## DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

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 AMENOMENTS BY COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENOMENTS 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: C C 0123 (EC) CERTIFICATE(S):G1 15 08 50972 047. [EC]REP Shanghai International Holding Corp. GmbH(Europe) EUROPEAN REPRESENTATIVE: 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					
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## DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

## Appendix: list of (harmonised - EN) standards

No.	Serial Number	Title and Description	
4	EN 60601-1:2006	Medical electrical equipment - Part 1: General requirements for	
1	(IEC 60601-1:2005)	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	

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