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:	Oxygen Concentrator, CONTEC21
CLASSIFICATION - ANNEX IX:	Class Ⅱa, Rule 11
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, 2024-02-05
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	IEC60601-1:2005+AMD1:2012+AMD2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
4	IEC60601-1-2:2014+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 60601-1-6:2020	Medical electrical equipment - Part 1-6:General requirements for basic safety and essential performance-Collateral Standard: Usability
6	IEC 62366-1:2020	Medical devices - Application of usability engineering to medical devices
7	IEC 62304:2006+AMD1:2015	Medical device software-Software life-cycle processes
8	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
9	ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
10	ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
11	IEC60601-1-8:2006+AMD1:2012+AMD2:2020	Medical electrical equipment - Part 1-8: General requirements for basic safety essential performance- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
12	ISO 80601-2-69:2020	Medical electrical equipment - Part 2-69:Particular requirements for the basic safety and essential performance of oxygen concentrator equipment
13	ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
14	ISO 18562-2:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter

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15	ISO 18562-3:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds (VOCs)
16	BS EN 15058:2017	Stationary source emissions. Determination of the mass concentration of carbon monoxide. Standard reference method: non-dispersive infrared spectrometry
17	ISO 19702:2015	Guidance for sampling and analysis of toxic gases and vapours in fire effluents using Fourier Transform Infrared (FTIR) spectroscopy
18	ASTM D5110-98（2017）	Standard Practice for Calibration of Ozone Monitors and Certification of Ozone Transfer Standards Using Ultraviolet Photometry