

## 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 : Ultrasound Doppler System and probes**

(See attachment 1)

**GMDN Code:** 34040, Foetal Doppler system and 41917, Foetal Doppler system probe

**Classification: IIa** (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 Product Assurance AS: Veritasveien 3 1363 Høvik Norway. (Certificate no.: 243267-2017-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.6.0

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

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

Place of Issue: Gyeonggi-do, Korea

Date of Issue: November 23, 2022

Signed for and behalf of Bistos Co., Ltd

Hyeon Ju Oh

Person Responsible for Regulatory Compliance



Head office : 7<sup>th</sup> Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

Factory

: 104~109ho & 116~122ho, Jungang Induspia 3, 27, Sagimakgol-ro 105beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

**Attachment 1. Model list**

Trade name	Model No.	Probes
HI-bebe	BT-200L	AY-DOP-200L(2M)
	BT-200C	AY-DOP-200C(2M)
	BT-200S	AY-DOP-200S(2M)
	BT-200T	AY-DOP-200T(3M)
HI-dop	BT-200V	AY-DOP-200V(2M) AY-DOP-200V(4M) AY-DOP-200V(5M) AY-DOP-200V(8M)

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