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

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| **MANUFACTURER:** | **CONTEC MEDICAL SYSTEMS CO., LTD**<br>No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA |
| **MEDICAL DEVICE:** | Electronic Sphygmomanometer，CONTEC08A |
| **CLASSIFICATION - ANNEX IX:** | Class Ⅱa, Rule 10 |
| **CONFORMITY ASSESSMENT ROUTE:** | Annex Ⅱ excluding chapter 4 |

WE, （CONTEC MEDICAL SYSTEMS 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.

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| **NOTIFIED BODY:** | TÜV SÜD PRODUCT SERVICE GMBH<br>RIDLERSTR 65, D-80339 M NCHEN, GERMANY |
| **IDENTIFICATION NUMBER:** | CE 0123 |
| **(EC) CERTIFICATE(S):** | G1 050972 0050 Rev.04 |
| **EUROPEAN REPRESENTATIVE:** | Shanghai International Holding Corp. GmbH(Europe)<br>Eiffestrasse 80, 20537 Hamburg Germany |

**START OF CE-MARKING:** 2010-01-14 (Date or Lot or serial number)

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| **PLACE, DATE OF DECLARATION:** | QINHUANGDAO, 2020-06-18 |
| **SIGNATURE:** | President |

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## Appendix: list of (harmonised - EN) standards

| NO. | Reference | Title |
|---|---|---|
| 1 | EN 60601-1: 1990+A1:1993+A2:1995 (IEC60601-1:1988+A1:1991+A2: 1995) | Medical Devices Part1: 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 Devices Part 1-4: General Requirements for Safety - Programmable Medical Electrical Equipment |
| 4 | EN 60601-1-6:2007 (IEC 60601-1-6:2006) | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability |
| 5 | EN 60601-1-8:2007 (IEC 60601-1-8:2006) | Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems |
| 6 | EN ISO 9919:2009 (ISO 9919:2005) | Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use |
| 7 | EN 1060-1:1995+A2:2009 | Non-invasive sphygmomanometers - Part 1: General requirements |
| 8 | EN 1060-3:1997+A2:2009 | Non-invasive sphygmomanometers - Part 3: supplementary requirements for electromechanical blood pressure measuring systems |
| 9 | EN 62304:2006 | Medical device software –Software life cycle processes |