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:	Patient Monitor, CMS8000
CLASSIFICATION - ANNEX IX:	Class Ⅱb, 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):	G1 050972 0050 Rev.04
EUROPEAN REPRESENTATIVE:	Prolinx GmbH Brehmstr. 56, 40239, Duesseldorf, Germany

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2024/03/12
SIGNATURE:	_____President

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Appendix: list of (harmonised - EN) standards

NO.	Standards	Title and Description
1	ISO 13485:2016	Medical devices Quality management systems Requirements for regulatory purposes
2	ISO 14971:2019	Medical devices Application of risk management to medical devices
3	IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices
4	IEC 62304:2006+ AMD1:2015	Medical device software - Software life cycle processes
5	ISO 10993-1:2018	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
6	IEC 60601-1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
7	IEC60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
8	IEC 60601-1-6:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
9	IEC60601-1-8:2012	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
10	IEC 60601-2-27:2011	Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment

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11	IEC 80601-2-30:2018	Medical electrical equipment -Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
12	IEC 60601-2-34:2011	Medical electrical equipment -Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
13	IEC 80601-2-49:2018	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
14	ISO 80601-2-55:2018	Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of respiratory gas monitors
15	ISO 80601-2-56:2017 +A1:2018	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
16	ISO 80601-2-61:2017	Medical electrical equipment -Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
17	ISO 20417:2021	Medical devices Information to be supplied by the manufacturer
18	ISO 15223-1:2021	Medical devices Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements