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/EEC
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 M NCHEN, GERMANY
IDENTIFICATION NUMBER:	CE 0123
(EC) CERTIFICATE(S):	G1 050972 0050 Rev.04
EUROPEAN REPRESENTATIVE:	Shanghai International Trading Corp. GmbH(Hamburg) Eiffestrasse 80, 20537 Hamburg Germany

START OF CE-MARKING: 2011-01-14 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2020-06-18
SIGNATURE:	President

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Appendix: list of (harmonised - EN) standards

NO.	Reference	Title
1	EN60601-1:1990+A1:1993+A2:1995	Medical electrical equipment- Part 1: General requirements for safety
2	EN 60601-1-2:2007	Medical electrical equipment- Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
3	EN60601-1-4:1996+A1:1999	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
4	EN 60601-1-6:2007	Medical electrical equipment-Part 1-6: General requirements for basic safety and essential performance-Collateral Standard: Usability
5	EN ISO23747:2009 (ISO 23747:2007)	Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans
6	EN 62304:2006	Medical device software-Software life-cycle processes