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

| | |
|---|---|
| **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:** | Portable ECG Monitor PM10 |
| **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.

| | |
|---|---|
| **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.03 |
| **EUROPEAN REPRESENTATIVE:** | Shanghai International Holding Corp. GmbH(Europe)<br>Eiffestrasse 80, 20537 Hamburg Germany |

**START OF CE-MARKING:** 2015-11-11 (Date or Lot or serial number)

| | |
|---|---|
| **PLACE, DATE OF DECLARATION:** | QINHUANGDAO, 2019-11-07 |
| **SIGNATURE:** | President |

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

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

| No. | Serial Number | Title and Description |
|---|---|---|
| 1 | EN ISO 13485: 2012 | Medical devices – Quality management systems – Requirements for regulatory purposes |
| 2 | EN ISO 14971:2012 | Medical devices – Application of risk management to medical devices |
| 3 | IEC 60601-1:2012 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| 4 | 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 |
| 5 | EN 60601-1-6:2010 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance- Collateral Standard: Usability |
| 6 | IEC 60601-1-11:2015 | 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 |
| 7 | IEC 60601-2-25:2011 | Medical electrical equipment –Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs |
| 8 | IEC 60601-2-47:2012 | Medical electrical equipment –Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems |
| 9 | EN 62304:2006 | Medical device software –Software life -cycle processes |
| 10 | EN 62366:2008 | Medical devices - Application of usability engineering to medical devices |
| 11 | EN 980:2008 | Symbols for use in the labelling of medical devices |
| 12 | EN1041:2008 | Information supplied by the manufacturer of medical devices |
| 13 | EN ISO 10993-1:2009 | Biological evaluation of medical devices.-part 1:Evaluation and testing |