



# BIO SIGNAL TOTAL SOLUTION

## Product

- Fetal Monitor
- Fetal Doppler
- Infant Incubator
- Infant Warmer
- Phototherapy
- Electric Breast Pump
- Patient Monitor
- Vascular Doppler
- Head Lamp

# Fetal Monitor

## BT-350

LCD Monitor / LED Monitor



BT-350L



BT-350E

- 7" TFT color LCD / Large size LED
- Display mode variation
  - Graph mode, Number mode, Trend mode
- Multi language support
- Trend : 450 hours (3 hours/patient)
- Desktop & Wall mount
- CTG Analysis (BT-350L)
- USB Data Saving
- CCV (Cross-Channel Verification) Function

## BT-300

LED Monitor



- Clear display & Sound
- Compact & Light Design
- Easy to use each function
- High sensitivity ultrasound probe

# Fetal Doppler

## BT-200 (Hi-bebe)

Sound / Mono / Color



BT-200S



BT-200L / 200T

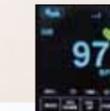


BT-200C

- LCD / OLED display
- High quality sound
- High sensitivity probe (2,3MHz)
- Hand-held style
- Low battery indicator
- Waterproof Probe

## BT-220 (Hi-bebe S)

Sound / Mono / Color



BT-220C



BT-220L

- 2.4" Color LCD display
- Acoustic stimulator (BT-220C,L)
- Body fat analysis (BT-220C)
- Mother HR function (BT-220C)
- USB Rechargeable (BT-220C,L)
- Waterproof Probe

## BT-250

Desktop Doppler



- 3.2" Color LCD display
- Data Save : 4 Hours
- Multi languages support
- Built-in rechargeable battery
- High quality sound
- High sensitivity(2MHz)
- Compact & Light
- Waterproof probe

Specifications	BT300	BT350E	BT350L
Ultrasound Frequency	0.985MHz		
FHR Range	Twin / 30 ~ 240 bpm		
Fetal Movement	Auto-detection & print		
UC	0 ~ 99 units		
Print Function	1, 2, 3cm/min speed & Auto print (Off, 10, 20, 30, 40, 50, 60min) & FHR II offset		
Display	Medium 7-segment LED	Large 7-segment LED	7" TFT color LCD
Diagnosis	No	No	Yes
Trend(Data Save)	No	No	Yes(450 hours)
USB Function (data transfer)	No	Yes	Yes
Central Monitoring System	BCM350 (RS-232C / Bluetooth or WiFi)		
Warranty	2 years (Accessory Excluded)		
Options	Rechargeable battery, Acoustic stimulator, Cart, Wall mounted bracket (BT-350)		

Specifications	BT200S	BT200L	BT200C	BT200T	BT220L	BT220C	BT250	
Ultrasound Frequency	2MHz			3MHz	2, 3MHz		2MHz	
FHR Range	50 ~ 240 bpm					30 ~ 240 bpm		
Display	No	Mono LCD	Color LED	Mono LCD	Mono LCD	2.4" TFT color	3.2" TFT Color	
Battery Time (hours)	5					4	5	
Power	1.5V AA battery x 2						100~240V / rechargeable	
Rechargeable Battery	-						Yes	
PC Interface	BCM200 (Sound card)						RS-232C	
Trend (Data Save)	No	No	No	No	No	No	4 hours	
Acoustic Stimulate Function	No	No	No	No	Yes	Yes	No	
Options	-					USB cable		Cramp

# Infant Incubator

## BT-500

- Accurate humidity control
- Comfortable & soft tilting structure
- 7" Color LCD Display
- Powerful Lifting Stand (option)
- O2 Monitoring / O2 Servo Control (option)
- MASIMO SpO2 & CCD Camera (option)
- Correct Weighting Scale (option)
- Various Alarm Functions
- Low Noise Hood



Air / Skin temperature  
Humidity Servo control



MASIMO SpO2 & CCD  
Camera & External Monitor  
(Option)



Mattress tilt



Built-in x-ray tray

Specifications	BT500
Display	7" TFT color LCD
Dimension / Weight	1,024mm(W) x 690mm(D) x 1,354mm(H) / 99.3kg
Air / Skin Temperature Control Range	23.0 ~ 37.0°C±0.5°C / 35 ~ 37.5°C±0.5°C (override < 39.0°C)
Humidity Control / Measurement Range	40 ~ 95%±5% RH / 15 ~ 99%±5% RH
Humidity Control System	Steam
Water Tank Capacity	1,000 ml
Mattress Size & Tilt	730(L) x 27(H) x 380(D) mm / 12°
Noise Level	< 45dB
Options	Lifting Stand : 651(min) ~ 851(max)mm
	Drawer
	Plate
	IV pole
	O2 monitoring : 18 ~ 100% ±5%
	O2 servo control : 21% ~ 65%
	Weighing scale : 0 ~ 10Kg ±50g
Shelf	
	MASIMO Spo2 & CCD camera & external monitor

