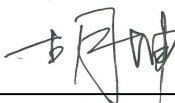


**DECLARATION OF CONFORMITY  
TO COUNCIL DIRECTIVE 93/42/EEC  
CONCERNING MEDICAL DEVICES**

<b>MANUFACTURER:</b>	<b>CONTEC MEDICAL SYSTEMS CO., LTD</b> No.112 Qinhuang West Street, Economic & Technical Development Zone, Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA
<b>MEDICAL DEVICE:</b>	Electrocardiograph ECG1212G
<b>CLASSIFICATION - ANNEX IX:</b>	Class II a, Rule 10
<b>CONFORMITY ASSESSMENT ROUTE:</b>	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.	
<b>NOTIFIED BODY:</b>	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
<b>IDENTIFICATION NUMBER:</b>	<b>CE</b> 0123
<b>(EC) CERTIFICATE(S):</b>	<u>G1 050972 0050 Rev.04</u>
<b>EUROPEAN REPRESENTATIVE:</b>	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany

**START OF CE-MARKING:** 2020-12-14 (Date or Lot or serial number)

<b>PLACE, DATE OF DECLARATION:</b>	QINHUANGDAO, 2020-12-14
<b>SIGNATURE:</b>	 _____ 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