# 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:** | Pulse Oximeter CMS50D+ |
| **CLASSIFICATION - ANNEX IX:** | Class Ⅱb, 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:** 2010-03-20 (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. | Serial Number | Title and Description |
|---|---|---|
| 1 | EN 60601-1:1990+ A1:1993+ A2:1995 | Medical electrical equipment - Part 1: General requirements for safety |
| 2 | EN 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 |
| 3 | EN 60601-1-1:2001 | Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems |
| 4 | EN 60601-1-2: 2007 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility -Requirements and tests |
| 5 | EN 60601-1-6:2010 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance- Collateral Standard: Usability |
| 6 | EN 60601-1-8:2007 | 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 |
| 7 | ISO 80601-2-61：2011 | Medical electrical equipment —Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment |
| 8 | EN 62304:2006 | Medical device software –Software life -cycle processes |
| 9 | EN 62366:2008 | Medical devices - Application of usability engineering to medical devices |