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 ECG1200G	
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:	C E ₀₁₂₃	
(EC) CERTIFICATE(S):	G1 050972 0050 Rev.04	
EUROPEAN REPRESENTATIVE:	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany	
START OF CE-MARKING:	2012-04-20 (Date or Lot or serial number)	

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2020-06-18		
Signature:	Presid	ent	
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Appendix: list of (harmonised - EN) standards

No.	Reference	Title of Standard
1	IEC 60601-1:2012	Medical electrical equipment - Part 1: General requirements for
		basic safety and essential performance
2		Medical electrical equipment - Part 1-2: General requirements for
	IEC 60601-1-2:2014	basic safety and essential performance - Collateral Standard:
		Electromagnetic disturbances - Requirements and tests
3		Medical electrical equipment-Part 1-6:General requirements for
	IEC 60601-1-6:2013	basic safety and essential performance-Collateral Standard:
		Usability
		Medical electrical equipment –Part 2-25: Particular
4 IEC 60601-2-25:2011	IEC 60601-2-25:2011	requirements for the basic safety and essential performance of
	electrocardiographs	
	5 IEC 62366-1:2015	Medical devices - Application of usability engineering to
5		medical devices
6	IEC 62304:2015	Medical device software-Software life-cycle processes