EU Declaration of Conformity

Manufacturer:
SRN: TW-MF-000007935
Radiant Innovation Inc.

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

Altenhofstrasse 80, D-66386 St. Ingbert, Germany

We, the manufacturer, herewith declare that the products

Probe 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, EN ISO 80601-2-56:2017+A1:2020, EN ISO 10993-1:2020,EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 15223-1:2021, 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

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.

Apr. 06, 2022 HsinChu
Place , date

James Huang / General Manager
Legally binding signature, Function