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 Baby Sound B
CLASSIFICATION - ANNEX IX:	Class Ⅱa, 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 16 06 50972 050
EC REP **EUROPEAN REPRESENTATIVE:**	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany

START OF CE-MARKING: 2008-11-11 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2016-11-01
SIGNATURE:	_____President

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

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
7	EN 62366:2008 (IEC 62366:2007)	Medical devices - Application of usability engineering to medical devices
8	EN 62304:2006 (IEC 62304:2006)	Medical device software - Software life-cycle processes

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INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC
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EC REP **EUROPEAN REPRESENTATIVE:**	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany

START OF CE-MARKING: 2008-12-05 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2016-11-01
SIGNATURE:	_____President

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2	EN 60601-1-2: 2007 (IEC60601-1-2:2007)	Medical Devices Part 1-2: General Requirements for Safety –Collateral Standards: Electromagnetic Compatibility – Test and Requirements and Amendment 1
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	EN 62366:2008 (IEC 62366:2007)	Medical devices - Application of usability engineering to medical devices