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:	Electrocardiograph ECG1212G
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 MÜNCHEN, 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: 2020-12-14 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2020-12-14
SIGNATURE:	_____President

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Appendix: list of (harmonised - EN) standards

No.	Reference	Title of Standard
1	EN ISO 13485:2016	Medical devices Quality Management Systems-Requirements for Regulatory Purposes
2	EN ISO14971: 2012	Medical Devices - Application of Risk Management to Medical Devices
3	EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
4	IEC 60601-1-6:2013	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
5	IEC 60601-2-25:2011	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
6	EN 60601-1-2: 2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance Collateral standard: Electromagnetic disturbances - Requirements and tests
7	EN 1041: 2008	Information supplied by the manufacturer with medical devices
8	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
9	IEC 62304:2015	Medical device software Software life cycle processes
10	IEC 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
11	ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing