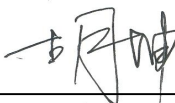


**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC
CONCERNING MEDICAL DEVICES**

| | |
|---|---|
| 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: | Electrocardiograph ECG1212G |
| CLASSIFICATION - ANNEX IX: | Class II a, 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 RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY |
| IDENTIFICATION NUMBER: | CE 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: 2020-12-14 (Date or Lot or serial number)

| | |
|------------------------------------|---|
| PLACE, DATE OF DECLARATION: | QINHUANGDAO, 2020-12-14 |
| SIGNATURE: |  _____ President |

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

Appendix: list of (harmonised - EN) standards

| No. | Reference | Title of Standard |
|-----|-------------------------|--|
| 1 | EN ISO 13485:2016 | Medical devices Quality Management Systems- Requirements for Regulatory Purposes |
| 2 | EN ISO14971: 2012 | Medical Devices - Application of Risk Management to Medical Devices |
| 3 | EN 60601-1:2006/A1:2013 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| 4 | IEC 60601-1-6:2013 | 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 | EN 60601-1-2: 2015 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance Collateral standard: Electromagnetic disturbances - Requirements and tests |
| 7 | EN 1041: 2008 | Information supplied by the manufacturer with medical devices |
| 8 | EN ISO 15223-1:2016 | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements |
| 9 | IEC 62304:2015 | 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 |