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

MANUFACTURER:	**Meditech Equipment Co.,Ltd** 89 Laoshan Road ,Building 69, Laoshan District,Qingdao, Shandong Province, China
MEDICAL DEVICE:	**Spirometer Spirox P**
CLASSIFICATION - ANNEX IX:	Class IIa, Rule 10
CONFORMITY ASSESSMENT ROUTE:	Annex IX excluding chapter 4

WE, （MEDITECH EQUIPMENT 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:	MEDCERT GmbH Pilatuspool 2. 20355 Hamburg, GERMANY
IDENTIFICATION NUMBER:	CE 0482
(EC) CERTIFICATE(S):	7368GB410191111
EUROPEAN REPRESENTATIVE:	OBELIS S. A Registered Address: Bd. Général Wahis, 53 1030 Brussels,Belgium Tel: +32.2 732 59.54,Fax: +32.2.732.60.03
START OF CE-MARKING:	_____(Date or Lot or serial number)

PLACE, DATE OF DECLARATION: QINNGDAO,

SIGNATURE: _____President

Appendix: list of (harmonised - EN) standards

NO.	Reference	Title
1	EN 60601-1:1990+ A1:1993+ A2:1995	Medical electrical equipment - Part 1: General requirements for safety
2	EN 60601-1-2: 2007 (IEC60601-1-2:2007)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
3	EN 60601-1-4:1996/A1: 1999 (IEC 60601-1-4:1996/A1:1999)	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
4	EN 60601-1-6:2007 (IEC 60601-1-6:2006)	Medical electrical equipment – Part 1-6: General requirements for safety- Collateral standard: usability
5	EN 60601-1-8: 2007 (IEC 60601-1-8: 2006)	Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
6	EN 60601-2-27:2006 (IEC 60601-2:27: 2005)	Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
7	EN 60601-2-30:2000 (IEC 60601-2-30: 1999)	Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
8	EN 60601-2-34:2000 (IEC 60601-2-34: 2000)	Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment
9	EN 60601-2-49: 2001 (IEC 60601-2-49: 2001) EN 62304: 2006	Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
10	(IEC 62304: 2006)	Medical device software - Software life-cycle processes
11	EN 1060-1:1995+A2:2009	Non-invasive sphygmomanometers - Part 1: General Requirements

12	EN 1060-3:1997+A2:2009	Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems
13	EN 12470-4:2000+A1:2009	Clinical thermometers - Part 4: Performance of electrical thermometers for continuous measurement
14	EN ISO 9919: 2009 (ISO 9919: 2005)	Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeters equipmet for medical use
15	EN ISO 21647:2009 (ISO 21647: 2004/ AC:2006)	Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors