文件變更申請單

企業雲端團隊工作管理中心

文件編號	QDOCCB-0011	文件名稱	EU Declaration of Conformity of IET
版本	005	機密等級	2
申請部門	文件管制中心	申請人	鍾佩玲Paggy
發行日期	2024/07/23		
附件	檔案分類	附件名稱	
	1 主文	QDOCCB-0011-DOC IET-MDR_005.docx	

	版次	改版原因	發行日期
變更履歷	005	Add new models	2024/07/23
	004	Add Intended purpose	2024/06/27
	003	取得MDR認證，發行正式版DOC	2024/05/07
	002	歐體代表地址變更	2022/07/29
	001		2022/04/15

RADIANT INNOVATION INC. 熱映光電股份有限公司 DCC RECEIVE JUL 23 2024 文件管制中心 文件發行

簽核歷程	副理	總經理
	品質保證課	RII
	陳婉羚Lynn	黃幼謙James
	2024/07/22 09:08:06	2024/07/23 11:50:24

EC 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

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

We, the manufacturer, herewith declare that the products

Infrared Ear Thermometer:

TH709LE, TH809, TH809S, TH809J, TH819SJE, TH839S, TH889S, TH889SE, TH889J, THi09Z, THP59J(U), THP79JU, Comfort quick (00000656000000), MD1882, THIR-2, TH839, 42302041, 25575, 100-00102-00

Intended purpose:

The infrared ear thermometer is electronic thermometer using an infrared detector (thermopile detector) to detect body temperature from ear canal in people of all ages.

Basic UDI-DI： 471081045IETE8

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

Applied harmonised standards, nationalstandards or other normative documents

EN 20417:2021, EN ISO 15223-1:2021, EN 60601-1-2:2015+A1:2021, EN 60601-1:2006+A1:2013, EN 60601-1-11:2015, EN ISO 14971:2019, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN 60601-1-6:2010+A1:2015, EN 62304:2006+A1:2015, EN 62366-1:2015+A1:2020, EN ISO 80601-2-56:2017+A1:2020

The medical device has been assigned to class IIa, according to Annex VIII Section 6, 6.2, rule 10 of the MDR (EU) 2017/745. It bears the mark

CE **1639**

The product concerned has been designed and manufactured under a quality management system according to ANNEX IX excluding Chapter II of MDR (EU) 2017/745.

Compliance of the designated product with the MDR (EU) 2017/745 has been assessed and certified by the Notified Body

Notify body :	**SGS Belgium NV**
Address:	**Noorderlaan 87 2030 Antwerp Belgium**
Country :	**Belgium**
Certificate No.:	**TW24/00000261**
Issue date:	**26 March 2024**
Expiry date:	**26 March 2029**

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

Radiant Innovation Inc.

HsinChu, July. 17, 2024
Place , date

James Huang / General Manager
Legally binding signature, Function