Bio Signal Total Solution

Fetal Monitor
Fetal & Vascular Doppler
Patient Monitor
Infant Incubator
Infant Warmer
Phototherapy
Breast Pump
Thermometer
Head Lamp

bistos

Fetal Monitor

BT-380 Fetal & Maternal Monitor

- 1MHz Frequency with Twin Doppler
- 10.1" Color Touch Screen
- Fetal Monitoring : FHR, UC, DECG
  Maternal Monitoring : ECG, NIBP, SpO2, TEMP
- Option: DECG, Rechargeable battery, Acoustic Stimulator, Wifi, Cart

BT-350 LCD Fetal Monitor

- 1MHz Frequency with Twin Doppler
- 7" color TFT LCD Display
- CTG Analysis
- Option : Rechargeable battery, Acoustic Stimulator, Carrying bag, Cart

BT-350 LED Fetal Monitor

- 1MHz Frequency with Twin Doppler
- Large 7 Segment LED Display
- Waterproof Probe (IPX 8)
- Option : Rechargeable battery, Acoustic Stimulator, Carrying bag, Cart

BT-300 LED Fetal Monitor

- 1MHz Frequency with Twin Doppler
- Waterproof Probe (IPX 8)
- Option : Rechargeable battery, Acoustic Stimulator, Carrying bag, Cart

Fetal & Vascular Doppler

BT-200 Fetal Doppler

- 2/3 MHz Frequency
- Various Display Type (Sound only, LCD, Color)
- Waterproof Probe
- FHR and Sound management

BT-220 Fetal Doppler

- 2/3 MHz Frequency
- 2.4" Color LCD Display with FHR Trend Display
- Acoustic Stimulator Function
- BMI and Body fat Analysis

BT-250 Fetal Doppler

- 2/3 MHz Frequency
- 3.2" color TFT LCD Display with FHR Trend Display
- Rechargeable Battery

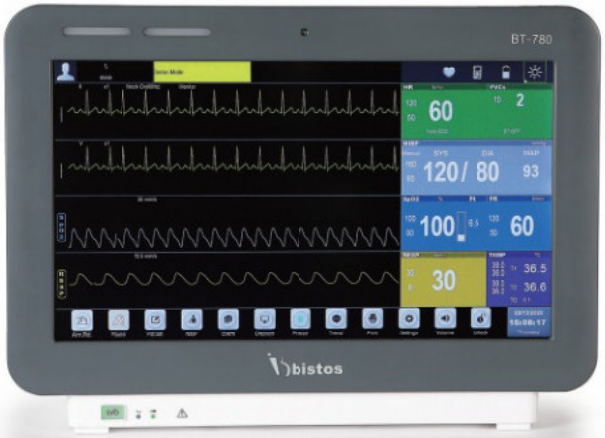
BT-200 Vascular Doppler

- 2, 4, 5, 8 MHz Frequency
- LCD Display
- Interchangeable Waterproof Probe
- Low Battery Indicator

Patient Monitor

BT-780 Patient Monitor

- ECG, Resp., SpO2, NIBP, Temp., CO_2, IBP, Multi-gas, C.O.
- 15.6" Color Touch Screen
- Ultra slim design
- 5 hours operation on battery
- Smart Hook & stand
- HL 7 support
- Option : CO_2, IBP, Multi-gas, C.O., Printer, Masimo SpO2, WIFI



BT-770 Patient Monitor

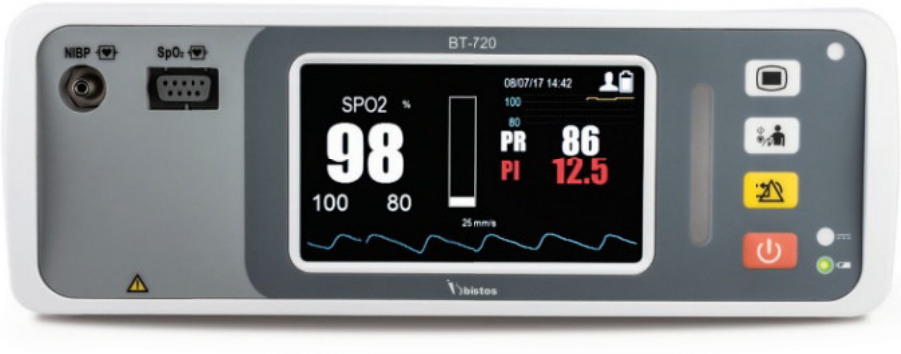
- ECG, Resp., SpO2, NIBP, Temp., CO_2, IBP, Multi-gas, C.O.
- 12.1" Color Touch Screen
- Ultra slim design
- 5 hours operation on battery
- Smart Hook & stand
- HL 7 support
- Option : CO_2, IBP, Multi-gas, C.O., Printer, Masimo SpO2, WIFI

