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:	Patient Monitor , CMS8000
CLASSIFICATION - ANNEX IX:	Class Ⅱb, Rule 10
CONFORMITY ASSESSMENT ROUTE:	Annex Ⅱ excluding chapter 4
GMDN CODE:	33586

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.02
EC REP **EUROPEAN REPRESENTATIVE:**	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany

START OF CE-MARKING: 2010-3-20 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2019-07-23
SIGNATURE:	President

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No.	Serial Number	Title and Description
1	IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices
2	IEC 62304:2015	Medical device software - Software life-cycle processes
3	EN ISO 10993-1:2009 (ISO 10993-1:2009)	Biological evaluation of medical devices. Evaluation and testing
4	IEC 60601-1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
5	IEC60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
6	IEC 60601-1-6:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
7	IEC60601-1-8:2012	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
8	IEC 60601-2-27:2011	Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
9	IEC 80601-2-30:2009	Medical electrical equipment -Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
10	IEC 60601-2-34:2011	Medical electrical equipment -Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
11	IEC 60601-2-49:2011	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
12	ISO 80601-2-55:2011	Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of respiratory gas monitors
13	ISO 80601-2-56:2009	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
14	ISO 80601-2-61:2011	Medical electrical equipment -Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment