Declaration of Conformity to Council Directive 93/42/EEC concerning Medical Devices

Manufacturer: Beijing Choice Electronic Technology Co., Ltd.
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European Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraβe 80 20537 Hamburg GERMANY

Product： Fingertip Pulse Oximeter

Customers type no.:	Manufactures type no:
Microlife OXY300	MD300C2G/MD300C29

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 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 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 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 057571 0003 Rev.00
Start of CE-marking:	2014-02-14
Place, Date of Declaration:	Beijing, 2020-03-27
Signature:	Lei Chen Name: Lei Chen Position: Quality Director