DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

MANUFACTURER:	**CONTEC MEDICAL SYSTEMS CO., LTD** No.24 Huanghe West Road Economic & Technical Development Zone ,Qinhuangdao,Hebei Province, 066004,P.R.China
MEDICAL DEVICE:	Pulse Oximeter SAT200
CLASSIFICATION - ANNEX IX:	Class Ⅱb, Rule 10
CONFORMITY ASSESSMENT ROUTE:	Annex Ⅱ without chapter 4

WE, （CONTEC MEDICAL SYSTEMS CO., LTD）HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES. MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE.

STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 M NCHEN, GERMANY
IDENTIFICATION NUMBER:	CE 0123
(EC) CERTIFICATE(S):	G1 13 06 50972 019
EC REP **EUROPEAN REPRESENTATIVE:**	Shanghai International Trading Corp. GmbH(Hamburg) Eiffestrasse 80, 20537 Hamburg Germany

START OF CE-MARKING: 2006-09-28 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:

SIGNATURE: _____President

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Appendix: list of (harmonised - EN) standards

NO.	Reference	Title
1	EN ISO 13485:2003/AC:2009	Medical devices - Quality management systems- Requirements for regulatory purposes
2	EN ISO 14971: 2009	Medical devices - Application of risk management to medical devices
3	EN60601-1:1990+A1:1993+A2:1995 (IEC60601-1:1988+A1:1991+A2:1995)	Medical electrical equipment- Part 1: General requirements for safety
4	EN 60601-1-2:2007 (IEC60601-1-2:2007)	Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
5	EN60601-1-4:1996+A1:1999 (IEC60601-1-4:1996/A1:1999)	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
6	EN 60601-1-6:2007 (IEC60601-1-6:2006)	Medical electrical equipment-Part 1-6:General requirements for basic safety and essential performance-Collateral Standard: Usability
7	EN ISO 9919:2009 (ISO 9919:2005)	Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
8	EN 62304:2006	Medical device software-Software life-cycle processes
9	EN 1041: 2008	Information supplied by the manufacturer with medical devices
10	EN 980: 2008	Symbols for use in the labelling of medical devices
11	EN ISO10993-1: 2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
12	EN ISO 14155-1:2009 (ISO 14155-1:2003)	Clinical investigation of medical devices for human subjects- Part 1: General requirements
13	EN ISO 14155-2:2009 (ISO 14155-2:2003)	Clinical investigation of medical devices for human subjects- Part 2: Clinical investigation plans