檔　　號：
保存年限：

正本

台灣醫療暨生技器材工業同業公會
收 110. 04. 29 文
檔號: 110324

衛生福利部　函

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241
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受文者：台灣醫療暨生技器材工業同業公會

發文日期：中華民國110年4月27日
發文字號：衛授食字第1101603290號
速別：普通件
密等及解密條件或保密期限：
附件：

主旨：本部於中華民國110年4月27日以衛授食字第1101603288號公告發布「紅外線耳溫槍」等8項為「醫療器材許可證核發與登錄及年度申報準則」第6條第1項附表二說明第7點第2款第2目之品項，及前開品項之醫療器材臨床前測試資料切結書，請查照並轉知所屬。

說明：旨揭公告及其附件請至行政院公報資訊網、本部網站「衛生福利部法規檢索系統」下「最新動態」網頁或本部食品藥物管理署網站(http://www.fda.gov.tw)「公告資訊」下「本署公告」網頁自行下載。

正本：新北市醫療器材商業同業公會、台灣醫療器材門市發展協會、新北市生技產業發展聯盟、台灣醫療暨生技器材工業同業公會、中華民國醫療器材商業同業公會全國聯合會、臺北市醫療器材商業同業公會、桃園市醫療器材商業同業公會、臺中市醫療器材商業同業公會、彰化縣醫療器材商業同業公會、嘉義市醫療器材商業同業公會、台南市直轄市醫療器材商業同業公會、臺南市醫療器材商業同業公會、高雄市醫療器材商業同業公會、台灣省醫療器材商業同業公會聯合會、屏東縣醫療器材商業同業公會、高雄市直轄市醫療器材商業同業公會、台灣口腔生物科技暨醫療器材產業發展促進協會、台灣牙科器材同業交流與公益協會、台北市生物技術服務商業同業公會、社團法人中華民國助聽器同業聯合協進會、中華民國助聽器商業同業公會全國聯合會、台北市助聽器商業同業公會、桃園縣助聽器商業公會、台中市助聽器商業同業公會、彰化縣助聽器商業同業公會、高雄市助聽器商業同業公會、中華民國眼鏡發展協會、台灣區眼鏡工業同業公會、台北市眼鏡商業同業公會、台灣省鐘錶眼鏡商業同業公會聯合會、高雄市鐘錶眼鏡商業同業公會、台灣生技醫療照護輔具協會、社團法人臺灣輔具產業發展協會、中華民國儀器商業同業公會全國聯合會、臺北市

儀器商業同業公會、桃園市儀器商業同業公會、臺中市儀器商業同業公會、台南市儀器商業同業公會、高雄市儀器商業同業公會、新竹市儀器商業同業公會、台灣橡膠暨彈性體工業同業公會、台灣省橡膠製品商業同業公會聯合會、台北市國際工商協會、台灣生物產業發展協會、台灣先進醫療科技發展協會、台北市美國商會政府及公共事務部、歐洲在臺商務協會、台北市日本工商會、南港軟體工業園區二期管理委員會、財團法人金屬工業研究發展中心(高雄)、財團法人台灣商品檢測驗證中心、社團法人中華無菌製劑協會、台灣省進出口商業同業公會聯合會、新北市進出口商業同業公會、桃園市進出口商業同業公會、台中市進出口商業同業公會、台中縣進出口商業同業公會、台南市進出口商業同業公會、台南縣進出口商業同業公會、高雄縣進出口商業同業公會、高雄市進出口商業同業公會、台灣臨床檢驗標準協會、台灣製藥工業同業公會、中華民國西藥商業同業公會全國聯合會、台灣省西藥商業同業公會聯合會、中華生物醫學工程協進會、中華民國金屬家具商業同業公會全國聯合會、中華民國生物醫學工程學會、台灣顯示器產業聯合總會、台灣醫藥品法規學會、台灣科學工業園區科學工業同業公會、財團法人工業技術研究院量測技術發展中心、財團法人生物技術開發中心、台灣區電機電子工業同業公會、台灣藥物臨床研究協會、台北市西藥商業同業公會、中華民國開發性製藥研究協會、中華民國製藥發展協會、中華民國全國商業總會、中華民國全國工業總會、台灣研發型生技新藥發展協會、經濟部工業局、科技部新竹科學園區管理局、科技部南部科學園區管理局、科技部中部科學園區管理局、財團法人塑膠工業技術發展中心、財團法人醫藥品查驗中心、財團法人醫藥工業技術發展中心、台北市進出口商業同業公會、中華民國西藥代理商業同業公會、台北市西藥代理商業同業公會、台灣藥品行銷暨管理協會

