

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) Eiffestraße 80, 20537 Hamburg Germany
Product Name:	Fingertip Pulse Oximeter
Product Model:	MD300C15D, MD300CH3
UMDNS Code:	17148
Classification - Annex IX:	<i>Class IIa, rule 10 to Annex IX of the MDD</i>
Conformity assessment Route:	<i>Annex II excluding (4)</i>

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 13485:2012 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 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 980:2008 Symbols for use in the labelling of medical devices
EN 62304: 2006 Medical device software-Software life-cycle processes

File Name: Declaration of conformity

Edition: H

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

Identification number **CE** 0123

(EC) Certificate(s): No. G1 16 02 78179 025

Start of CE-marking: 2006-06-01

Place, Date of Declaration: Beijing, 2016-02-19

Signature: 

Name: Lei Chen
Position: Quality Director