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
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
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(EC) Certificate(s):	No. G1 17 11 78179 032
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Place, Date of Declaration:	Beijing, 2018-04-16
Signature:	Lei Chen Name: Lei Chen Position: Quality Director