

EC Declaration of Conformity (in accordance with ISO/IEC 17050-1)



Issuer's name : Bistos Co., Ltd.

Issuer's address : 7th Fl., A Bldg., Woolim Lions Valley 5-cha, 144-3, Sangdaewon-dong, Jungwon-gu,
Seongnam-si, Gyeonggi-do, Korea

Object of the declaration :

Product name : Cardiotocograph with Fetal Doppler System probes and Cardiotocograph transducers

Model Name : BT-350

The object of the declaration described above is in conformity with the requirements of the following documents :

Has been classified as Class IIa (Annex IX Rule 10) and is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by directive 2007/47/EC is subject to the procedures set out in Annex II of Directive 93/42/EEC as amended by directive 2007/47/EC under the supervision of Notified Nemko AS

Document No.	Title	Edition / Date of Issue
NK-11-SM-0389	General requirements for basic safety and essential performance(IEC 60601-1:2005 + CORR.1(2006) + CORR.2(2007))	24 Oct. 2011
NK-11-E-217	EMC Test Report(IEC60601-1-2:2007 Third Edition)	03 June 2011
NK-11-SM-0389-1	IEC60601-2-37:2007 (Second Edition) Test Report	24 Oct. 2011
EU1308401	Certificate of Conformity with European Directive	15 Aug 2013

Additional Information

- 1) Testing Lab. : NEMKO KOREA Co., Ltd. (Yong-In City, Republic of KOREA)
- 2) Certification Notified Body : NEMKO AS (NB. No. : 0470)

Signed for and on behalf of :
Bistos Co., Ltd. In KOREA

EC Representative
Medical Econet GmbH
Im Erlengrund 20 D-46149 Oberhausen
/ Germany

Hoo-Jeong Lee, CEO of BISTOS Co., Ltd.

(30 Sep, 2013)

Head office : 7th Fl., A Bldg., Woolim Lions Valley 5-cha, 144-3, Sangdaewon-dong, Jungwon-gu,
Seongnam-si, Gyeonggi-do, Korea