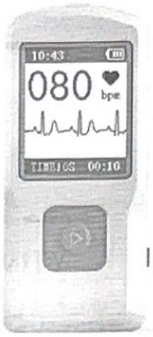
DECLARATION OF CONFORMITY

NO.: 69450401PM10NX-MDD&RED

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: **PM10 PORTABLE ECG MONITOR**	**PRODUCT PHOTO:** 
MDD CLASSIFICATION - ANNEX IX	Class Ⅱa,Rule 10
MDD CONFORMITY ASSESSMENT ROUTE:	Annex Ⅱ excluding chapter 4
RED CONFORMITY ASSESSMENT ROUTE:	Annex II
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 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. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE. THIS EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE ANUFACTURER.	
STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.	
MDD NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 München, GERMANY	**IDENTIFICATION NUMBER:** CE 0123
MDD (EC) CERTIFICATE(S): G1 050972 0050 Rev.04	
EUROPEAN REPRESENTATIVE:	Prolinx GmbH Brehmstr. 56, 40239, Duesseldorf, Germany
PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2024-05-27
SIGNATURE:	President

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Appendix : list of (harmonised - EN) standards

list of (harmonised - EN) standards of 93/42/EEC		
No.	**Standards**	**Title and Description**
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	EN ISO 14971:2019 /A11:2021	Medical devices - Application of risk management to medical devices
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 basic safety and essential performance - Collateral Standard：Electromagnetic disturbances - Requirements and tests
5	EN 60601-1-6:2010 /A2:2021	Medical electrical equipment - Part 1-6：General requirements for basic safety and essential performance - Collateral standard：Usability
6	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
7	EN 60601-2-25:2015	Medical electrical equipment - Part 2-25：Particular requirements for the basic safety and essential performance of electrocardiographs
8	EN 60601-2-47:2015	Medical electrical equipment - Part 2-47：Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
9	EN 62366-1:2015 /A1:2020	Medical device-Application of usability engineering to medical devices
10	EN 62304:2006 /A1:2015	Medical device software - Software life-cycle processes
11	EN ISO 10993-1:2020	Biological evaluation of medical devices — Part 1：Evaluation and testing within a risk management process
12	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
13	EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
list of (harmonised - EN) standards of 2014/53/EU		
No.	**Standards**	**Title and Description**
1	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 (article 3.2-Radio);
2	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) (article 3.1 (a)-Health);
3	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 (article 3.1 (b)-EMC);
4	Draft ETSI EN 301 489-17 V3.2.5 (2022-08)	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 (article 3.1 (b)-EMC).