

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

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
Tel: +86-10-88203956 Fax: +86-10-88204632
E-mail: cc@choicemmed.com

European Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY
Tel: +49-40-2513175 Fax: +49-40-255726
E-mail: antonsissi@hotmail.com

Product Name: Fingertip Pulse Oximeter

Product Model: MD300C55

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.

We, the manufacturer, are exclusively responsible for the DoC.

Standards applied:

EN ISO 13485:2016/AC:2018 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+A1:2015 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 80601-2-61:2017 Medical electrical equipment —Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

ISO10993-1:2018 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

IEC 62304-2006+A1: 2015 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:

C E 0123

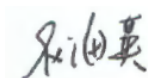
(EC) Certificate(s):

No. G1 057571 0003 Rev.00

Start of CE-marking: 2016-05-06

Place, Date of Declaration: Beijing, 2020-03-27

Signature:



Name: Haiying Zhao

Position: Quality Director