

**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 MÜNCHEN, GERMANY

**IDENTIFICATION NUMBER:**

**CE** 0123

**(EC) CERTIFICATE(S):**

G1 15 08 50972 047

**EC REP**

**EUROPEAN REPRESENTATIVE:**

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

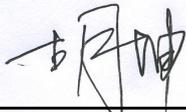
**START OF CE-MARKING:**

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

**PLACE, DATE OF DECLARATION:**

QINHUANGDAO, 2015-12-21

**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