

# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.: 243269-2017-CE-KOR-NA-PS Rev. 5.0

Project No.: PRJC-533956-2015-MSL-KOR

Valid Until: 01 September 2023

This is to certify that the quality system of:

### **Bistos Co., Ltd.**

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

For design, production and final product inspection/testing of:

### **Monitoring devices of vital physiological parameters and Utilising non-ionizing radiation**

Has been assessed with respect to:

### **The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended**

and found to comply

Place and date:  
Høvik, 30<sup>th</sup> April 2021

Check Validity

For the issuing office:  
Notified Body 2460  
DNV Product Assurance AS



Hazem Tinawi  
Technical Reviewer

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, [www.dnv.com](http://www.dnv.com)

ICP-4-5-i1-MDD-f2, rev.0

Further details of the product(s) and conditions for certification are given overleaf.

## Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

## Certificate history:

Revision	Description	Issue Date
0.0	Replaces certificate EU1308401, Rev2.0 (NB 0470) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460)	01 September 2017
1.0	EU Rep change	13 April 2018
2.0	Re-certification for Fetal monitor and Neonatal Phototherapy unit (BT-300, BT-350, FM-20, Biocare FM-1, BT-400) Scope extension for pulse oximeter and patient monitor (BT-710, BT-720, BT-740, BT-770) The accessories (Feotal Doppler system probe and Cardiotocograph transducers) are removed (AY-DOP-300, AY-DOP-350, AY-UC-300, AY-UC-350)	01 September 2018
3.0	Editorial change	13 February 2020
4.0	Scope extension to new model (BT-780)	26 April 2021
5.0	<b>Editorial change in model name (typo error)</b>	<b>30<sup>th</sup> April 2021</b>

## Products covered by this Certificate:

Product Description	Product Name	Class
Fetal monitor	<ul style="list-style-type: none"> <li>BT-300</li> <li>BT-350</li> <li>FM-20</li> <li>Biocare FM-1</li> </ul>	Ila
Neonatal Phototherapy unit	<ul style="list-style-type: none"> <li>BT-400</li> </ul>	Ila
Pulse Oximeter	<ul style="list-style-type: none"> <li>BT-710</li> </ul>	IIb
Patient Monitor	<ul style="list-style-type: none"> <li>BT-720</li> <li>BT-740</li> <li>BT-770</li> <li>BT-780</li> </ul>	IIb

The complete list of devices is filed with the Notified Body

**Sites covered by this certificate**

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

**EU Representative**

OBELIS S.A, Bd. General Wahis, 53, 1030 Brussels, Belgium

## Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate