# 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:** | Electrocardiograph, ECG1212G |
| **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/EC.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE.
THIS EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER.

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 MÜNCHEN, GERMANY |
| **IDENTIFICATION NUMBER:** | CE 0123 |
| **(EC) CERTIFICATE(S):** | G1 050972 0050 Rev.04 |
| **EUROPEAN REPRESENTATIVE:** | Prolinx GmbH<br>Brehmstr. 56, 40239, Duesseldorf, Germany |

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| **PLACE, DATE OF DECLARATION:** | QINHUANGDAO, 2024/01/10 |
| **SIGNATURE:** | _____President |

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

| No. | Standards | Title and Description |
|---|---|---|
| 1 | EN ISO 13485:2016 | Medical devices Quality Management Systems-Requirements for Regulatory Purposes |
| 2 | ISO 14971:2019 | Medical devices - Application of risk management to medical devices |
| 3 | IEC 60601-1:2005 + A1:2012 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| 4 | IEC 60601-1-6:2010 + A1:2013 | Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability |
| 5 | IEC 60601-2-25:2011 | Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs |
| 6 | IEC 60601-1-2:2014 | General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility . |
| 7 | ISO 20417:2021 | Medical devices - Information to be supplied by the manufacturer |
| 8 | EN ISO 15223-1:2021 | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements |
| 9 | IEC62304:2006+AMD1:2015 | Medical device software Software life cycle processes |
| 10 | IEC 62366-1:2015 | Medical devices - Part 1：Application of usability engineering to medical devices |
| 11 | ISO 10993-1:2018 | Biological evaluation of medical devices - Part 1: Evaluation and testing |