EC Certificate Full Quality Assurance System: TW11/10106



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

SGS United Kingdom Ltd Systems & Services Certification 202B Worle Parkway, Weston-super-Mare, BS22 6WA UK t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

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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, TH10K, TH10KZ, 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