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 REPUBILIC OF CHINA.
European Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraβe 80 20537 Hamburg GERMANY
Product Name:	Fingertip Pulse Oximeter
Product Model:	MD300C23
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

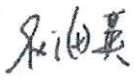
ISO10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

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 0032 Rev.01
Start of CE-marking:	2016-05-06
Place, Date of Declaration:	Beijing, 2019-05-22
Signature:	 Name: Haiying Zhao Position: Quality Director