DECLARATION OF CONFORMITY

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

EU REP

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:	69450401PM10NX
Product and Trade Name:	Portable ECG Monitor
EMDN Code:	Z12050301
Catalogue Number/model:	PM10
Product Photo:	
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.

And the DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 16 APRIL 2014 ON THE HARMONISATION OF THE LAWS OF THE MEMBER STATES RELATING TO THE MAKING AVAILABLE ON THE MARKET OF RADIO EQUIPMENT.

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
MDR CONFORMITY ASSESSMENT PROCEDURE:	Annex IX excluding chapter II
RED CONFORMITY ASSESSMENT PROCEDURE:	Annex II
(EC) CERTIFICATE(S):	G15 050972 0058 Rev. 00
PLACE, DATE OF ISSUE:	Qinhuangdao,2025/05/27
NAME AND FUNCTION, SIGNATURE:	HUKUN,Chairman/ manufacturer

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Appendix: list of (harmonised - EN) standards

list of (harmonised - EN) standards of (EU) 2017/745		
No.	**Standards**	**Title and Description**
1	EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
2	EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
3	EN 60601-1:2006/A2:2021	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
4	EN 60601-1-2:2015/A1:2021	Medical electrical equipment-Part 1-2: General requirements for safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
5	EN 60601-1-11:2015/A1:2021	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
6	EN 60601-1-6:2010/A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
7	EN 62366-1:2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
8	EN 62304:2006/A1:2015	Medical device software-Software life-cycle processes
9	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)
10	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
11	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)
list of (harmonised - EN) standards of 2014/53/EU		
No.	**Standards**	**Title and Description**
1	ETSI EN 301 489-1 V2.2.3 (2019-11)	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility
2	ETSI EN 301 489-17 V3.3.1 (2024-09)	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband and Wideband Data Transmission Systems; Harmonised Standard for ElectroMagnetic Compatibility
3	EN 62479-2010	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
4	ETSI EN 300 328 V2.2.2 (2019-07)	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum