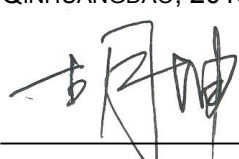


**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC
CONCERNING MEDICAL DEVICES**

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 SONOTRAX B
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):	<u>G1 050972 0050 Rev.03</u>
EUROPEAN REPRESENTATIVE:	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany

START OF CE-MARKING: 2007-12-16 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2019-11-07
SIGNATURE:	 _____ President

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

Appendix: list of (harmonised - EN) standards

NO.	Reference	Title
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	EN60601-1-4:1996+A1:1999 (IEC60601-1-4:1996/A1:1999)	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
4	EN 60601-1-6:2007 (IEC60601-1-6:2006)	Medical electrical equipment-Part 1-6:General requirements for basic safety and essential performance-Collateral Standard: Usability
5	EN 60601-2-37:2008 (IEC60601-2-37:2007)	Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
6	IEC 61266: 1994	Ultrasonics - Hand-held probe Doppler fetal heartbeat detectors - Performance requirements and methods of measurement and reporting
7	EN 62304:2006	Medical device software-Software life-cycle processes