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

MANUFACTURER:	**CONTEC MEDICAL SYSTEMS CO., LTD** No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA
MEDICAL DEVICE:	Patient Monitor PM50
CLASSIFICATION - ANNEX IX:	Class Ⅱb, Rule 10
CONFORMITY ASSESSMENT ROUTE:	Annex Ⅱ excluding 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 050972 0050 Rev.03
EUROPEAN REPRESENTATIVE:	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany

START OF CE-MARKING: 2010-03-20 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2019-11-07
SIGNATURE:	President

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Appendix: list of (harmonised - EN) standards

NO.	Reference	Title
1	EN 60601-1: 1990+A1:1993+A2:1995 (IEC60601-1:1988+A1:1991+A2: 1995)	Medical Devices Part1: General Requirements for Safety
2	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
3	EN 60601-1-4:1996+A1:1999 (IEC 60601-1-4:1996/A1:1999)	Medical Devices Part 1-4: General Requirements for Safety - Programmable Medical Electrical Equipment
4	EN 60601-1-6:2007 (IEC 60601-1-6:2006)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
5	EN 60601-1-8:2007 (IEC 60601-1-8:2006)	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
6	EN ISO 9919: 2009 (ISO 9919: 2005)	Medical electrical equipment –Particular requirements for the basic safety and essential performance of pulse oximeters equipmet for medical use
7	EN 60601-2-30:2000 (IEC 60601-2-30:1999)	Medical electrical equipment –Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
8	EN 60601-2-49:2001 (IEC 60601-2-49:2001)	Medical electrical equipment –Part 2-49:Particular requirements for the safety of multifunction patient monitoring equipment.
9	EN 1060-1:1995+ A2: 2009	Non-invasive sphygmomanometers - Part 1: General requirements Includes Amendment A1: 2002
10	EN 1060-3:1997+ A2: 2009	Non-invasive sphygmomanometers - Part 3: supplementary requirements for electromechanical blood pressure measuring systems
11	EN 62304:2006	Medical device software –Software life cycle processes