

EC Declaration of Conformity

Manufacturer:

Radiant Innovation Inc.

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

whose single Authorized Representative:
Medical Technology Promedt Consulting GmbH

Altenhofstrasse 80, D-66386 St. Ingbert, Germany

Additional facilities:

KunShan Radiant Innovation Co., Ltd.

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

We, the manufacturer, herewith declare that the products

Infrared Forehead Thermometer:

- **THIOF – NUK FEVER THERMOMETER FLASH**
- **PO# 45419574**
- **Firmware Version 0179**
- **Customer and Distributor Brand name: NUK**
- **Customer and Distributor name: MAPA GmbH, 27404 Zeven, Industriestraße 21-25, Germany**

meet the provisions of Directive 93/42/EEC which apply to them.

Applied harmonised standards, national standards or other normative documents

EN 1041:2008+A1:2013, EN ISO 15223-1:2016, EN 60601-1:2006+A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010+A1:2015, EN 60601-1-11:2015, EN 62304:2006+A1:2015, EN 62366:2008+A1:2015, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 14971:2012, EN ISO 80601-2-56:2012, EN ISO 13485:2016

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 Belgium NV
Noorderlaan 87 2030 Antwerpen
Country : Belgium
Certificate No.: TW19/20026
Issue date: Feb 16, 2011
Expiry date: Feb 16, 2023

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

Radiant Innovation Inc.

A handwritten signature in black ink, appearing to read 'Micheline WU', written over a horizontal line.

Micheline WU / Account Manager

HsinChu , January 4, 2022

Place , date

Legally binding signature, Function