

EU Declaration of Conformity

Manufacturer:

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:
**Medical Technology Promedt Consulting
GmbH**

Altenhofstrasse 80, D-66386 St. Ingbert, Germany

We, the manufacturer, herewith declare that the products

Prove Cover:

PC840, PC7200, PCL-A40

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 1041:2008+A1:2013, EN ISO 14971:2019, ISO 80601-2-56:2017+A1:2018, EN ISO 10993-1:2018, EN ISO
10993-5:2009, ISO 10993-10:2010, EN ISO 15223-1:2016, EN ISO 13485:2016, EN 60601-1-2:2015, EN 60601-1-
6:2010+A1:2015, EN 60601-1-11:2015, EN 60601-1:2006+A1:2013+A12:2014**

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



GMDN code: 13116

UMDNS code: 16576

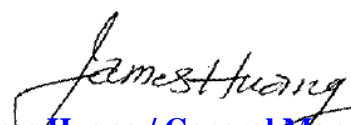
The product concerned has been designed and manufactured under a quality management system according
to ISO 13485.

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

Radiant Innovation Inc.

Jul. 21, 2021 HsinChu

Place , date


James Huang / General Manager
Legally binding signature, Function