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

Manufacturer:	Beijing Choice Electronic Technology Co., LTD. Room 320, West Building 4, No.83 Fuxing Road, 100039 Beijing,P.R.China.
European Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraβe 80, 20537 Hamburg Germany
Product:	Pulse Oximeter MD300C1, MD300C1-E, MD300C11, MD300C1C, MD300C12, MD300C13, MD300C2, MD300C21, MD300C21C, MD300C22, MD300C221, MD300C23, MD300C201, MD300C202, MD300C203, MD300C204, MD300C205, MD300C3, MD300C31, MD300C32, MD300C33, MD300C35, MD300C3A, MD300C3B, MD300C310, MD300C312, MD300C313, MD300C313-E, MD300C320, MD300C330, MD300C360, MD300C4, MD300C5, MD300C51, MD300C52, MD300C53, MD300C54, MD300C, MD300D, MD300E, MD300F, MD300C8, MD300C8-E, MD300C21P, MD300C12P, LTD800 and LTD805
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 13485:2012 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 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
Identification number	CE 0123
(EC) Certificate(s):	No. G1 13 04 78179 007
Start of CE-marking:	2006-06-01
Place, Date of Declaration:	Beijing, 2013-11-08
Signature:	_____ *Name: Lei Chen* *Position: Quality Director*