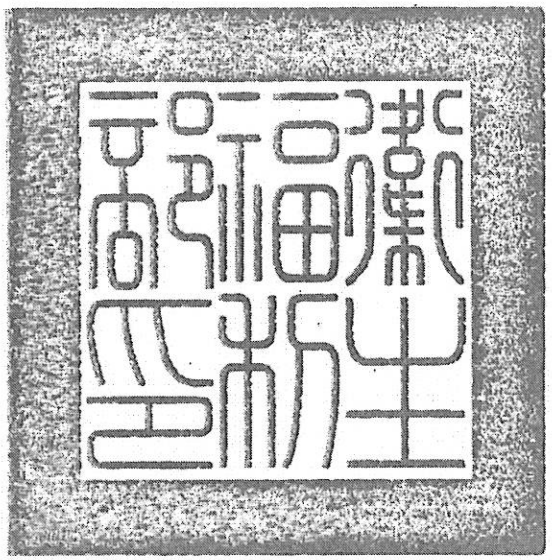
副本：

部長陳時中

1060329011

檔　　號：
保存年限：

衛生福利部　公告



發文日期：中華民國110年4月27日
發文字號：衛授食字第1101603288號
附件：醫療器材臨床前測試資料切結書1份

主旨：公告「紅外線耳溫槍」等8項為醫療器材許可證核發與登錄及年度申報準則第6條第1項附表二說明第7點第2款第2目之品項，自中華民國一百十年五月一日生效。

依據：醫療器材管理法第25條及醫療器材許可證核發與登錄及年度申報準則第6條第1項附表二。

公告事項：

一、公告「紅外線耳溫槍」、「電子體溫計」、「外科用覆蓋巾」、「外科手術衣」、「紅外線額溫槍」、「外科手術燈」、「靜電器(電位治療器)」、「紅外線燈(治療器)」為醫療器材許可證核發與登錄及年度申報準則第6條第1項附表二說明第7點第2款第2目之品項。

二、前開品項之醫療器材臨床前測試資料切結書，詳如附件。

三、本部105年7月1日部授食字第1051603544號公告自中華民國一百十年五月一日起不再適用。

部長陳時中

醫療器材臨床前測試資料切結書

110年5月1日

Affidavit of Pre-clinical Testing Conformity for Medical Device

填寫前請注意 Instruction:

1. **本切結書限同一製造業者曾有相同分級分類品項之類似品經衛生福利部核准上市之醫療器材製造業者簽署。**

   Only the manufacturer whose similar medical device(s) has/have ever received market approval from the Ministry of Health and Welfare (MOHW) in Taiwan with the same classification number, referring to the table of the Annex "Conformity Assessment of Medical Device to the recognized standards and guidance", is eligible to file this conformity affidavit.

2. **以下各項資訊請依據原廠檢驗資料及附表所列對應基準（或標準）據實填寫，並由製造業者權責人員及醫療器材申請商共同簽署(如列印超出1頁請加蓋騎縫章戳)，得以替代查驗登記及變更登記申請案有關表列臨床前測試及原廠品質管制之檢驗規格與方法、原始檢驗紀錄及檢驗成績書（以下簡稱臨床前測試資料）。**

   To exempt from submission of pre-clinical testing documents, the statement filed below must be true and accurate in accordance with the technical information provided by the device manufacturer and per attached standard/guidance that may apply. Signatures from both the device manufacturer and the medical device dealer are also required for the conformity affidavit (In case the affidavit document is longer than 1 page, please also put down the signatures/stamps across the pages).

3. **本產品上市後檢驗將依據附表所列基準(或標準)進行測試判定，不符合者將依醫療器材管理法相關規定論處。**

   The device will be subject to post-market inspection in accordance with the stated standards or guidance as listed in the following table of the Annex "Conformity Assessment of medical Device to the recognized standards and guidance". In case of noncompliance findings, the legal responsibility will be followed according to the Medical Devices Act.

