No. DOC - 200 - 10

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 (GMDN Code: 34040)

Model No. : BT-200

Accessories : Foetal Doppler system probes (GMDN Code: 41917)

(AY-DOP-200L(2M), AY-DOP-200C(2M), AY-DOP-200S(2M), AY-DOP-200T(3M), AY-DOP-200V(4M), AY-DOP-200V(5M), AY-DOP-200V(8M)**)**

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 GL Presafe AS: Veritasveien 3 1363 Høvik Norway. (Certificate no.: 243267-2017-CE-KOR-NA-PS Rev. 1.0)
- 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 PRESAFE AS (Veritasveien 3, N-1363 Høvik, Norway)

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

Date of issue: June 11, 2019
Signed for and on behalf of
Bistos Co., Ltd.

박종혁

Jonghyuk, Park
Quality Management Representative