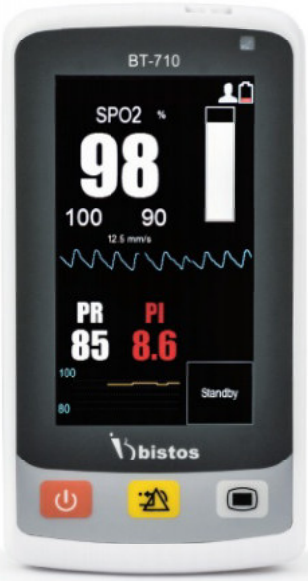
BT-740 Patient Monitor

- ECG, Resp., SpO2, NIBP, Temp., CO_2, IBP, Multi-gas, C.O.
- 8.4" Color Touch Screen
- Ultra slim design
- 6 hours operation on battery
- Smart Hook & stand
- HL 7 support
- Option : CO_2, IBP, Multi-gas, CO, Printer, Masimo SpO2, WIFI

BT-720 Vital Sign Monitor

- SpO2, Pulse
- 4.3″ Color Touch Screen
- 8 hours operation on battery
- Fan-less design
- Rechargeable by USB charger
- Option : NIBP, Temp





BT-710 Pulse Oximeter

- SpO2, Pulse
- Hand-held design
- 4.3″ Color Touch Screen
- 8 hours operation on battery
- Fan-less design
- Rechargeable by USB charger
- Option : CO_2

BT-750 Patient Monitor

- ECG, Resp., SpO2, NIBP, Temp., CO_2, IBP
- 10.4″ Color LCD Display
- 4 hours operation on battery
- Multi language support
- Option : CO_2, IBP, Printer, LAN, Cart, Wall mount

Neonate Care

BT-500 Infant Incubator

- Air / Skin Temperature servo control
- Humidity Servo Control
- Tilting bed
- Option : O2 Servo Control, O2 Monitoring, Masimo SpO2 & CCD Camera & External monitor, Lifting Stand, Weighing scale, Basket, IV Plate, IV Pole, Shelf

BT-550 Infant Warmer

- Infrared Heater
- Pre-warm / Baby / Manual Mode
- APGAR Timer
- Option : Tilting, Masimo SpO2, Lifting Stand, Weighing scale, Basket, IV Plate, IV Pole, Oxygen delivery, Suction

BT-400 Phototherapy

- Blue LED Lamp
- Intensity Control (High/Low)
- 100,000 hours LED lifetime
- Timer function

BT-450 Phototherapy

- Blue LED (455 nm to 465 nm)
- Intensity Control (High/Low)
- Blanket Type
- 10 hours operation on battery
- Alarm for High Temperature

BT-100 Breast Pump

- Portable Type with Dual Pumping
- Massage / Expression / Memory Mode
- Backflow Prevention
- BPA / Latex Free

BT-150 Breast Pump

- Desktop Type with Dual Pumping
- Massage / Expression / Program Mode
- Various Vacuum Level and Cycle Control
- Option : Carrying bag, Car charging cable,
  Nursing Night Lamp, Additional bottle set,
  Rechargeable battery, Bluetooth for mobile app

Non-Contact Thermometer

- Fever Alert Function (Blue/Red Color)
- Measurement of Body and Object
- Protective Cap for Sensor (BT-35)
- Faster Measurement Time (BT-36)

BT-410 Head Lamp

- Power LED Light with 6,000K Color Temperature
- Adjustable illumination (BT-410F)
- Adjustable Light Spot (BT-410A)
- Option: Loupe, Astral Lamp, Additional battery

BIO SIGNAL TOTAL SOLUTION

Bistos Co., Ltd. (Headquarter)

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E-mail. info@bistosamericainc.com

