

EU Quality Management System Certificate TW24/00000261

The management system of

Radiant Innovation Inc.

SGS

1F, No. 3, Industrial E. 9th Rd., Science-Based Industrial Park HsinChu, 300, Taiwan
SRN Number: TW-MF-000007935

has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 23 July 2024 until 26 March 2029 and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 26 March 2024



Authorised by

Virginie Siloret

Global Medical Device

Certification Manager

SGS Belgium NV NB1639

SGS House Noorderlaan 87 2030 Antwerp Belgium

t +32 (0)3 545-48-48 - www.sgs.com

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Radiant Innovation Inc.

MDR EU Quality Management System certificate (Annex IX QMS)

Issue 3

Class IIa

MDA 0203, MDS1009, MDS1010

Non-contact Forehead Thermometer

(model: THD2FE, THAC2F, THi0F, TH02F, TH03F, TH09F, Thermoeas(02023033000000), THD2FE (00010796000000), 423035, THF850, 10256380)

Basic UDI-DI: 471081045IFTEB

Infrared Ear Thermometer

(model: TH709LE, TH809, TH809S, TH809J, TH819SJE, TH839S, TH889S, TH889SE, TH889J, THi09Z, THP59J(U), THP79JU, Comfort quick (00000656000000), MD1882, THIR-2, TH839, 42302041, THP59JU, 25575, 100-00102-00)

Basic UDI-DI: 471081045IETE8

Multi-function Infrared Thermometer

(model: THAD0K, THCT0K, THi0K, THi0KZ, TH50Z, TH520, TH52Z, UT-801, CTD711)

Basic UDI-DI: 471081045MFIT8T

Conditions for & limitation to the validity of the certificate:

For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available "on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - TW/TPE/613333 - S2A 1.2

Authorized representative name and address (if relevant): Medical Technology Promedt Consulting GmbH; Ernst-Heckel-StraBe 7, 66386 St. Ingbert, Germany

Previous certificate number: N/A

Change in between this certificate and previous one: correction of a typo mistake in authorized representative name



EU Quality Management System Certificate TW24/00000261,
continued

Radiant Innovation Inc.

SGS

MDR EU Quality Management System certificate (Annex IX QMS)

Issue 3

Sites

Radiant Innovation Inc.

1F, No. 3, Industrial E. 9th Rd., Science-Based Industrial Park HsinChu, 300, Taiwan

KunShan Radiant Innovation Co., Ltd.

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

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