# Infant Warmer

## BT-550

- Far Infrared Heater
- 7 inch LCD Display
- Apgar Timer
- Swivel Head
- LED Examination Lamp
- Good design
- Wide Rnge of Accessories



Swivel Head ( Left90° & Right90°)



LED Examination Lamp



Heat Source



Tilting (option)  
(15°±2° to backward or forward)



7 inch TFT LCD Display



Tripod water level



Both sides Drawers (option)



Three sides open protective barriers



Lifting Stand (option)

Specifications	BT550
Display	7 inch TFT color LCD
Dimension / Weight	1,184(L) x 1,890(H) x 846(D)mm / 98Kg
Control Mode	Pre warm / Baby / Manual
Skin Temperature Display / Control Range	26 ~ 42°C±0.5°C / 34 ~ 38°C±0.5°C
Heater Output Setting Range / Power	0 ~ 100% (5%p resolution) / 26mW/cm2 (±20%)
LED Examination Lamp	40W(10W x 4, <3,000lm) 3 steps control
Alarm	Visual and Sound Alarms
APGAR Timer	0min ~ 59min 59sec (1, 5, 10min Beep)
Mattress Size	495(L) x 27(H) x 810(D) mm
Options	Tilt : ±15°
	Drawer
	Plate
	IV pole
	Lifting Stand : 615 ~ 815mm
	Weighting scale : 0 ~ 10Kg ±50g
	MASIMO Spo2

# Phototherapy

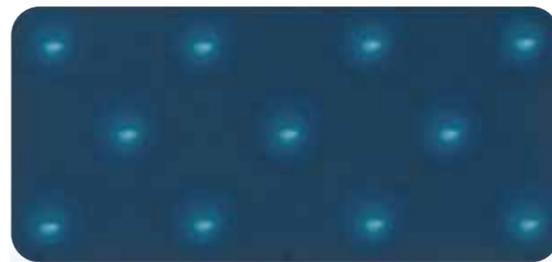
## BT-400

- Lamp : Blue LED
- High Intensity of Radiation
- Compact design
- Flexible neck
- Wide effective area
- Time counter & Setting
- Easy to Use
- Various installation



Adjustable head

Timer & adjustable intensity



Power 11 LED

Light Source	11 Blue LEDs
Wave length	Peak between 450 – 475 nm
Intensity	20 ~ 100 uW/cm <sup>2</sup> /nm
Effective Area	40 x 20 cm
Life Time	About 20,000 hours
Variation in Intensity Over 6 Hours	< 10%
Power	AC 100 ~ 240V (50/60Hz)
Display	2.4" TFT color LCD Operating hours, Total operating hours, Timer, Intensity
Option	Cart, Eye shield, Shade

# Vascular Doppler & LED Head Lamp

## BT-200 (Hi-dop) Vascular Doppler



- hand held style
- clear Sound
- compact and light
- High-Sensitive Doppler Probe
- 4 Ranges of probes
- Easy to use
- Low power consumption
- Long time continuous use (6 hours)

Specifications	Specifications
Ultrasound Frequency	2, 4, 5, 8MHz
HR Range	50 ~ 240 bpm
Display	Mono LCD
Battery Time (hours)	5 hours
Power	1.5V AA battery x 2
Options	-

## BT-410

### LED Head Lamp



BT-410A

BT-410F

- Light & comfortable
- Low battery display
- Quick battery recharge
- Ultra bright LED
- Easy to adjust Head band
- More than 50,000 hours LED life
- Removable battery module

Specifications	BT410A	BT410F
Mode	Adjustable focus	Fixed focus
Illumination	30,000lx / 50,000lx (Astral)	15,000 ~ 30,000lx (Adjustable)
LED Life Time	50,000 hours	
Color Temperature	6,000 Kelvin	
Battery Module	Operating Time	4 hours
	Recharge	800 times
	Output	3.7 V
Charger	Input	AC 100 ~ 240 V (50/60Hz)
	Charging Time	4 hours
Options	X 3.5 Loupe, Battery module, Astral lamp (BT-410A)	

