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:	SPIROMETER , SP10
CLASSIFICATION - ANNEX IX:	Class Ⅱa, 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):	G1 050972 0050 Rev.04
EUROPEAN REPRESENTATIVE:	Prolinx GmbH Brehmstr. 56, 40239, Duesseldorf, Germany

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2024/03/20
SIGNATURE:	_____President

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

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 60601-1:1990+A1:1993+A2:1995	Medical electrical equipment- Part 1: General requirements for safety
4	EN 60601-1-2:2007	Medical electrical equipment- Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
5	EN ISO23747:2009	Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans
6	EN 60601-1-6:2007	Medical electrical equipment-Part 1-6:General requirements for basic safety and essential performance-Collateral Standard: Usability
7	EN 62304:2006	Medical device software-Software life-cycle processes
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
10	EN ISO 10993-1:2009	Biological evaluation of medical devices.-part 1:Evaluation and testing