

**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, ECG1200G
CLASSIFICATION - ANNEX IX:	Class II a, 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
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IDENTIFICATION NUMBER:	CE 0123
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(EC) CERTIFICATE(S):	<u>G1 050972 0050 Rev.04</u>
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EUROPEAN REPRESENTATIVE:	Prolinx GmbH Brehmstr. 56, 40239, Duesseldorf, Germany
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PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2024/01/10
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SIGNATURE:



President

TF-CE110613-09

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Appendix: list of (harmonised - EN) standards

No.	Standards	Title and Description
1	IEC 60601-1:2005+AMD1:2012+AMD2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2	IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3	IEC 60601-1-6:2006	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	IEC 62304:2006	Medical device software - Software life-cycle processes
6	ISO 14971:2019	Medical devices - Application of risk management to medical devices
7	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
8	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
9	EN ISO10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing