

# 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, OXYO Pro

**CLASSIFICATION - ANNEX IX:**

Class IIb, 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



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**START OF CE-MARKING:**

\_\_\_\_\_ (Date or Lot or serial number)

**PLACE, DATE OF**

QINGGDA

**SIGNATUR**

Presiden

TF-CE150303-09

Ver.A

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**Appendix: list of (harmonized - EN) standards**

<b>No.</b>	<b>Serial Number</b>	<b>Title and Description</b>
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