CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Certificate No.: EU1308401
Order No.: 238607

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 1690 of 15th December 2005 relating to medical devices pursuant to act no. 6 of 12th January 1995 relating to medical devices, transposing directive 93/42/EEC as amended by directive 2007/47/EC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the Annex given below:

Name and address of the manufacturer:	Bistos Co., Ltd. 7th FL., A Bldg., Woolim Lions Valley 5-cha 144-3, Sangdaewon-dong, Jungwon-gu, Seongnam-si Gyeonggi-do, Korea
Device category:	MD 1302 Monitoring devices of vital physiological parameters
GMDN Code:	37796, 41917, 37258
Models:	See Appendix 1 to this certificate
Standards/provisions:	The audit of the quality system was based upon and assessed according to the provisions in Annex II of the EC-Directive 93/42/EEC, with the exemption of section 4.
Date of last audit:	2012-08-22
Date of the end of the validity:	2018-09-01
Nemko EC notification No.:	0470

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC directive will be fulfilled by the manufacturer and the factory. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

Date of issue: 2013-08-15

Signature: Arild R. Hansgård
Lead assessor

Date of verification: 2013-08-15

Signature: Lars Forssander
Lead assessor

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Gyeonggi-do, Korea

Device category: MD 1302 Monitoring devices of vital physiological parameters

Appendix 1: Page 1 of 1.

The certificate referred to above includes the following device/model:

Device Designation	Model	GMDN code
Cardiotocograph	BT-300	37796
Cardiotocograph	BT-350	37796
Cardiotocograph	Biocare FM-1	37796
Foetal Doppler System Probes	AY-DOP-300	41917
Foetal Doppler System Probes	AY-DOP-350	41917
Cardiotocograph Transducers	AY-UC-300	37258
Cardiotocograph Transducers	AY-UC-350	37258

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