

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:

Electrocardiograph, EKG6012 EKG1212T

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



OBELIS S. A

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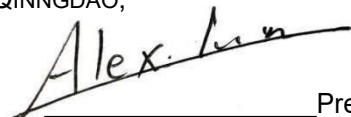
START OF CE-MARKING:

_____ (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