Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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 057571 0003 Rev. 00

Manufacturer:

Beijing Choice Electronic Technology Co., Ltd.
2nd Floor
3rd Floor and Room 410-412 4th Floor
No. 2 Building, No. 9 Shuangyuan Road
Shijingshan District
100041 Beijing
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Pulse Oximeter, Vital Sign Monitor, Pulse Oximeter Sensor, Handheld ECG Monitor, Fetal Doppler, Fingertip Pulse Oximeter with Forehead Thermometer, Wireless Thermometer, Blood Pressure Monitor, Handheld Multi-parameter Patient 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.: BJ19901031

Valid from: 2020-03-27
Valid until: 2024-05-21

Date, 2020-03-27

Christoph Dicks
Head of Certification/Notified Body

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

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

TÜV®

Product Service

Confirmation Statement related to the EC Certificate (MDD)

List of Sites involved in the Product Realisation Processes

No. GDS 057571 0005 Rev. 00

Manufacturer:

Beijing Choice Electronic Technology Co., Ltd.
2nd Floor
3rd Floor and Room 410-412 4th Floor
No. 2 Building, No. 9 Shuangyuan Road
Shijingshan District
100041 Beijing
PEOPLE'S REPUBLIC OF CHINA

This List of Sites is only valid in combination with the following EC Certificate (MDD):

G1 057571 0003 Rev. 00

The following pages list all sites under the manufacturer's quality system where product realisation processes are conducted for those devices covered by the aforementioned EC Certificate pursuant to the Directive 93/42/EEC (MDD) concerning medical devices.

Report No.: BJ19901031

Valid until: 2024-05-21

Issue Date: 2020-04-29

R. Köhler

(Randolf Köhler)
PS-MHS-FA-0 – Foreign Affairs

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

Product Service

Confirmation Statement related to the EC Certificate (MDD)

List of Sites involved in the Product Realisation Processes

No. GDS 057571 0005 Rev. 00

Sites:

Beijing Choice Electronic Technology Co., Ltd.
2nd Floor, 3rd Floor and Room 410-412 4th Floor, No. 2 Building, No. 9 Shuangyuan Road, Shijingshan District, 100041 Beijing, PEOPLE'S REPUBLIC OF CHINA

Tianjin Choice Medical Devices Co., Ltd.
2-3 Floor, Building 4, No. 17 Yuanquan Road, Wuqing Development Zone, 301700 Tianjin, PEOPLE'S REPUBLIC OF CHINA

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