4. **未檢附之臨床前測試資料應留廠備查，如有需要，衛生福利部得要求醫療器材商/製造業者限期內提出以供審核；如未依限檢附，或檢附資料內容與切結書所載不符者，該醫療器材商日後申辦產品查驗登記，衛生福利部將不再接受其以本切結書替代臨床前測試相關資料。**

   The submission-exempted pre-clinical testing documents should be maintained within the manufacturer premises and by its dealer in Taiwan, which are subject to review upon request by the MOHW. Noncompliance with such request will result in future denial of the exemption privilege.

5. **醫療器材品項及附表所列對應基準或標準皆依據現行之國際標準/基準等參考資料制定，惟個別產品可能有特殊設計或宣稱功能，且足以影響其安全及效能者，衛生福利部可能要求醫療器材商/製造業者提供表列項目外之驗證評估資料。**

   The claimed items and the corresponding recognized standards/guidance refer to the existing international standards/guidance. However, the MOHW may request additional information

for complete evaluation of a device if the device features specific technological characteristics that raise safety and efficacy issues not covered by the stated conformity assessment.

壹、醫療器材製造業者經衛生福利部核准上市之相同分級分類品項之類似產品許可證資料:

Information of the similar device(s) from the same manufacturer with the same classification number in the same class which has/have received market approval from the MOHW:

醫療器材許可證字號 Medical device License Number	
產品中文名稱 Product Name (Chinese)	
產品英文名稱 Product Name (English)	
規格/型號 Model or type	

貳、申請查驗登記產品及其符合性聲明:

Product applied for registration and the Declaration of Pre-clinical testing conformity:

產品中文名稱 Product Name (Chinese)	
產品英文名稱 Product Name (English)	
規格/型號 Model or type	

臨床前測試符合性聲明(請依附表、「醫療器材品項及其應符合之臨床前測試基準或標準」內容填列，以"及"列出者須全部符合，以"或"列出者可擇一符合；如基準或標準中未訂有規格者，須另提供廠規或與類似品比對之數據資料)

Declaration of Pre-clinical testing conformity

(Please fill in the form referring to the guidance/standards listed in the Table of the Annex "Conformity Assessment of Medical Device to the recognized Standards and Guidance". When quoted as "and", all the stated information must be supplied accordingly; when quoted as "or", it is sufficient to provide one of the stated information. If there are no specifications given by the stated guidance/standards, then the data based on the manufacturer's own specification or the comparative data comparing the device with a predicate device must be provided).

一、請擇一勾選填列：check on one box only:

□符合公告之臨床前測試基準(依 C 欄所列，請詳列基準名稱)

The device stated above conforms to the guidance published by the MOHW (please fill in the corresponding guidance referring to the "Guidance for pre-clinical testing" in column C of the Annex).

_____

□符合本項產品對應之功能性及安全性標準(依 D 兩欄所列，請詳列標準名稱及年份)

The device stated above conforms to the recognized performance/safety standards (please fill in the corresponding standards and the published years referring to the "Recognized Standards" in column D of the Annex).

1. 功能性(垂直)標準/List of performance standard (standard/year):

   _____

2. 共通安全性(水平)標準/List of safety standard (standard/year):

   _____

二、請擇一勾選填列： check on one box only:

□前列基準/標準中已訂有全項規格。The applied guidance/standards listed above provide all the acceptance criteria and specifications.

□前列基準/標準中未訂有規格者，另提供廠規或與類似品比對數據備查，附於後。There are no specifications given by the stated guidance/standards. Instead, data based on the manufacturer's own specification or the comparative data comparing the device with a predicate device are attached in case of review.

茲向衛生福利部切結以上所填資料均屬正確，且未檢附之臨床前測試資料均留廠備查，如有錯誤或不實，具結製造業者及醫療器材商願受撤銷許可證及醫療器材管理法規定之處分，決無異議。

We, the device manufacturer and the medical device dealer in Taiwan, hereby declare that the information stated above is true and correct, and we acknowledge that we will take full legal responsibility for any false statement made herein. All pre-clinical supporting documentations are retained at the premises of the manufacturer/Taiwan dealer and can be submitted upon request by the MOHW.