# Patient Monitor

## BT-700

Vital Sign Monitor



- 3.2" LCD display
- SpO2, Temp.
- Trend : 4 hours
- Compact and light
- Easy F/W upgrade (USB)
- Apply nurse call state
- Temperature - (optional)

# Electric Breast Pump

## Hi bebe *plus*

Electric Breast Pump : BT-100



## BT-750

Multi-parameter Patient Monitor



- 10.4" Color LCD display
- ECG(2ch), SpO2, NIBP, Temp.(2ch), IBP, RESP.
- PVC and ST level display Pacemaker detection
- Detection of 12 kinds of arrhythmia
- Trend : 72 hours
- Central monitoring system (LAN)



- Memory customized expression sequence
- Vacuum control in 10 levels
- Auto switch off after 30 minutes
- Sufficient vacuum for dual expression
- Backflow prevention



- Rechargeable battery (2,5hour operation)
- Convenient and graceful design
- 3 operating mode (express , massage, memory)
- Operating time display
- Silent

Specifications		BT700	BT750
Display		3.2" color LCD	Ultrasound 10.4" color LCD
Battery Operating Time		3 hours	3 hours
SpO2	Measuring Range	1% ~ 100%	
	Pulse Rate	30 ~ 250 bpm	20 ~ 300 bpm
NiBp	Mode	Auto, Manual, STAT	
	Auto Mode(min)	1,2,3,4,5,10,15,30,45,60,90,120,240	1,3,5,10,30,60,90,120,240
	Neonate/Adult Systolic	20/30 ~ 120/250 mmHg	30/50 ~ 130/255 mmHg
	Neonate/Adult Diastolic	10/20 ~ 110/210 mmHg	20/30 ~ 100/220 mmHg
ECG	Lead	-	3/5 Leads
	Sweep Speed	-	12.5, 25, 50 mm/s
Resp	Resp	-	0 ~ 150 breaths/min
	Sweep Speed	-	6.25, 12.5, 25 mm/s
Temp	Range	20 ~ 45℃	30 ~ 45℃
Options		NiBp, Temp	Printer, IBP, EtCO2

Specifications	BT100 Hello Mom
Type of Pump	Personal Use (Dual Express)
Adjustable Speed / Vacuum	Yes
Size / Weight	110(H) x 70(W) x 45(D) mm / 370g
Boot up & Shut down Time	< 1sec
Pumping Session	Timer & Memory
Automatic Turn Off	30minutes
Backflow Prevention	Yes
Memory Function	Yes
Vacuum Pressure	270mmHg
Expression Pressure Variation	10 steps
Massage Pressure Variation	10 steps



# BIO SIGNAL TOTAL SOLUTION

**Bistos Co., Ltd.**

\* All specifications are subject to change without notice.

7th Fl. A bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu Seongnam-si, Gyeonggi-do, Korea (Zip. 462-739)

Tel : +82 31 750 0340

Fax : +82 31 750 0344

E-mail : sales@bistos.co.kr

[www.bistos.co.kr](http://www.bistos.co.kr)

# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.: 243267-2017-CE-KOR-NA-PS Rev. 2.0

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

Valid Until: 27 May 2024

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:

### **Ultrasound Doppler System with Foetal Doppler System Probes, Electric breast pump, Infant warmer, and Infant incubator**

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

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

Place and date:  
Høvik, 17 March 2021

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



Eugenie Winger Husebye  
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.

## 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 EU1012401, Rev 3.0 (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	<b>Recertification (Certificate no. 215934-2017-CE-KOR-NA-PS has been merged after the recertification audit completed)</b>	<b>17 March 2021</b>

## Products covered by this Certificate:

Product Description	Product Name	Class
Ultrasound Doppler system with Probes	<ul style="list-style-type: none"> <li>▪ BT-200L - AY-DOP-200L (2M)</li> <li>▪ BT-200C - AY-DOP-200C (2M)</li> <li>▪ BT-200S - AY-DOP-200S (2M)</li> <li>▪ BT-200T - AY-DOP-200T (3M)</li> <li>▪ BT-200V - AY-DOP-200V (2M) - AY-DOP-200V (4M) - AY-DOP-200V (5M) - AY-DOP-200V (8M)</li> <li>▪ F-10 - AY-2MHZDOP-010</li> <li>▪ BT-220L - AY-DOP-220 (2M) - AY-DOP-220 (3M)</li> <li>▪ BT-220C - AY-DOP-220 (2M) - AY-DOP-220 (3M)</li> <li>▪ BT-250 - AY-DOP-250 (2M)</li> </ul>	Ila
Electric Breast Pump	<ul style="list-style-type: none"> <li>▪ BT-100</li> <li>▪ Milk Genie</li> <li>▪ BT-150, BT-150L, BT-150B, BT-150S</li> </ul>	Ila

