# 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:** Automated External Defibrillator: Defi 5s

**CLASSIFICATION - ANNEX IX:** IIb, According to Rule 9
**CONFORMITY ASSESSMENT ROUTE:** ANNEX II excluding 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

CE

**IDENTIFICATION NUMBER:** 0482

EC REP

**(EC) CERTIFICATE(S):** 7368GB410210525A

**EUROPEAN REPRESENTATIVE:** OBELIS S. A
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**START OF CE-MARKING:** **2021-05-25** (Date or Lot or serial number)

**PLACE. DATE :** **OINGDAO. 01.06.2021**

**SIGNATURE:** **Alex Lin** President