No. DOC - 400 - 13

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 : Neonatal Phototherapy Unit

Model No. : BT-400

GMDN code : 35239, Overhead infant phototherapy unit

Classification: IIa (according to Rule 9 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.: 243269-2017-CE-KOR-NA-PS Rev. 5.0)
- 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.3.0

- 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 own responsibility of the manufacturer.

Place of Issue: Gyeonggi-do, Korea
Date of Issue: May 3, 2021

Signed for and behalf of Bistos Co., Ltd

정혜선

Hyesun Jeong, RA