


**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:	Electronic Sphygmomanometer CONTEC08D/CONTEC08E
CLASSIFICATION - ANNEX IX:	Class II a, Rule 10
CONFORMITY ASSESSMENT ROUTE:	Annex II excluding chapter 4
<p>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.</p>	
<p>STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.</p>	
NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER:	CE 0123
(EC) CERTIFICATE(S):	<u>G1 050972 0050 Rev.04</u>
EUROPEAN REPRESENTATIVE:	Prolinx GmbH Brehmstr. 56, 40239, Duesseldorf, Germany

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2024/01/08
SIGNATURE:	 _____ President

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Appendix: list of (harmonised - EN) standards for CONTEC08D

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	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
4	IEC 60601-1-2: 2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility -Requirements and tests
5	IEC60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
6	IEC 80601-2-30:2009 +AMD1:2013	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
7	ISO 80601-2-61:2011	Medical Electrical Equipment-Particular Requirements for the Basic Safety and Essential Performance of Pulse Oximeter Equipment for Medical Use
8	IEC 60601-1-11:2010	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
9	IEC 62304:2006	Medical device software - Software life cycle processes
10	IEC 62366:2007	Medical devices - Application of usability engineering to medical devices
11	ISO 15223-1:2021	Medical devices Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements
12	ISO 20417:2021	Medical devices Information to be supplied by the manufacturer
13	ISO 10993-1:2009	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process

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Appendix: list of (harmonised - EN) standards for CONTEC08E

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