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 9
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.

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:	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2021-05-08
SIGNATURE:	_____President

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Appendix: list of (harmonised - EN) standards

NO.	Reference	Title
1	IEC60601-1:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2	IEC 60601-1-2: 2020	Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic disturbances - Requirements and tests
3	IEC 60601-1-6:2013	Medical electrical equipment-Part 1-6:General requirements for basic safety and essential performance-Collateral Standard: Usability
4	IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices
5	IEC 62304:2015	Medical device software - Software life-cycle processes
6	ISO10993-1: 2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
7	ISO 80601-2-69 : 2020	Medical electrical equipment - Part 2-69:Particular requirements for the basic safety and essential performance of oxygen concentrator equipment
8	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
9	IEC 60601-1-8:2020	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 medicacl electrical systems