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:	Dynamic ECG Systems TLC5000
CLASSIFICATION - ANNEX IX:	Class Ⅱa, 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.02
EC REP **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, 2019-07-23
SIGNATURE:	President

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Appendix: list of (harmonised - EN) standards

NO.	Reference	Title
1	EN60601-1:1990+A1:1993+A2:1995 (IEC60601-1:1988+A1:1991+A2:1995)	Medical electrical equipment- Part 1: General requirements for safety
2	EN 60601-1-1:2001	Medical electrical equipment - Part 1-1:General requirements for safety - Collateral standard: safety requirements for medical electrical systems
3	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
4	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
5	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
6	IEC 60601-2-47:2001	Medical electrical equipment –Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
7	EN 62304:2006	Medical device software-Software life-cycle processes