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/EC.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE.
THIS EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER.

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

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2023/12/29
SIGNATURE:	_____President

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

Appendix: list of (harmonised - EN) standards

No.	Standards	Title and Description
1	EN ISO 13485:2016	Medical devices Quality Management Systems-Requirements for RegulatoryPurposes
2	ISO 14971:2019	Medical devices - Application of risk management to medical devices
3	IEC 60601-1:2005 + A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
4	IEC 60601-1-6:2010 + A1:2013	Medical electrical equipmentPart 1-6: General requirements forbasic 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	IEC 60601-1-2:2014	General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility .
7	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
8	EN ISO15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
9	IEC62304:2006+AMD1:2015	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: Evaluationand testing