


**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 Probe GSE0032
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, 2024/04/01
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	EN 60601-1:2006	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
4	EN 60601-1-2:2007 (IEC60601-1-2:2007)	Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
5	EN 60601-1-6:2010 (IEC 60601-1-6:2010)	Medical electrical equipment-Part 1-6:General requirements for basic safety and essential performance-Collateral Standard: Usability
6	ISO10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
7	ISO 80601-2-61:2011	Medical electrical equipment —Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
8	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