# EU Declaration of Conformity

*Manufacturer:*

**Radiant Innovation Inc.**

**1F, No. 3, Industrial E. 9th Rd., Science-BasedIndustrial 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

**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

CE

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*