



APPROVAL

EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60014693 0001

Report No.: 10003608 005

Manufacturer: Radiant Innovation Inc.,
1F, No.3, Industrial E. 9th Rd.,
Science-Based Industrial Park
HsinChu, Taiwan 300
Taiwan

Scope: Design and Development, Manufacturing and Sales of
Medical Devices
Production facilities: see attachment
Products: see attachment
Replaces Approval, Registration No. HD 600005278 0001

Date of Expiry: 30.05.2011

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 31.05.2006

Notified Body


Dipl.-Ing. D. Meier



TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: HD 60014693 0001
Report No.: 10003608 007

Manufacturer: Radiant Innovation Inc.,
1F, No.3, Industrial E. 9th Rd.,
Science-Based Industrial Park
HsinChu, Taiwan 300
Taiwan

Scope:

Production facilities:

Taiwan Factory
Radiant Innovation Inc.
1F, No.3, Industrial E. 9th Rd.,
Science-Based Industrial Park,
HsinChu, Taiwan
R.O.C.

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

Products:

- Infrared Ear Thermometers with & without Probe Cover
- Infrared Forehead Thermometers



Certification Body

Cologne, 09.07.2008


X. Ren