
528437 Zhongshan, Guangdong, PEOPLE'S REPUBLIC OF  
CHINA