SGS

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

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 16 February 2014 until 16 February 2019 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 20 January 2017 Issue 4. 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 01 0311 M2

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EC Certificate Full Quality Assurance System: TW11/10106, continued

Radiant Innovation Inc.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 4

Detailed scope

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

For placing on the market of Class III devices covered by this certificate, an EC Design Examination

Certificate according to Annex II (Section 4) is required.

Additional facilities

KunShan Radiant Innovation Co., Ltd.

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