

Certificate CN22/00001923.01

SGS

Guangdong Transtek Medical Electronics Co., Ltd.

Unified Social Credit Code: 914420007408365594

Business Registration Address: Area A, No. 105, Dongli Road, Torch Development Zone, Zhongshan City, Guangdong Province, P.R. China

Business Operation Address: Area A, No. 105, Dongli Road, Torch Development Zone, Zhongshan City, Guangdong Province, P.R. China

Has been assessed under the management system of the certified organisation defined in the main certificate CN22/00001923 as meeting the requirements of

ISO 9001:2015

For the following activities

Design and production of blood glucose meters, household electronic scales, smart watches, smart bands, blood pressure monitors and earphones; Production of digital thermometers

This certificate is valid from 08 December 2022 until 07 December 2025 and remains valid subject to satisfactory surveillance audits. Issue 2.

The validity of this certificate depends on the validity of the main certificate.

Jonathan M. Hall

Authorised by
Jonathan Hall
Global Head - Certification Services

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The certification information can be verified on the web site of Certification and Accreditation Administration of the People's Republic of China www.cnca.gov.cn



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Certificate

No. Q5 082800 0040 Rev. 03

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

Certification Mark:



Scope of Certificate: **Design and Development, Production and
Distribution of Blood Pressure Monitors, Medical
Electronic Scale, Body Fat Monitor and Blood
Pressure Cuff; Production and Distribution of Fetal
Heart Rate Monitor**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 082800 0040 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_082800_0040_Rev_03)

Report No.: GZ2301406

Valid from: 2024-05-06

Valid until: 2027-05-05

Date, 2024-04-26

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 082800 0040 Rev. 03

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

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

Design and Development, Production and Distribution of Blood
Pressure Monitors, Medical Electronic Scale, Body Fat Monitor;
Production and Distribution of Fetal Heart Rate Monitor

Guangdong Transtek Medical Electronics Co., Ltd
Zhongshan Torch Development Branch
4th Floor, Building 7, No.3 Jiuzhou Avenue, Torch Development
District, 528437 Zhongshan, Guangdong, PEOPLE'S REPUBLIC
OF CHINA

Design and Development, Production and Distribution of Blood
Pressure Cuff

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