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, 30th April 2021

Check Validity

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

Hazem Tinawi
Technical Reviewer

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	**Editorial change in model name (typo error)**	**30th April 2021**

Products covered by this Certificate:

Product Description	Product Name	Class
Fetal monitor	▪ **BT-300** ▪ BT-350 ▪ FM-20 ▪ Biocare FM-1	IIa
Neonatal Phototherapy unit	▪ BT-400	IIa
Pulse Oximeter	▪ BT-710	IIb
Patient Monitor	▪ BT-720 ▪ BT-740 ▪ BT-770 ▪ BT-780	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

Notified Body Confirmation Letter Reference: C615266

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Bistos Co., Ltd.
7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro,
Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea
SRN Number (if available): KR-MF-000035951

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

Place and date:
Høvik, 2023.08.22

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Menaka Singh
Management Representative

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Fetal monitor (BT-350, FM20) / 88000123MEFM03009A	Class IIb	N/A	- Certificate number: 243269-2017-CE-KOR-NA-PS (Rev. 5.0); - NB number NB: 2460; - Expiry date: 01 Sep 2023
Neonatal Phototherapy unit (BT-400) / 88000123MEPU0400G9	Class IIa	N/A	- Certificate number: 243269-2017-CE-KOR-NA-PS (Rev. 5.0); - NB number NB: 2460; - Expiry date: 01 Sep 2023
Pulse Oximeter (BT-710) / 88000123MEPO710BV	Class IIb	N/A	- Certificate number: 243269-2017-CE-KOR-NA-PS (Rev. 5.0); - NB number NB: 2460; - Expiry date: 01 Sep 2023
Patient Monitor (BT-720) / 88000123MEPM0700DY	Class IIb	N/A	- Certificate number: 243269-2017-CE-KOR-NA-PS (Rev. 5.0); - NB number NB: 2460; - Expiry date: 01 Sep 2023
Patient Monitor (BT-740, BT-770, BT-780) / 88000123MEPM0701E2	Class IIb	N/A	- Certificate number: 243269-2017-CE-KOR-NA-PS (Rev. 5.0); - NB number NB: 2460; - Expiry date: 01 Sep 2023
Fetal monitor (BT-300, Biocare FM-1) / 88000123MEFM03009A	Class IIb	N/A	- Certificate number: 243269-2017-CE-KOR-NA-PS (Rev. 5.0); - NB number NB: 2460; - Expiry date: 01 Sep 2023
Ultrasound Doppler system with Probes ▪ BT-200L - AY-DOP-200L (2M) ▪ BT-200C - AY-DOP-200C (2M) ▪ BT-200S - AY-DOP-200S (2M) ▪ BT-200T	Class IIa	N/A	- Certificate number: 243267-2017-CE-KOR-NA-PS (Rev. 2.0); - NB number NB: 2460; - Expiry date: 27 May 2024

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
- AY-DOP-200T (3M) ▪ BT-200V - AY-DOP-200V (2M) - AY-DOP-200V (4M) - AY-DOP-200V (5M) - AY-DOP-200V (8M) ▪ Flux200 diaped® - AY-DOP-200V (2M) - AY-DOP-200V (4M) - AY-DOP-200V (5M) - AY-DOP-200V (8M) ▪ F10 - AY-2MHZDOP-010 / Basic UDI DI : 88000123MEFD020062			
Ultrasound Doppler system with Probes ▪ BT-220L - AY-DOP-220 (2M) - AY-DOP-220 (3M) ▪ BT-220C - AY-DOP-220 (2M) - AY-DOP-220 (3M) / Basic UDI DI : 88000123MEFD022068	Class IIa	N/A	- Certificate number: 243267-2017-CE-KOR-NA-PS (Rev. 2.0); - NB number NB: 2460; - Expiry date: 27 May 2024
Ultrasound Doppler system with Probes ▪ BT-250 - AY-DOP-250 (2M) / Basic UDI DI : 88000123MEFD02506H	Class IIa	N/A	- Certificate number: 243267-2017-CE-KOR-NA-PS (Rev. 2.0); - NB number NB: 2460; - Expiry date: 27 May 2024
Electric Breast Pump (BT-100) / Basic UDI DI : 88000123MEBP01008D	Class IIa	N/A	- Certificate number: 243267-2017-CE-KOR-NA-PS (Rev. 2.0); - NB number NB: 2460; - Expiry date: 27 May 2024
Electric Breast Pump (BT-150, BT-150L, BT-150B, BT-150S) / Basic UDI DI : 88000123MEBP01508U	Class IIa	N/A	- Certificate number: 243267-2017-CE-KOR-NA-PS (Rev. 2.0); - NB number NB: 2460; - Expiry date: 27 May 2024
Infant warmer (BT-550) / Basic UDI DI : 88000123MEWM0550GY	Class IIb	N/A	- Certificate number: 243267-2017-CE-KOR-NA-PS (Rev. 2.0); - NB number NB: 2460; - Expiry date: 27 May 2024

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Infant incubator (BT-500) / Basic UDI DI : 88000123MEIN0500B6	Class IIb	N/A	- Certificate number: 243267-2017-CE-KOR-NA-PS (Rev. 2.0); - NB number NB: 2460; - Expiry date: 27 May 2024

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/08/22	C615266	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607
- Significant changes to design or intended purpose of the devices
- Changes in the quality system affecting production
- Periodical audits not held within the timeframe