

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.**

We, the manufacturer, herewith declare that the products

Infrared Ear/Forehead Thermometer:

A&D UT-801/ Radiant THAD0K

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 15223-1:2016, EN 60601-1-2:2007/AC:2010, EN 60601-1:2006+A1:2013, EN 60601-1-11:2010, EN ISO 14971:2012, 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, 2011

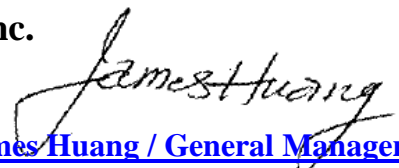
Expiry date: Feb 16, 2022

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

Radiant Innovation Inc.

Februay 19, 2019. HsinChu

Place , date


James Huang / General Manager

Legally binding signature, Function

Radiant Innovation Inc.