

**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 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:

CE 0123

(EC) CERTIFICATE(S):

G1 14 03 50972 028

EC REP

EUROPEAN REPRESENTATIVE:

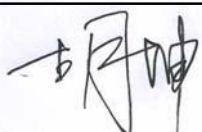
Shanghai International Holding Corp. GmbH(Europe)
Eiffestrasse 80, 20537 Hamburg Germany

START OF CE-MARKING:

2007-12-26 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:

SIGNATURE:



President

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Appendix: list of (harmonised - EN) standards

No.	Serial Number	Title and Description
1	EN 60601-1: 1990+A1:1993+A2:1995	Medical Devices Part1: General Requirements for Safety and Amendment 1, Amendment 2
2	EN 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	EN 60601-1-4:1996+A1: 1999	Medical Devices Part 1-4: General Requirements for Safety - Programmable Medical Electrical Equipment
4	EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
5	EN 62304:2006	Medical device software - Software life-cycle processes
6	EN 62366:2008	Medical devices - Application of usability engineering to medical devices
7	EN 60601-2-25: 1995+A1:1999	Particular requirements for the safety of electrocardiographs