

## **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) Eiffestraße 80, 20537 Hamburg Germany
Product:	See attached list
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 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 C€ 0123

(EC) Certificate(s): No. G1 14 02 78179 011

Start of CE-marking: 2006-06-01

Place, Date of Declaration: Beijing, 2014-05-22

Signature:   
Name: Lei Chen  
Position: Quality Director

**See attached list**

MD300C2, MD300C21, MD300C21C, MD300C21-P, MD300C22, MD300C23, MD300C25,  
MD300C26, MD300C28, MD300C29, MD300C2A, MD300C2B, MD300C2D, MD300C2E,  
MD300C2F, MD300C2G, MD300C2H, MD300C2I, MD300C203, MD300C221,  
MD300C201, MD300C202, MD300C204, MD300C205  
MD300C20, MD300C2021, MD300C2029  
MD300C5, MD300C52, MD300C53, MD300C54

MD300C1, MD300C11, MD300C1C, MD300C12, MD300C13, MD300C15, MD300C16,  
MD300C17, MD300C18, MD300C19, MD300C10, MD300C1A, MD300C1B, MD300C1D,  
MD300C1E, MD300C1F, MD300C1G, MD300C1H, MD300C1I, MD300C15D  
MD300C4, MD300C41, MD300C42  
MD300C971,

MD300CF3, MD300CF31, MD300CF32, MD300CF33, MD300CF35, MD300CF36,  
MD300CF37, MD300CF38, MD300CF39, MD300CF30, MD300CF3A, MD300CF3B,  
MD300CF3C, MD300CF3D, MD300CF3E, MD300CF3F, MD300CF3G, MD300CF3H,

MD300CF61, MD300CF62, MD300CF63, MD300CF66,

MD300C61, MD300C611, MD300C612, MD300C613, MD300C614, MD300C615,  
MD300C616, MD300C617, MD300C618, MD300C610, MD300C61A, MD300C61B,  
MD300C61F, MD300C61G, MD300C61H, MD300C61I, MD300C61J, MD300CH1,  
MD300CH117, MD300CH127

MD300C63, MD300C631, MD300C632, MD300C633, MD300C634, MD300C635,  
MD300C636, MD300C637, MD300C638, MD300C630, MD300C63A, MD300C63B,  
MD300C63F, MD300C63H, MD300C63J, MD300C63I, MD300CH3, MD300CH317,

MD300C91, MD300C911, MD300C912, MD300C916,

MD300C92, MD300C921, MD300C922, MD300C925, MD300C926,