

TÜV SÜD Product Service GmbH • Ridlerstraße 65 • 80339 Munich • Germany

To whom it might concern

Munich, 2020-04-08 Order No.: 713184477

Confirmation concerning EC Certificate G1 082800 0026 Rev. 01

We confirm that the following certificate:

G1 082800 0026 Rev. 01 (valid until 2024-05-26)

issued to the legal medical device manufacturer:

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

covers the Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding(4) with the scope:

Blood Pressure Monitor

and the following devices:

Blood Pressure Monitor, Model Code: TMB-986-S
Blood Pressure Monitor, Model Code: TMB-1018-S
Blood Pressure Monitor, Model Code: TMB-1117-S
Blood Pressure Monitor, Model Code: TMB-1490-AS
Blood Pressure Monitor, Model Code: TMB-1490-CS
Blood Pressure Monitor, Model Code: TMB-1598-S
Blood Pressure Monitor, Model Code: TMB-1597-BN
Blood Pressure Monitor, Model Code: TMB-1775
Blood Pressure Monitor, Model Code: TMB-1775-A
Blood Pressure Monitor, Model Code: TMB-1776
Blood Pressure Monitor, Model Code: H-BP100SBP-CE
Digital Blood Pressure Device, Model Code: 2000



With this letter we confirm that the above-mentioned devices are covered by a quality assurance system that has been established by the manufacturer and is certified by the notified body TÜV SÜD Product Service GmbH.

After issuing the declaration of conformity in accordance with the medical device directive 93/42/EEC by the manufacturer, the above-mentioned medical devices can be labelled with CE mark (CE 0123) and placed on the market in the European Economic Area.

The above-mentioned certificate is valid.

R. Köhler

i.A. Randolf Köhler

TÜV SÜD PRODUCT SERVICE GMBH

Medical Health Services

Foreign Affairs