Specifications : BT-780 15.6" Multi-parameter Patient Monitor

Functional Characteristics	
Display	
Type	Color TFT touch screen LCD
Size and resolution	15.6", 1366 x 768 pixels
LED	
Alarm indicator	Yellow & red
Adaptor power indicator	1 green
Battery status indicator	1 green
Audio	
Speaker	Alarm sound (45 ~ 85dB), key pressing sound
	QRS sound, PR sound
	Alarm sound meets the IEC60601-1-8
Data Storage	
Trend	168hours, resolution : 1min
Alarm event	200 physiological and 100 technical alarm events
NiBp measurement result	1,000 groups
Function	
Multi-language	English, Turkish, Spanish, French, Polish, German, Italian, Hungarian
Trend	Graphic/tabular
Alarm	
Mode	Visual, audible, information, parameter flashing
Alarm delay	Off, 1s, 2s, 3s, 4s, 5s, 6s, 7s, 8s
Pause duration	1, 2, 3, 4, 5, 10, 15min or permanent
System	Low battery
Interface	
Auxiliary	Nurse call
RJ45 (LAN)	CMS
USB	S/W upgrade
ECG	
Standard compliance	IEC60601-2-27
Lead type	3Lead : I, II, III
	5Lead : I, II, III, aVR, aVL, aVF, V
Display sensitivity (gain)	Auto, 1.25, 2.5, 5, 10, 20mm/mV
Wave sweep speed	12.5, 25, 50mm/s
Band width	Diagnostic mode : 0.05 ~ 130Hz
	Monitoring mode : 0.5 ~ 40Hz
	Surgery mode : 1 ~ 25Hz
	Strong filter mode : 5 ~ 20Hz
CMRR	> 100dB
Notch	50/60Hz (can be set on or off)
Differential input	> 5MΩ
Electrode polarization voltage range	±400mV
Baseline recovery time	< 5s after defibrillation (monitor and surgery mode)
Calibration signal	1mV (peak-peak), accuracy ±3%
Lead-off detection current	Measuring electrode : < 0.1μA
	Drive electrode : < 1μA
HR measuring range	Adult : 15 ~ 300bpm
	Pediatric/Neonate : 15 ~ 350bpm
HR measuring resolution	1bpm
HR measurement accuracy	±1bpm or ±1%, whichever is greater
HR accuracy & response to irregular rhythm	Ventricular bigeminy : 80±1bpm
	Slow alternating ventricular bigeminy : 60±1bpm
	Rapid alternating ventricular bigeminy : 120±1bpm
	Bidirectional systoles : 90±2bpm

HR time to alarm for tachycardia	0.5/1/2mV, 206bpm ventricular tarchycardia : < 10s
	1/2/4mV, 195bpm ventricular tarchycardia : < 5s
HR alarm upper limit (bpm)	Adult : 16 ~ 300, 1bpm step
	Pediatric/Neonate : 16 ~ 350, 1bpm step
HR alarm lower limit (bpm)	Adult : 15 ~ 299, 1bpm step
	Pediatric/Neonate : 15 ~ 349, 1bpm step
Pacing pulse identification	Detection range : ±2mV ~ ±700mV
	Pulse width : 0.2ms ~ 2.0ms
Pacing pulse average HR	15s data
Pacing pulse interval of HR Refreshing	Every second
Pacing pulse HR change response time	≤ 10sec
Pacing pulse tall T-wave suppression	2mV
Alarm	Communication, configuration, selfcheck error
	Lead off
	HR high/low, PVCS high
	Asystole, VF/VTA, R on T, Tachycardia/bradicardia, PVC frequent/couplet/singlr/bigeminy/trigeminy, Miss Beat
	Pacemaker not capture/work
	Signal weak, ST-I, II, II high/low
Respiration	
Measurement method	Trans-Thoracic impedance
Operation modes	Auto
Measuring lead	Lead RA-LA, RA-LL, LA-RL, LL-RL
Wave gain	X0.5, x1, x2
Respiratory impedance range	0.2 ~ 3 Ω
Base line impedance	500 ~ 2,000Ω
Sensitivity	1,2,3,4,5
Wave sweep speed	6.25mm/s, 12.5mm/s, 25mm/s
Measurement accuracy	±2rpm
Measurement range	0 ~ 120rpm
Alarm	RR high/low
	Apnea
	Respiration artifact
Temperature	
Standard compliance	ISO80601-2-56
Measurement method	Thermistor
Measuring range	0℃ ~ 50.0℃ (32℉ ~ 122.0℉)
Resolution	0.1℃
Measurement accuracy	±0.1℃ or ±0.2℉ (without probe)
Number of channel	2
T1/T2 alarm upper limit	0.1℃ ~ 50.0℃, 0.1℃/℉ step
T1/T2 alarm lower limit	0℃ ~ 49.9℃, 0.1℃/℉ step
Temperature difference alarm upper limit	0℃ ~ 50.0℃, 0.1℃/℉ step
Alarm	T1, T2 Sensor off
	T1/T2 high/low, TD high
NiBp	
Standard compliance	IEC80601-2-30
Measurement method	Automatic oscillometric method
Operating mode	Manual, automatic, continuous(STAT)
Useful life	100,000 times
Measurement interval in automatic mode	1/2/3/4/5/10/15/30/60/90/120/180/240/480min
Typical measurement time	20~40s
Normal mode measuring range (mmHg)	Systolic : Adult(30~280), Pediatric(30~230), Neonate(30~145)
	Mean : Adult(10~240), Pediatric(10~175), Neonate(10~115)
	Diastolic : Adult(10~220), Pediatric(10~165), Neonate(10~105)
Measurement accuracy	Maximum average error: ±5mmHg
	Maximum standard deviation: 8mmHg
Resolution	1mmHg

