

## 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.

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

We, the manufacturer, herewith declare that the products

**Infrared Ear/Forehead Thermometer:**

TH90K(E),TH709L(E),TH709T(E),TH109(E),TH809(E),TH839(E),TH889(E),TH10N(E),TH80N(E),TH83N(E),TH88N(E),TH10F(E),TH80F(E),TH83F(E),TH88F(E),TH03F,TH05F,TH06F,TH20F,TH22F,TH23F,TH005,TH007,TH008,TH500,TH50Z, TH520,TH560,TH56Z,TH01BN,TH01BF,TH60N,TH60F,TH839J,TH809J,TH889J,TH58F,TH59N,TH52Z,TH709L(E),TH709T(E),THA0F,THC0F,THP59JU,THP09J,THP39J,THP59J,THP89J,TH008A,TH008B,TH008F,TH007A,TH007B,TH007F,TH005,TH005B,TH005F,TH60NE,TH60FE,THM0F,THB0F,TH889S(E),TH809S(E),TH839S(E)

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

Applied harmonised standards, national standards or other normative documents

EN 1041:2008,EN ISO 14155-1:2009,EN 980:2008,EN 60601-1-2:2007,EN 60601-1:1990+A1+A2,EN 60601-1:2006,EN 14971:2009,EN 12470-5:2003,ASTM E1965-98(2003),EN ISO 10993-1:2009,EN ISO 10993-5:2009,EN ISO 10993-10:2010,EN 60601-1-6:2010,EN 62304:2006,EN 62366:2008,EN 60601-1-4:1996+A1

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

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

**Radiant Innovation Inc.**

**Dec. 14, 2011 HsinChu**

Place, date

  
**Chu-Chien Feng / Chairman**  
Legally binding signature, Function