

**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, ECG100G

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 050972 0050 Rev.02

EC REP

EUROPEAN REPRESENTATIVE:

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

START OF CE-MARKING:

2010-03-20 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:

QINHUANGDAO, 2019-07-23

SIGNATURE:

 President

TF-CE090602.1-09

Ver: J

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Appendix: list of (harmonised - EN) standards

No.	Reference	Title
1	EN 60601-1: 1990/A1:1993 /A2:1995	Medical electrical equipment - Part 1: General requirements for safety
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 60601-1-6:2007	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: usability
5	EN 60601-2-25:1995/A1:1999	Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs
6	EN 62304: 2006	Medical device software - Software life-cycle processes