Infant warmer	▪ BT-550	IIb
Infant incubator	▪ BT-500	IIb

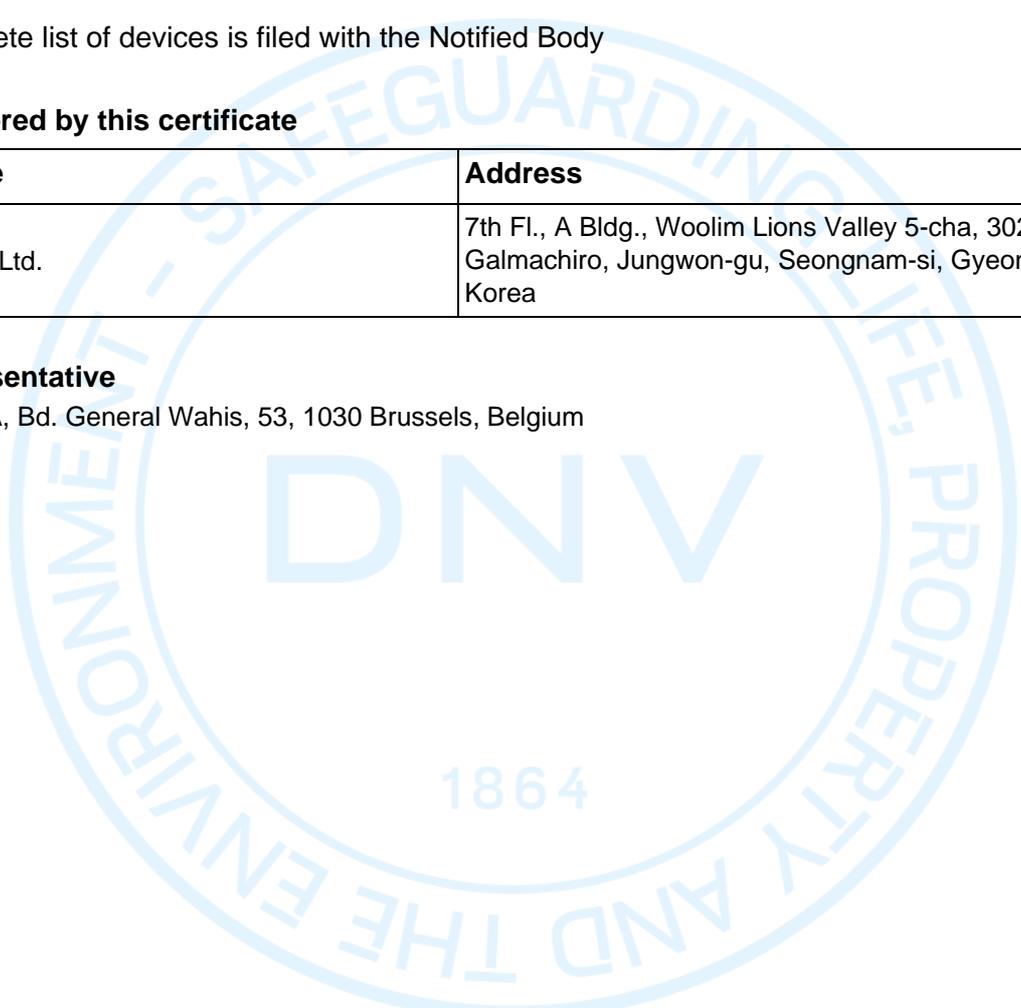
The complete list of devices is filed with the Notified Body

**Sites covered by this certificate**

Site Name	Address
Bistos Co., Ltd.	7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachiro, 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



# 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
<b>5.0</b>	<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>	IIa
Neonatal Phototherapy unit	<ul style="list-style-type: none"> <li>▪ BT-400</li> </ul>	IIa
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



Certificate No.: 243269-2017-CE-KOR-NA-PS Rev. 5.0  
Place and date: Høvik, 30th April 2021

