EC Certificate Full Quality Assurance System: Certificate TW19/20026

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 27 April 2021 until 16 February 2023
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 16 February 2011

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

Certification is based on reports numbered TW/TPE K603835

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Radiant Innovation Inc.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 2

Detailed scope

Infrared Ear Thermometers with & without Probe Cover and Infrared Forehead Thermometers for measuring human body temperature.

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