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:	Portable ECG Monitor PM80
CLASSIFICATION - ANNEX IX:	Class Ⅱa,Rule 10
CONFORMITY ASSESSMENT ROUTE:	Annex Ⅱ without 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 13 10 50972 023
EC REP **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:

SIGNATURE: _____ President

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Appendix: list of (harmonised - EN) standards

No.	Reference	Title of Standard
1	IEC 60601-1: 1988 +A1:1991+A2:1995	Medical electrical equipment; Part 1: General requirements for safety
2	IEC 60601-1-6:2006	Medical electrical equipment Part 1-6: General requirements for safety - Collateral Standard: Usability
3	EN60601-1-4:1996 +A1:1999	Medical electrical equipment; Part 1: General requirements for safety –4 Collateral standard: Programmable electrical medical systems
4	IEC 60601-1-2: 2007	Medical electrical equipment Part 1: General requirements for safety -2 Collateral standard: Electromagnetic compatibility - Requirements and tests
5	IEC62304:2006	Medical device software Software life cycle processes
6	IEC60601-2-25: 1993 + A1:1999	Medical electrical equipment – Part 2-25: Particular requirements for the safety of electrocardiographs
7	IEC 60601-2-47:2001	Medical electrical equipment –Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems