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) Eiffestraβe 80 20537 Hamburg GERMANY
Product：	Wireless Fingertip Pulse Oximeter OX200
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/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 60601-1-11:2010 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
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 ISO15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

Notified Body:	TÜV SÜD Product service GmbH Ridlerstr 65, D-80339 München, Germany
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Place, Date of Declaration:	Beijing, 2020-03-27
Signature:	Lei Chen Name: Lei Chen Position: Quality Director