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:	Pulse Oximeter, OXY-B
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):	7368GB410210525A
EUROPEAN REPRESENTATIVE:	OBELIS S. A Registered Address: Bd.GénéralWahis,53 1030 Brussels,Belgium Tel: +32 2 732 59.54,Fax: +32.2.732.60.03

START OF CE-MARKING: **2021-05-25** (Date or Lot or serial number)

PLACE, DATE OF	QINGGDA 01.06.2021
SIGNATUR	Presiden

Appendix: list of (harmonized - EN) standards

No.	Serial Number	Title and Description
1	IEC 60601-1: 2012	Medical electrical equipment- Part1: General requirements for basic safety and essential performance
2	IEC 60601-1-2: 2014	Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic disturbances – Requirements and tests
3	EN 60601-1-6:2010 (IEC 60601-1-6:2010)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
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 60601-1-11:2010 (IEC 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
6	EN 62366:2008 (IEC 62366:2007)	Medical devices - Application of usability engineering to medical devices
7	EN 62304:2006 (IEC 62304:2006)	Medical device software - Software life-cycle processes