

EU Declaration of Conformity

Manufacturer:

SRN: TW-MF-000007935

Radiant Innovation Inc.

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

Additional facilities:

KunShan Radiant Innovation Co., Ltd.

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

whose single Authorized Representative:

SRN: DE-AR-000000085

**Medical Technology Promedt Consulting
GmbH**

**Ernst-Heckel-Straße 7, D-66386 St. Ingbert,
Germany**

Probe Cover:

PC840, PC7200, PCL-A40

Intended purpose:

The Probe Cover is an accessory for the thermometer that used only with Infrared Ear Thermometer (RADIANT®) for measuring human body temperature and need to replace the probe cover after each use to ensure an accurate reading and avoid cross contamination.

Basic UDI-DI : 471081045PROBECOVER1Y5

meet the provisions of MDR (EU) 2017/745 and ISO 13485 which apply to them.

Applied harmonised standards, national standards or other normative documents

EN ISO 20417:2021, EN ISO 14971:2019, EN ISO 80601-2-56:2017+A1:2020, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-23:2021, EN ISO 15223-1:2021, EN ISO 13485:2016, EN 60601-1-6:2010+A1:2015

There are no applicable CS are available.

The medical device has been assigned to class I according to Annex VIII Rule 5 of the Regulation (EU) 2017/745. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to EU Medical Device Regulation [MDR (EU) 2017/745] Article 19, ANNEX IV (EU Declaration of Conformity) coupled with ANNEX II (Technical documentation) & III (Technical documentation on post-market surveillance)

This declaration of conformity is issued under the sole responsibility of Radiant Innovation Inc.. We hereby declare that the medical device(s) specified above meet the provision of the Regulation(EU) MDR 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

Place of Issue: HsinChu, Taiwan

Date of Issue: Aug. 27, 2024

signed on behalf of manufacturer by

Name: James Huang

Title: General Manager of Radiant Innovation Inc.

A handwritten signature in black ink, appearing to read 'James Huang', is written over a horizontal line.