No. DOC - 700 - M05

EC Declaration of Conformity

We, **Bistos Co., Ltd.**, (7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea) hereby declare that medical device described hereafter:

Product : Patient monitor

GMDN code : 33586

Classification: IIb (according to Rule 10 of Annex IX of Council Directive 93/42/EEC as amended by 2007/47/EC)

EC Representative : Obelis s.a. (Bd. Général Wahis 53 1030 Brussels / BELGIUM**)**

- is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by 2007/47/EC.
- is subject to the procedures set out in Annex II excluding section 4 of Council Directive 93/42/EEC as amended by 2007/47/EC under the supervision of Notified Body 2460, DNV GL Nemko Presafe AS: Veritasveien 3 1363 Høvik Norway. (Certificate no.: 243269-2017-CE-KOR-NA-PS Rev. 2.0)
- is in conformity with the harmonized standards.

This declaration is supported by following Quality Management System certification:

Certification No. 243275-2017-AQ-KOR-NA-PS Rev.2.0

- is complies ISO 13485:2016/NS-EN ISO 13485:2016 requirements
- is issued by DNV GL NEMKO PRESAFE AS (Veritasveien 3, N-1363 Høvik, Norway)

This declaration of conformity is issued under the own responsibility of the manufacturer.

Date of issue: April 16, 2019
Signed for and on behalf of
Bistos Co., Ltd.

박종혁

Jonghyuk, Park
Quality Management Representative

ATTACHMENT 1. MODEL LIST

Categories	Model No.
Patient Monitor	BT-720, BT-740 and BT-770
With the following Accessories	ECG 3-Lead ECG wires and cable 5-Lead ECG wires and cable ECG electrode
	SpO2 SpO2 sensor and extension probe
	NIBP NIBP cuff and cuff connection Gas path connector and Gas pipe for blood pressure cuff
	Temperature Temperature probe
	External plug-in printer