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:	Sleep apnea screen meter, RS01
CLASSIFICATION - ANNEX IX:	Class Ⅱa, Rule 10
CONFORMITY ASSESSMENT ROUTE:	Annex Ⅱ.3 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 15 08 50972 047
EC REP **EUROPEAN REPRESENTATIVE:**	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany

START OF CE-MARKING: 2014-02-11 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION: QINHUANGDAO, 2015-12-21

SIGNATURE: _____ President

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

Appendix: list of (harmonised - EN) standards

NO.	Reference	Title
1	EN 60601-1:2012	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
2	EN 60601-1-2:2007	Medical electrical equipment- Part 1-2: General requirements for safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
3	EN 60601-1-8:2007	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance -Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
4	ISO 80601-2-61：2011	Medical electrical equipment —Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
5	EN 60601-1-6:2010	Medical electrical equipment-Part 1-6:General requirements for basic safety and essential performance-Collateral Standard: Usability
6	EN 62366:2008	Medical devices - Application of usability engineering to medical devices
7	EN 60601-1-11:2010	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
8	EN 62304:2006	Medical device software-Software life-cycle processes