

DECLARATION OF CONFORMITY TO REGULATION(EU) 2017/745 ON MEDICAL DEVICES



CONTEC MEDICAL SYSTEMS CO., LTD.
No.112 Qinhuang West Street, Economic & Technical
Development Zone, Qinhuangdao, Hebei Province,
PEOPLE'S REPUBLIC OF CHINA

SRN of Manufacturer :CN-MF-000007715



Prolinx GmbH
Brehmstr. 56, 40239, Duesseldorf, Germany

SRN of Authorised Representative:DE-AR-000005129

This EU declaration of conformity is issued under the sole responsibility of the manufacturer.
We keep all supporting documentation and ensure that the authorised representative has the
necessary documentation permanently available.

BASIC UDI-DI: 69450401ECG1212G5V

PRODUCT AND TRADE NAME: Electrocardiograph

EMDN CODE: Z12050301

CATALOGUE NUMBER/MODEL: E18M/E12/E3M/E3/E6/ECG90A/ECG300G/
ECG600G/ECG1200G/ECG1212G

RISK CLASS OF THE DEVICE: Class IIa, according to ANNEX VIII Rule 10

We, (CONTEC MEDICAL SYSTEMS CO., LTD.) herewith declare that the stated medical
devices meet REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE
COUNCIL of 5 April 2017 on medical devices.

The harmonised standards and/or CS used and in relation to this conformity see annex.

NOTIFIED BODY: TÜV SÜD Product service GmbH
Ridlerstr 65, D-80339 München, Germany

NOTIFIED BODY IDENTIFICATION NUMBER: 0123

CONFORMITY ASSESSMENT PROCEDURE: Regulation (EU) 2017/745, Annex IX
excluding chapter II

(EC) CERTIFICATE(S): G15 050972 0058 Rev. 00

PLACE, DATE OF ISSUE: Qinhuangdao, 2025/05/16

NAME AND FUNCTION, SIGNATURE: HUKUN, Chairman/ manufacturer

EU210223-DOC	Ver: A
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Appendix: list of (harmonised - EN) standards

No.	Standard	Title and Description
1	EN 60601-1:2006/A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2	EN 60601-1-2:2015/A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3	EN 60601-2-25:2015	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
4	EN 60601-1-6:2010/A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
5	EN 62366-1:2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
6	EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes
7	EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
8	EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
9	ISO 15223-1:2021/Amd 1:2025	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
10	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)
11	EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)