EC Certificate
Full Quality Assurance System

Certificate No.: EU1308401 Date: 2015-04-23

Order No.: 266286

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):	MD 1302 Monitoring devices of vital physiological parameters MD 1402 Utilising non-ionizing radiation
GMDN code:	37796, 41917, 37258 and 35239
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:	2012-08-22
End of the validity:	2018-09-01
Nemko EC notification No.:	0470
Remarks:	This certificate replaces the certificate EU1308401 issued 2014-09-16

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.

Ragnar Stranger Christiansen
For Nemko AS

Digitally signed by Grabazei Alexandru
Date: 2019.11.18 14:44:02 EET
Reason: MoldSign Signature
Location: Moldova

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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	2013-08-15
1	Recertification another product	2015-04-23

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

Device Category	Model Name	GMDN Code
MD 1302, Cardiotocograph	BT-300	37796
MD 1302, Cardiotocograph	BT-350	37796
MD 1302, Cardiotocograph	Biocare FM-1	37796
MD 1302, Foetal Doppler System Probes	AY-DOP-300	41917
MD 1302, Foetal Doppler System Probes	AY-DOP-350	41917
MD 1302, Cardiotocograph Transducers	AY-UC-300	37258
MD 1302, Cardiotocograph Transducers	AY-UC-350	37258
MD 1402, Neonatal Phototherapy unit	BT-400	35239