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:	Fetal Monitor, CMS800G
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/EC.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE.
THIS EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER.

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 050972 0050 Rev.04
EUROPEAN REPRESENTATIVE:	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg Germany

PLACE, DATE OF DECLARATION:	QINHUANGDAO, 2023/12/01
SIGNATURE:	_____President

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Appendix: list of (harmonised - EN) standards

NO.	Standards	Title and Description
1	IEC 60601-1:2005+AMD1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2	IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3	IEC60601-1-6:2010+AMD1:2013+AMD2: 2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
4	IEC 60601-2-37:2007+AMD1:2015	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
5	IEC 61157:2007+AMD1:2013	Standard means for the reporting of the acoustic output of medicaldiagnostic ultrasonic equipment
6	IEC 62304:2006+AMD1:2015	Medical device software - Software life cycle processes
7	IEC 62366-1:2015+AMD1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
8	ISO 14971:2019	Medical devices - Application of risk management to medical devices
9	ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer
10	ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
11	ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
12	ISO 13485:2016	Medical devices - Quality management systems Requirements for regulatory purposes