

**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:

Pocket Fetal Doppler , Sonoline B&Sonoline A

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 M NCHEN, 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:

2009-08-17 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:

QINHUANGDAO, 2019-07-22

SIGNATURE:



President

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Appendix: list of (harmonised - EN) standards

No.	Serial Number	Title and Description
1	EN 60601-1:2006 (IEC 60601-1:2005)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2	EN 60601-1-2: 2007 (IEC60601-1-2:2007)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
3	EN 60601-1-6:2010 (IEC 60601-1-6:2010)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
4	EN 60601-2-37:2008 (IEC 60601-2-37:2007)	Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
5	IEC61157:1992	Requirements for the Declaration of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment
6	EN 62366:2008 (IEC 62366:2007)	Medical devices - Application of usability engineering to medical devices
7	EN 62304:2006 (IEC 62304:2006)	Medical device software - Software life-cycle processes