

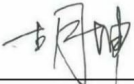


**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC
CONCERNING MEDICAL DEVICES**

| | |
|---|---|
|  MANUFACTURER: | CONTEC MEDICAL SYSTEMS CO., LTD No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA |
| MEDICAL DEVICE: | Pulse Oximeter Probe, ESA0008 |
| CLASSIFICATION - ANNEX IX: | Class II b, Rule 1 |
| 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. | |
| NOTIFIED BODY: | TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 M NCHEN, GERMANY |
| IDENTIFICATION NUMBER: |  0123 |
| (EC) CERTIFICATE(S): | <u>G1 050972 0050 Rev.04</u> |
|  EUROPEAN REPRESENTATIVE: | Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany |

START OF CE-MARKING: 2009-07-23 (Date or Lot or serial number)

| | |
|------------------------------------|---|
| PLACE, DATE OF DECLARATION: | QINHUANGDAO, 2019-07-23 |
| SIGNATURE: |  _____ President |

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Appendix: list of (harmonised - EN) standards

| NO. | Reference | Title |
|-----|----------------------|---|
| 1 | IEC60601-1:2012 | Medical electrical equipment- Part 1: General requirements for safety |
| 2 | IEC60601-1-2:2014 | Medical electrical equipment- Part 1-2: General requirements for safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests |
| 3 | ISO 80601-2-61: 2017 | Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use |