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:	Ambulatory Blood Pressure Monitor，ABDM50
CLASSIFICATION - ANNEX IX:	Class Ⅱa, 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, 2024-01-26
SIGNATURE:	President Hu Kun胡坤

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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 60601-1:2005+AMD1:2012	Medical electrical equipment- Part1: General requirements for basic safety and essential performance
4	IEC 60601-1-2:2014	Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
5	IEC60601-1-6:2010+AMD1:2013+AMD2: 2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
6	IEC 62366-1:2015+AMD1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
7	IEC 62304:2006+AMD1:2015	Medical device software-Software life-cycle processes
8	EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
9	ISO 20417:2021	Medical devices-Information to be supplied by the manufacturer
10	IEC 80601-2-30:2018	Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
11	ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
12	IEC 60601-1-11:2015	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