

**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, ECG100G
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
IDENTIFICATION NUMBER:	CE 0123
(EC) CERTIFICATE(S):	<u>G1 050972 0050 Rev.04</u>
EUROPEAN REPRESENTATIVE:	Prolinx GmbH Brehmstr. 56, 40239, Duesseldorf, Germany

PLACE, DATE OF DECLARATION: QINHUANGDAO, 2024/01/10

SIGNATURE:



President

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Appendix: list of (harmonised - EN) standards

No.	Standards	Title and Description
1	IEC 60601-1: 1988 +A1:1991+A2:1995	Medical electrical equipment; Part 1: General requirements for safety
2	IEC 60601-1-2: 2007	Medical electrical equipment Part 1: General requirements for safety -2 Collateral standard: Electromagnetic compatibility - Requirements and tests
3	IEC60601-1-6:2006	Medical Electrical Equipment-Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
4	IEC60601-2-25: 1993 +A1:1999	Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs
5	IEC62304:2006	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 ISO 10993-1:2009 (ISO 10993-1:2009)	Biological evaluation of medical devices- Part1: Evaluation and testing(ISO 10993-1:2003)
10	EN ISO 13485:2016 (ISO 13485:2016)	Medical devices - Quality management systems - Requirements for regulatory purposes