

EC Declaration of Conformity

Manufacturer:

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

KunShan Radiant Innovation Co., Ltd.
No.20, TaiHong Road, WuSongJiang Development
Zone, YuShan Town, KunShan City, JiangSu, China.

Authorized European Representative:
**Medical Technology Promedt Consulting
GmbH**

Altenhofstrasse 80, D-66386 St. Ingbert, Germany

We, the manufacturer, herewith declare that the product

Infrared Forehead Thermometer Model name:

- **THI0KZ - NUK FEVER THERMOMETER 3IN1**

- **THI0F - NUK FEVER THERMOMETER FLASH**

- **Customer and Distributor Brand name: NUK**

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

meets the provisions of Directive 93/42/ECC which apply to them.

Applied harmonised standards, national standards or other normative documents:

**EN 1041:2008, EN ISO 15223-1:2016, EN 60601-1-2:2015, EN 60601-1:2006+A1:2013,
EN 60601-1-11:2015, EN ISO 14971:2012, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009,
EN ISO 10993-10:2013, EN 60601-1-6:2010, EN 62304:2006/AC:2008, EN 62366:2008,
EN ISO 80601-2-56:2012, EN 12470-5:2003**

The medical device has been assigned to class IIa according to Annex IX Rule 10 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

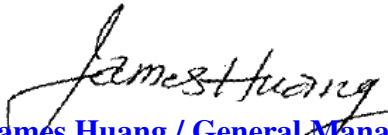
Expiry date: Feb 16, 2022

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

Radiant Innovation Inc.

Hsinchu, Sep. 24, 2019

Place, date


James Huang / General Manager
Legally binding signature, function