

EC Declaration of Conformity

Manufacturer:

Radiant Innovation Inc.

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

whose single Authorized Representative:

**Medical Technology Promedt Consulting
GmbH**

Altenhofstrasse 80, D-66386 St. Ingbert, Germany

Additional facilities:

KunShan Radiant Innovation Co., Ltd.

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

We, the manufacturer, herewith declare that the products

Infrared Ear/Forehead Thermometer:

**TH90K(E), TH709L(E), TH709T(E), TH809(E), TH839(E), TH889(E), TH03F, TH05F, TH06F, TH20F, TH22F,
TH23F, TH005, TH007, TH008, TH500, TH50Z, TH520, TH52Z, TH560, TH56Z, TH01BN, TH01BF, TH60N(E),
TH60F(E), TH809J(E), TH839J(E), TH889J(E), TH58F, TH59N, THA0F, THC0F, THP59J(U), THP79J(U),
TH005F, THM0F, THB0F, TH809S(E), TH839S(E), TH889S(E), TH30F, TH36F, THi0K, THi0KZ, THi0F,
THMC09(E), THMC09P, THMC2FE, THD2F(E), THD2FA(E), THAC2F, TH859S(J), THAD0K, TH02F, TMS-01A,
THW07N, THWB7N, THCT0K, THCT0KX, THDR2F, TMS-51A, THP59JB, THP79JB, THP89JB, TH879S(J)**
meet the provisions of Directive 93/42/EEC which apply to them.

Applied harmonised standards, national standards or other normative documents

**EN 1041:2008+A1:2013, EN ISO 15223-1:2016, EN 60601-1:2006+A1:2013, EN 60601-1-2:2015, EN 60601-1-
6:2010+A1:2015, EN 60601-1-11:2015, EN 62304:2006+A1:2015, EN 62366:2008+A1:2015, EN ISO 10993-
1:2009/AC:2010, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 14971:2012, EN ISO 80601-2-56:2012,
EN 12470-5:2003, EN ISO 13485:2016**

The medical device has been assigned to class IIa according to Annex IX Rule 10 of the Directive
93/42/EEC. It bears the mark



The product concerned has been designed and manufactured under a quality management system according
to Annex II, without the Annex II.4, of Directive 93/42/EEC, and the essential requirement of Annex I
pertaining to medical devices

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the
Notified Body


SGS Belgium NV
Noorderlaan 87 2030 Antwerpen
Country : Belgium
Certificate No.: TW19/20026
Issue date: Feb 16, 2011
Expiry date: Feb 16, 2022

The above mentioned declaration of conformity is exclusively under the responsibility of

Radiant Innovation Inc.

Jun. 10, 2020 HsinChu

Place, date


James Huang / General Manager

Legally binding signature, Function