

Declaration of Conformity to Council Directive 93/42/EEC concerning Medical Devices

Manufacturer:	Beijing Choice Electronic Technology Co., Ltd. Room 4104, No. A12 Yuquan Road, Haidian District, 100143 Beijing, PEOPLE'S REPUBLIC OF CHINA.
European Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg GERMANY
Product Name:	Fingertip Pulse Oximeter
Product Model:	See attached list
UMDNS Code:	17148
Classification:	Class IIa, rule 10 to Annex IX of the MDD
Conformity assessment Route:	Annex II excluding (4)

We, the manufacturer, herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC concerning medical devices.

All supporting documentation is retained at the premises of the manufacturer.

Standards applied:

- EN ISO 13485:2016/AC:2016 Medical devices- Quality management systems- Requirements for regulatory purposes
- EN ISO14971:2012 Medical devices - Application of risk management to medical devices
- EN 60601-1:2006/A1:2013 Medical electrical equipment-Part 1: General requirements for safety
- EN 60601-1-2:2015 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- EN 60601-1-6:2010 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- EN 60601-1-11:2010 Medical electrical equipment -- Part 1-11: General requirements for

basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

ISO 80601-2-61:2011 Medical electrical equipment —Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

EN ISO10993-1:2009/AC:2010 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

EN ISO10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

EN1041:2008 Information supplied by the manufacture of medical devices

EN ISO15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

EN 62304:2006/AC:2008 Medical device software-Software life-cycle processes

MEDDEV 2.7/1: 2016 CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC

Notified Body: TÜV SÜD Product service GmbH
Ridlerstr 65, D-80339 München, Germany

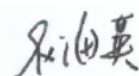
Identification Number: **CE** 0123

(EC) Certificate(s): No. G1 078179 0038 Rev.00

Start of CE-marking: 2016-05-06

Place, Date of Declaration: Beijing, 2020-01-02

Signature:



Name: Haiying Zhao

Position: Quality Director

Attached list

MD300CN310, MD300CN330, MD300CN340, MD300CN350, MD300CN356,
MD300CN360, MD300CN130, MD300CN150, MD300CN160

MD300C1, MD300C11, MD300C12, MD300C13, MD300C15, MD300C16,
MD300C17, MD300C18, MD300C19, MD300C1B, MD300C1C, MD300C1D,
MD300C1E, MD300C1F, MD300C15D

MD300C2, MD300C20, MD300C201, MD300C203, MD300C204, MD300C21,
MD300C21C, MD300C22, MD300C221, MD300C23, MD300C25, MD300C26,
MD300C29, MD300C2A, MD300C2B, MD300C2D, MD300C2E, MD300C2F

MD300C4, MD300C41

MD300C5, MD300C52, MD300C53, MD300C54

MD300C63, MD300C634, MD300CF3, MD300CH3

LTD800, LTD805

PM A10, PX-100-EU, LTD800, LTD805, ME5, FL313, FL323, TS 370PO,

TS 380PO, PM A19, PO 45, MD300CN140, MD300C55



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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

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