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, P.R.CHINA
European Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraβe 80 20537 Hamburg GERMANY
Product：	Fingertip Pulse Oximeter MD300C15D-H
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 13485:2012 Medical devices- Quality management systems- Requirements for regulatory purposes

EN ISO14971:2012 Medical devices –Application of risk management to medical devices

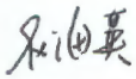
EN ISO10993-1: 2009/AC:2010 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system

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 delayed-type hypersensitivity

EN 60601-1:2006/A1:2013 Medical electrical equipment-Part1: General requirements for

safety and essential performance
EN 60601-1-2:2007/AC:2010 Medical electrical equipment-Part1-2: General requirements for safety and essential performance Collateral Standard： Electromagnetic compatibility – Requirements and tests
ISO 80601-2-61:2011 Medical electrical equipment-Particular requirements for basic safety and essential performance of pulse oximeter equipment for medical use
EN1041:2008 Information supplied by the manufacture of medical device
EN 980:2008 Symbols for use in the labelling of medical devices
EN 62304: 2006 Medical device software-Software life-cycle processes
EN60601-1-6: 2010 Medical electrical equipment-Part 1-6: General requirements for basic safety and essential performance-Collateral Standard: Usability
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 17 11 78179 032
Start of CE-marking:	2014-02-14
Place, Date of Declaration:	Beijing, 2018-04-16
Signature:	 Name: Haiying Zhao Position: Quality Director