

文件變更申請單

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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 1主文		附件名稱 QDOCCB-0011-DOC IET-MDR_005.docx	
變更履歷	版次	改版原因		發行日期
	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
	<div><div>RADIANT INNOVATION INC.</div><div>DCC RECEIVE</div><div>JUL 25 2024</div><div>文件管制中心 文件發行</div><div>熱映光電股份有限公司</div></div>			
簽核歷程	<div><div><div>副理</div><div>品質保證課</div><div>陳婉玲Lynn</div><div><div><div>✓</div></div></div><div>2024/07/22 09:08:06</div></div><div><div>總經理</div><div>RII</div><div>黃幼謙James</div><div><div><div>✓</div></div></div><div>2024/07/23 11:50:24</div></div></div>			

## EC Declaration of Conformity

*Manufacturer:*

**SRN: TW-MF-000007935**

**Radiant Innovation Inc.**

**1F, No. 3, Industrial E. 9<sup>th</sup> 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**

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, national standards 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



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.

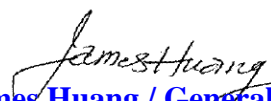
Compliance of the designated product with the MDR (EU) 2017/745 has been assessed and certified by the Notified Body

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

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*