

EC Declaration of Conformity

Manufacturer:

Radiant Innovation Inc.

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

KunShan Radiant Innovation Co., Ltd.

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

whose single Authorized Representative:
**Medical Technology Promedt Consulting
GmbH**

Altenhofstrasse 80, D-66386 St. Ingbert, Germany

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, THP09J, THP39J, THP59J,
THP59JU, THP79J, THP79JU, THP89J, TH005F, THM0F, THB0F, TH809S(E), TH839S(E), TH889S(E), TH30F,
TH36F, THi0K, THi0KZ, THi0F, THMC09(E), THMC09P, THMC2FE, THD2F(E), THD2FA, THAC2F, TH859S,
THAD0K, THP09JU, TH02F

meet the provisions of Directive 93/42/EEC which apply to them.

Applied harmonised standards, national standards or other normative documents

EN 1041:2008, EN ISO 15223-1:2012, EN 60601-1-2:2007/AC:2010, EN 60601-1:2006/AC:2010, EN 60601-1-
11:2010, EN ISO 14971:2012, EN 12470-5:2003, ASTM E1965-98(2009), EN ISO 10993-1:2009/AC:2010, EN
ISO 10993-5:2009, EN ISO 10993-10:2010, EN 60601-1-6:2010, EN 62304:2006/AC:2008, EN 62366:2008, EN
ISO 80601-2-56:2012

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 United Kingdom Ltd
202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK
Country : United Kingdom
Certificate No.: TW11/10106
Issue date: Feb 16, 2014
Expiry date: Feb 16, 2019

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

Radiant Innovation Inc.

James Huang / General Manager

May. 24, 2016 HsinChu

Place, date

Legally binding signature, Function