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:	ECG Workstation CONTEC8000G
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 CO MPLIANCE 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.04
EUROPEAN REPRESENTATIVE:	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany

START OF CE-MARKING: 2015-12-11 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2020-06-18
SIGNATURE:	President

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Appendix: list of (harmonised - EN) standards

No.	Serial Number	Title and Description
1	IEC 60601-1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2	EN 60601-1-2: 2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility -Requirements and tests
3	EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance- Collateral Standard: Usability
4	IEC 60601-2-25:2011	Medical electrical equipment –Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
5	EN 62304:2006	Medical device software –Software life -cycle processes
6	EN 62366:2008	Medical devices - Application of usability engineering to medical devices
7	EN ISO 10993-1:2009	Biological evaluation of medical devices.-part 1:Evaluation and testing