

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
243275-2017-AQ-KOR-NA-PS

Initial certification date:
12 August 2004

Valid:
26 February 2025 – 09 September 2027

This is to certify that the management system of

Bistos Co., Ltd.

7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si,
Gyeonggi-do, 13201, Republic of Korea

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016 / 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, Electric Breast Pump and Infrared Thermometers

Place and date:
Høvik, 26 February 2025



For the issuing office:
DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

Appendix to Certificate

Bistos Co., Ltd.

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
Bistos Co., Ltd.	7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13201, Republic of 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, Electric Breast Pump and Infrared Thermometers
Bistos Co., Ltd. (Factory)	522, Geumeo-ro, Pogok-eup, Cheoin-gu, Yongin-si, Gyeonggi-do, 17030, Republic of Korea	Manufacturing of Ultrasound Doppler system, Fetal monitor, Phototherapy, Patient Monitor, Pulse Oximeter, Incubator, Head-worn light, Infant Warmer and Electric Breast Pump and Infrared Thermometers