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 MD300CB3, MD300CB31, MD300CB32, MD300CB34
UMDNS Code:	17148
Classification - *Annex IX*:	*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 including the amendments by Council Directive 2007/47/EEC.
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 ISO10993-1:2009 Biological evaluation of medical devices-part 1: evaluation and testing
EN ISO10993-5:2009 Biological evaluation of medical devices-Part 5: Test for in vitro cytotoxicity
EN ISO10993-10:2010 Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity
EN60601-1:1990_A1:1993_A2:1995 Medical electrical equipment-Part 1: General requirements for safety
EN60601-1-2:2007 Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests
EN60601-1-4: 1996/A1:1999 Medical electrical equipment –Part 1-4: General requirements for safety-Collateral standard: Programmable electrical medical systems
EN ISO9919:2009 Medical electrical equipment-Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use (ISO9919:2005)
EN1041:2008 Information supplied by the manufacture of medical device
EN ISO 15223-1:2012 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements
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

Notified Body:	TÜV SÜD Product service GmbH Ridlerstr 65, D-80339 München, Germany
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(EC) Certificate(s):	No. G1 078179 0032 Rev.01
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Place, Date of Declaration:	Beijing, 2019-05-22
Signature:	Lei Chen *Name: Lei Chen* *Position: Quality Director*