

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

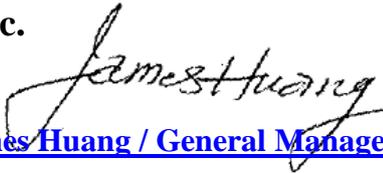
Expiry date: Feb 16, 2022

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

Radiant Innovation Inc.

February 19, 2019. HsinChu

Place, date


James Huang / General Manager

Legally binding signature, Function

Radiant Innovation Inc.