EC Certificate
Full Quality Assurance System

Certificate No.: EU1012401 Date: 2016-07-01

Order No.: 293263

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 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:

Manufacturer:	Bistos Co., Ltd. 7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do Korea
Device categorie(s):	Ultrasound Doppler System with Foetal Doppler System Probes
GMDN code:	34040, 41917, 36462
Models:	See page 2 of this certificate
Risk class as defined by the manufacturer:	IIa
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 audit:	2015-07-07
End of the validity:	2021-01-01
Nemko EC notification No.:	0470
Remarks:	This certificate replaces the certificate EU1012401 issued 2016-01-01

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.

Sholeh Ghassar

For Nemko AS

Nemko Norway
Nemko AS, Gaustadalléen 30, P.O. Box 73 Blindern, 0314 Oslo, Norway
TEL +47 22 96 03 30 FAX +47 22 96 05 50 EMAIL info@nemko.com
ENTERPRISE NUMBER NO974404532

nemko.com/no

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Manufacturer: Bistos Co., Ltd.
7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302,
Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do
Korea

Certificate History:

Revision	Description	Issue Date
0	Recertification	2010-12-01
1	Scope extension	2014-01-31
2	**Recertification**	**2016-07-01**

The certificate referred to above, includes the following devices/models:

Device Category	Model Name	GMDN Code
Ultrasound Doppler system:	BT-200	34040
Foetal Doppler system probe:	AY-2MHDOP-200L	41917
Foetal Doppler system probe:	AY-3MHDOP-200T	41917
Foetal Doppler system probe:	AY-4MHZDOP-200	41917
Foetal Doppler system probe:	AY-5MHZDOP-200	41917
Foetal Doppler system probe:	AY-8MHZDOP-200	41917
Ultrasound Doppler system:	BT-250	36462
Foetal Doppler system probe:	AY-2MHZDOP-250	41917
Ultrasound Doppler system:	BT-220C and BT-220L	34040
Foetal Doppler system probe:	AY-2MHZDOP-220C	41917
Foetal Doppler system probe:	AY-3MHZDOP-220C	41917

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Nemko AS, Gaustadalléen 30, P.O. Box 73 Blindern, 0314 Oslo, Norway
TEL +47 22 96 03 30 FAX +47 22 96 05 50 EMAIL info@nemko.com
ENTERPRISE NUMBER NO974404532

No. DOC - 220 - 01

bistos

EC Declaration of Conformity

Manufacturer : Bistos Co., Ltd.

7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

EC Representative : Medical Econet GmbH

Im Erlengrund 20 D-46149 Oberhausen / Germany

We hereby declare that medical device described hereafter

Product : Ultrasound Doppler System with Foetal Doppler System Probe

Model Name : BT-220C, BT-220L

(AY-2MHZDOP-220C, AY-3MHZDOP-220C)

- is in conformity with the essential requirements and provisions of the Medical Device Directive 93/42/EEC as amended by 2007/47/EC
- is in conformity with the harmonized standards
- is subject to the procedures set out in Annex II excluding section 4 of the Medical Device Directive 93/42/EEC as amended by 2007/47/EC under the supervision of Notified Body Number 0470, Nemko AS, Gaustadalléen 30, Blindern, 0314 Oslo, Norway

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Signed for and on behalf of
Bistos Co., Ltd.

Taeho Kim
Quality Management Representative