Initial inflation pressure (mmHg)	Adult : 160 (default) Pressure setting range:140mmHg, 160mmHg, 180mmHg
	Pediatric : 140 (default) Pressure setting range:140mmHg, 160mmHg
	Neonate : 100 (default) Pressure setting range:100mmHg, 120mmHg
Overpressure protection point (software)	Adult: 300mmHg
	Pediatric: 240mmHg
	Neonate: 150mmHg
Overpressure protection point (hardware)	Adult: 320~330mmHg
	Pediatric: 265~275mmHg
	Neonate: 160~165mmHg
Static Pressure accuracy	±3mmHg
Supply voltage	10V~14VDC
Maximum power consumption	3.6W
Quiescent current	50mA
Maximum current during measurement	180mA
Maximum current during inflation	300mA
Alarm	Communication, selfcheck, CFG error
	System error, measurement timeout
	Cuff loose, no, leak, type error
	Air pressure error
	Over range, signal weak/unstable/saturated
	Over pressure
	Module reset failed
	Systolic, mean, diastolic high/low
SpO2	
Standard compliance	ISO80601-2-61
Display range	0% ~ 100%
SpO2 display resolution	1%
SpO2 accuracy	Adult/Pediatric : 70 ~ 100% ±2%
	Neonate : 70 ~ 100% ±3%
	0 ~ 69% : Unspecified
Wave sweep speed	12.5mm/s, 25mm/s
Wave mode	Scan, fill
Pulse volume	0, 1, 2, 3, 4, 5, 6, 7, 8, 9 level
SpO2 alarm preset limits	Upper Alarm Limit : 86% ~ 100%
	Lower Alarm Limit : 85% ~ 99%
SpO2 alarm preset accuracy	±1%
SpO2 alerting signal generates delay	Off,1s,2s,3s,4s,5s,6s,7s,8s
SpO2 value refresh period	1s/time
SpO2 value refresh delay	< 10s
Average period	Low Sensitivity : 7 ~ 8s
	Intermediate Sensitivity : 4 ~ 6s
	Advanced Sensitivity : 2 ~ 3s
Perfusion index	0.05 ~ 20%
PR Measurement Range	25 ~ 250 bpm
PR Resolution	±1 bpm
PR Measurement accuracy	±2% or ±2bpm, whichever is greater
Alarm	Communication stop/error
	No sensor/ sensor off
	Search timeout
	Search pulse(weak)
	SpO2, RR high/low
IBP (Option)	
Standards compliant	IEC60601-2-34
Channel	2-ch, 4-ch
Pressure measurement range	-50 ~ 400 mmHg

Pressure measurement accuracy	±3 mmHg or±2%, whichever is greater
Pressure resolution	1 mmHg
PR measurement range	35 ~ 250 bpm
PR measurement accuracy	±3bpm
PR resolution	1bpm
Transducer sensitivity	5μV/V/mmHg
Transducer resistance range	300-3,000Ω
Supply voltage	+12VDC
Maximum power consumption	≤5W
Scan speed	12.5mm/s, 25mm/s
Alarm	IBP1, 2 communication stop/error
	IBP1, 2 sensor off
	Art-sys, PA-sys, P1-sys, P2-sys high
	Art-dia, PA-dia, P1-dia, P2-dia high
	Art-mean, PA-mean, CVP-mean, LAP-mean, RAP-mean, ICP-mean, P1-mean, P2-mean high
EtCO2 Mainstream & Sidestream (Option)	
Measurement parameters	EtCO2、FiCO2、AwRR
Measuring range	0-15%
Accuracy	±0.2%+2% of the reading
Resolution	EtCO2/FiCO2 : 1mmHg, AwRR : 1rpm
Rise time	200ms, typical at 50ml/min flow rate
Total response time	within 3 seconds(within 2m Nomoline sampling)
AWRR range	0-150bpm
AWRR Accuracy	±1 breath
Apnea delay	20s, 25s, 30s, 35s, 40s, 45s, 50s, 55s, 60s
Warm-up time	Full accuracy within 10 seconds
Sampling flow rate	50ml/min(+/-10ml/min)
Operating mode	Standby, measure
O2 compensation	Low, mid, high
N2O compensation	On, off
Alarm limit	EtCO2 lower limit : 0~149mmHg
	EtCO2/FiCO2 upper limit : 1~150mmHg
	AWRR lower limit : 0~119rpm
	AWRR upper limit : 1~120rpm
Alarm	Communication stop/error
	CO2 sensor off/error
	O2 sensor error/replace
	adaptor/sampling line no/check
	Parameter accuracy error
	O2, Air calibration error
	S/W, H/W error
	Motor accuracy error
	CO2 factory calibration error
	Adaptor, sampling line replace
	O2 port error
	CO2, O2, N2O out of accuracy
	CO2 temp., pressure out of accuracy
	CO2 zero required
	CO2 zeroing/sleeping
	CO2 module calibrating/calibration error
	EtCO2, FiCO2, AWRR high/low
	Apnea
C.O. (Cardiac Output : Option)	
Method	Thermodilution
Measurement range	C.O. : 0.2 ~ 20 L/min
	BT : 23 ~ 45℃±0.5 ℃
	IT : 0 ~ 20℃±0.5 ℃