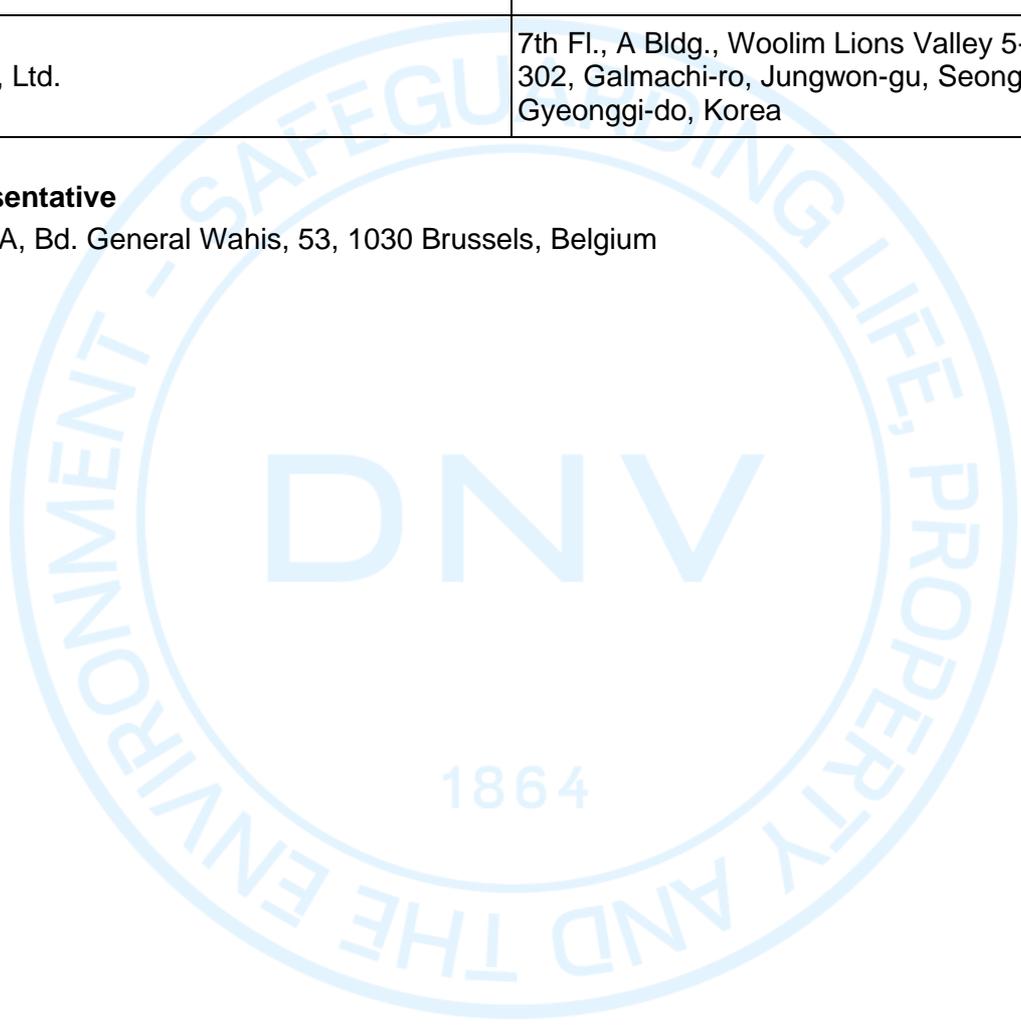
The complete list of devices is filed with the Notified Body

**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.

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- 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

# Management System Certificate

Certificate No.: 243275-2017-AQ-KOR-NA-PS Rev 4.0 Initial Certification Date: 12 August 2004 Valid Until: 09 September 2024

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

has been found to conform to the Quality Management System standard:

## **ISO 13485:2016/NS-EN ISO 13485:2016**

This certificate is valid for the following scope:

**Design and Development, Manufacturing, Sales, Distribution, and Servicing of Ultrasound Doppler system, Fetal monitor, Phototherapy, Patient Monitor, Pulse Oximeter, Incubator, Head-worn light, Infant Warmer and Electric Breast Pump.**

Place and date:  
Høvik, 23 June 2021

Check Validity



For the issuing office:  
DNV Product Assurance AS

*Tone Kolpus*  
**Tone Elise Kolpus**  
Lead Auditor

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

Site Name	Address	Site Specific Scope
Head Office	7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea	Design and Development, Sales, Distribution, and Servicing of Ultrasound Doppler system, Fetal monitor, Phototherapy, Patient Monitor, Pulse Oximeter, Incubator, Head-worn light, Infant Warmer and Electric Breast Pump.
Factory	116~122ho, Jungang Induspia 3, 27, Sagimakgol-ro 105beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea	Manufacturing of Ultrasound Doppler system, Fetal monitor, Phototherapy, Patient Monitor, Pulse Oximeter, Incubator, Head-worn light, Infant Warmer and Electric Breast Pump.

