

CE CERTIFICATE OF CONFORMITY  
WITH EUROPEAN DIRECTIVE



Certificate No.: EU1211401  
Order No.: 186187

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 1690 of 15<sup>th</sup> December 2005 relating to medical devices pursuant to act no. 6 of 12<sup>th</sup> January 1995 relating to medical devices, transposing directive 93/42/EEC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the Annex given below:

Name and address of the manufacturer: Bistos Co., Ltd.  
7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302,  
Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do  
Korea

Device category: Conventional Infant Incubator. MD 1302, Monitoring devices of vital physiological parameters

GMDN code: 36025

Models: BT- 500

Risk class as defined by the manufacturer: IIb

Standards/provisions: The audit of the quality system was based upon and assessed according to the provisions in Annex II of the EC-Directive 93/42/EEC, with the exemption of section 4.

Date of audit: 2012-08-22


Date of the end of the validity: 2017-12-01

Nemko EC notification No.: 0470

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC directive will be fulfilled by the manufacturer and the factory. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

Date of issue: 2012-11-09

Date of verification: 2012-11-09

  
Signature: Ragnar Stranger Christiansen  
Lead assessor

  
Signature: Arild R. Hansgård  
Lead auditor /Principal Engineer