

EC Declaration of Conformity

Manufacturer:

1F, No. 3, Industrial E. 9th Rd., Science-Based Industrial Park, HsinChu, Taiwan 300.

No.20, TaiHong Road, WuSongJiang Development Zone, YuShan Town, KunShan City, JiangSu, China.

We, the manufacturer, herewith declare that the product

Infrared Ear/Forehead Thermometer Model name:

- TH10F - NUK THERMOMETER FLASH

-Customer and Distributor Brand name: NUK

-Customer and Distributor name: MAPA GmbH, 27404 Zeven, Industriestraße 21-25, Germany,

Authorized European Representative:

Medical Technology Promedt Consulting GmbH

Altenhofstrasse 80, D-66386 St. Ingbert, Germany

meets the provisions of Directive 93/42/ECC 2007 which apply to it. All supporting documentation is retained under the premises of the manufacturer.

Applied harmonised standards, national standards or other normative documents:

EN 1041:2008, EN ISO 15223-1:2012, EN 60601-1-2:2007/AC:2010, EN 60601-1:2006/AC:2010, EN 60601-1-11:2010, EN ISO 14971:2012, EN 12470-5:2003, ASTM E1965-98(2009), EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN 60601-1-6:2010, EN 62304:2006/AC:2008, EN 62366:2008, EN ISO 80601-2-56:2012

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to Annex II, without the Annex II.4, of Directive 93/42/EEC, and the essential requirement of Annex I pertaining to medical devices.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

SGS United Kingdom Ltd
202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK
Country : United Kingdom
Certificate No.: TW11/10106
Issue date: Feb 16, 2011
Expiry date: Feb 16, 2016

Following the procedure relation to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

The above mentioned declaration of conformity is exclusively under the responsibility of

Radiant Innovation Inc.

Place, date

Sep, 16-2015

James Huang / General Manager

Legally binding signature, Function