

## EC Declaration of Conformity

Manufacturer:

**Radiant Innovation Inc.**

1F, No. 3, Industrial E. 9<sup>th</sup> 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:**

**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+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 62366-1:2015+A1:2020, EN ISO 10993-1:2018, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 14971:2019, EN ISO 80601-2-56:2017+A1:2020, 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, 2023

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

**Radiant Innovation Inc.**

**James Huang / General Manager**

**Feb. 11, 2022 HsinChu**

Place, date

Legally binding signature, Function

**Radiant Innovation Inc.**