Resolution factor	C.O. : 0.1L/min
	BT, IT : 0.1℃
Accuracy	C.O. : ±10%
	TB, TI : ±0.5℃
Scope of alarm limit	BT high limit : (Low limit +0.1) ~ 43℃
	BT low limit : 23.0 ~ (high limit -0.1) ℃
	Step size : 0.1℃
Alarm	BT sensor off
	BT high/low
	C.O. high
Printer (Option)	
Type	Thermal dot array
Print speed	12.5, 25, 50mm/s
Paper size	50mm(W) x 2m
Power	
Adaptor	Input : AC 100 ~ 240V (50/60Hz)
	Input Current: 1.6-0.6A
Consumption	13.5W
Rechargeable battery	11.1V Li-ion 4,400mA
	Operating Time : 5hrs
	Charging Time : 4hrs
Standard Configurations	
ECG cables and lead wire	1ea (5lead)
ECG electrode for adult	1pack (25pcs)
SpO2 adult reusable sensor	1ea
SpO2 extension cable	1ea
NiBp adult cuff	1ea
NiBp extension tube	1ea
Temperature sensor	1ea
Power adaptor	1ea
Bracket	1ea
Operation manual	1ea
Options (Function)	
IBP	Sensor cable & package
EtCO2 Mainstream (Bistos)	Airway adaptor & module
EtCO2 Sidestream (Bistos)	Sampling tube
EtCO2 IRMA Mainstream (Masimo)	Airway adaptor & module
EtCO2 ISA Sidestream (Masimo)	Sampling tube
C.O.	Sensor cable
Printer	Printer & paper
Cart	
Options (Accessory)	
ECG cables and lead wire	5/3 lead
ECG electrode	adult/neonate
SpO2 reusable sensor	adult/pediatric/neonate
SpO2 disposable sensor	adult/pediatric/neonate
Skin & rectal temperature sensor	adult/pediatric/neonate
NiBp cuff	adult(27~35cm)/pediatric(14~21.5cm)/neonate(4*9cm)
Physical Characteristics	
Dimension	
Main unit	410(W) X 298(H) X 120(D)
Packing	495(W) x 295(D) x 385(H)mm
Weight	
Main unit	< 4.9Kg
Packing	7kg
Environmental Conditions	
Operating temperature	5 ~ 40°C (41 ~ 104°F)
Operating humidity	30 ~ 85% non-condensing

Storage temperature	–20 ~ 60°C (–4 ~ 140°F)
Storage humidity	0 ~ 95% non-condensing
Warranty	
Main unit	2 years
Optional sensor & accessory	1 year
Certificates	
KFDA, CE	

EC CERTIFICATE
Full Quality Assurance System

Certificate No.: 243269-2017-CE-KOR-NA-PS Rev. 4.0 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

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

Place and date:
Høvik, 26 April 2021

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

Check Validity

Eugenie Winger Husebye
Technical Reviewer

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**

Products covered by this Certificate:

Product Description	Product Name	Class
Fetal monitor	▪ BT-200 ▪ 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

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

For the issuing office:
DNV Product Assurance AS

Tone Kolpus

Tone Elise Kolpus
Lead Auditor

Check Validity

NORWEGIAN ACCREDITATION

MSYS 018

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.