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 ,ECG90A
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 Ridlerstr 65, D-80339 München, Germany
IDENTIFICATION NUMBER:	CE 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: 2016-11-24 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:	**QINHUANGDAO**, 2020-06-18
SIGNATURE:	President

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No.	Serial Number	Title and Description
1	IEC 60601-1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2	IEC 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
3	IEC 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
4	IEC 60601-2-25:2011	Particular requirements for the basic safety and essential performance of electrocardiographs
5	IEC 62366:2007	Medical devices - Application of usability engineering to medical devices
6	IEC 62304:2006	Medical device software - Software life-cycle processes
7	EN ISO 10993-1:2009	Biological evaluation of medical devices. Evaluation and testing