

The management system of

## Radiant Innovation Inc.

1F, No. 3, Industrial E. 9th Rd., Science-based industrial park  
HsinChu 300, Taiwan, R.O.C.

has been assessed and certified as meeting the requirements of

### Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

**The scope of registration appears on page 2 of this certificate.**

This certificate is valid from 14 April 2015 until 16 February 2019 and  
remains valid subject to satisfactory surveillance audits.

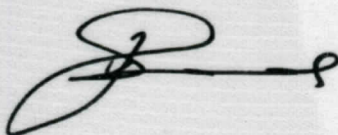
Re certification audit due before 20 January 2017

Issue 7. Certified since 16 February 2011

Certification is based on reports numbered K603835

This is a multi-site certification.  
Additional site details are listed on the subsequent page.

Authorised by



**SGS United Kingdom Ltd, Notified Body 0120**

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SGS CE 02 0315 M2

Page 1 of 2



# **Radiant Innovation Inc.**

## **Directive 93/42/EEC**

on medical devices, Annex II (excluding section 4)

Issue 7

Detailed scope

**Infrared Ear Thermometers with & without Probe Cover and Infrared Forehead Thermometers.**

TH90K, TH90KE, TH709L(E), TH709T(E), TH109, TH809, TH839, TH889, TH10N, TH80N, TH83N, TH88N, TH10F, TH80F, TH83F, TH88F, TH03F, TH05F, TH06F, TH20F, TH22F, TH23F, TH005, TH007, TH008, TH500, TH50Z, TH520, TH560, TH56Z, TH01BN, TH01BF, TH60N, TH60F, TH839J, TH889J, TH58F, TH59N, TH52Z, THA0F, THC0F, THB0F, THP59JU, THP09J, THP39J, THP59J, THP89J, THM0F, TH889S(E), TH809S(E), TH839S(E), TH30F, THi0K, THi0KZ, THP79JU THMC09, THMC09E, THMC09P, TH36F, THMC2FE, THD2FE, THD2FA

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

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

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