

## EC Declaration of Conformity

Manufacturer:

**Radiant Innovation Inc.**

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

Additional facilities:

**KunShan Radiant Innovation Co., Ltd.**

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

whose single Authorized Representative:

**Medical Technology Promedt Consulting  
GmbH**

Ernst-Heckel-Straße 7, 66386 St. Ingbert,  
Germany

We, the manufacturer, herewith declare that the products

**Infrared Ear/Forehead Thermometer:**

**TH709LE, TH809E, TH809S, TH809J, TH819SJE, TH839S, TH889S, TH889SE, TH889J, THi09Z, THP59J(U),  
THP79JU, THP59JB, THWB7N, TH03F, THi0F, THD2FE, THAC2F, TH02F, TH50Z, TH520, TH52Z,  
THAD0K, THCT0K, THi0K, THi0KZ.**

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 15223-1:2021, 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 62366-1:2015+A1:2020, EN ISO 10993-1:2020, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 14971:2019, EN ISO 80601-2-56:2017+A1:2020, EN 12470-5:2003, 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: Dec 31, 2028

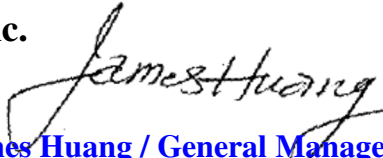
(Expiry date is according to REGULATION (EU) 2023/607)

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

**Radiant Innovation Inc.**

**Mar. 22, 2023 HsinChu**

Place , date

  
**James Huang / General Manager**

Legally binding signature, Function