


**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:	Pulse Oximeter CMS50DL
CLASSIFICATION - ANNEX IX:	Class II b, 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):	<u>G1 050972 0050 Rev.04</u>
EUROPEAN REPRESENTATIVE:	Prolinx GmbH Brehmstr. 56, 40239, Duesseldorf, Germany

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

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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 60601-1-6:2010+AMD1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
6	ISO 80601-2-61:2017	Medical electrical equipment —Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
7	ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
8	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
9	EN ISO10993-1: 2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
10	IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices
11	IEC 62304:2006	Medical device software - Software life cycle processes
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