

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
European Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg GERMANY
Product:	Pulse Oximeter MD300K2
UMDNS Code:	17148
Classification:	Class IIb, 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 13485:2012 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/AC:2013 Medical electrical equipment-Part 1: General requirements for safety
- EN 60601-1-2:2007/AC:2010 Medical electrical equipment-Part 1-2: General requirements for safety and essential performance-Collateral Standard: Electromagnetic compatibility – Requirements and tests
- ISO 80601-2-61:2011 Medical electrical equipment —Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- EN 60601-1-6:2010 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

EN 60601-1-8:2012 Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance -- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

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

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

EN 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 980:2008 Symbols for use in the labelling of medical devices

EN ISO 14155:2011 Clinical investigation of medical devices for human subjects-Good clinical practice

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

Identification Number: **CE** 0123

(EC) Certificate(s): No. G1 057571 0003 Rev.00

Start of CE-marking: 2015-12-03

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

Signature: Lei Chen

Name: Lei Chen

Position: Quality Director