ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 16 11 82800 026

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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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

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