製造業者名稱：Name of the manufacturer:	申請醫療器材商名稱(請蓋公司印鑑)：Name of the medical device dealer (with company stamp):
製造業者地址：Address of the Manufacturer:	申請醫療器材商地址：Address of the medical device dealer:
權責人員(簽章)及日期： Manufacturer official representative signature and date:	醫療器材商負責人(請蓋負責人印鑑)及日期 Head of medical device dealer signature, stamp and date:

附表、醫療器材品項及其對應臨床前測試基準或標準

110年5月1日更新

A.品項名稱 Device name	B.分級分類代碼 Classification number	C.對應臨床前測試基準 Guidance for pre-clinical testing	D.對應標準	
			1.功能性(垂直)標準 Essential performance (vertical) standards	2.共通安全性(水平)標準 General Safety (horizontal) standards
紅外線耳溫槍 (Infrared ear thermometer)	J.2910	紅外線耳溫槍臨床前測試基準	1. ISO 80601-2-56:2017/Amd 1: 2018 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement；或 2. ASTM E1965 - 98(2009) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature；或 3.中華民國國家標準 CNS 15042 間歇性測定患者體溫之紅外線體溫計(2007)	1. EC 60601-1:2005+Amd 1:2012 Medical Electrical Equipment – Part 1: General Requirements for basic Safety and Essential Performance；及 2. IEC 60601-1-2:2014 Medical electrical Equipment - Part 1-2: General requirements for basic safety and ssential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests；及 3. 產品與人體接觸部位(如探頭、護套等)：ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
紅外線額溫槍(Infrared Forehead thermometer)	J.2910	無	1. ISO 80601-2-56:2017/Amd 1: 2018 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement；或 2. ASTM E1965 - 98(2009) Standard Specification for Infrared	1. IEC 60601-1:2005+Amd 1:2012 Medical Electrical Equipment – Part 1: General Requirements for basic Safety and Essential Performance；及 2. IEC 60601-1-2:2014 Medical electrical Equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic

			Thermometers for Intermittent Determination of Patient Temperature；或 3.中華民國國家標準 CNS 15042 間歇性測定患者體溫之紅外線體溫計 (2007)	disturbances – Requirements and tests；及 3. 產品與人體接觸部位(如探頭、護套等)：ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
電子體溫計 (Clinical electronic thermometer)	J.2910	臨床電子體溫計臨床前測試基準	1. ASTM E 1112 Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature (2018)；或 2. ISO 80601-2-56:2017/Amd 1: 2018 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement；或 3.中華民國國家標準 CNS 15043 間歇性測定患者體溫之電子式體溫計 (2007)	1. IEC 60601-1:2005+Amd 1:2012 Medical Electrical Equipment – Part 1: General Requirements for basic Safety and Essential Performance；及 2. IEC 60601-1-2:2014 Medical electrical Equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests；及 3. 產品與人體接觸部位(如探頭、護套等)：ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
外科用覆蓋巾 (Surgical drape)	I.4370	外科用覆蓋巾臨床前測試基準	EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns	1. ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process；及 2. 進行滅菌確效 (Sterilization validation) (見備註)確保 SAL (Sterility assurance level)小於10^{-6}；及 3. 若為重複使用產品：ANSI/AAMI ST65 Processing of reusable surgical textiles for use in health care facilities (2008/R2018), section 6-Laundry processing

				recommendations and section 7-Inspection, testing, and maintenance of laundered textiles
外科手術衣 (surgical gowns)	I.4040	無	EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns	1. ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process；及 2. 進行滅菌確效 (Sterilization validation) (見備註)確保 SAL (Sterility assurance level)小於10^{-6}；及 3. 若為重複使用產品：ANSI/AAMI ST65 Processing of reusable surgical textiles for use in health care facilities (2008/R2018), section 6-Laundry processing recommendations and section 7-Inspection, testing, and maintenance of laundered textiles
外科手術燈 (Surgical lamp)	I.4580	外科手術燈臨床前測試基準	IEC 60601-2-41:2009+Amd 1: 2013Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis	1. IEC 60601-1:2005+Amd 1:2012 Medical Electrical Equipment – Part 1: General Requirements for basic Safety and Essential Performance；及 2. IEC 60601-1-2:2014 Medical electrical Equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances –Requirements and tests
靜電器(電位治療器) (Static Electric	O.0001	靜電器(電位治療器)臨床前測試基準	JIS T 2003:2018 Electric therapy apparatus for home use	1. IEC 60601-1:2005+Amd 1:2012 Medical Electrical Equipment – Part 1: General Requirements for basic Safety and Essential Performance；及

Therapy Apparatus)				2. IEC 60601-1-2:2014 Medical electrical Equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
紅外線燈(治療器) (Infrared Lamp (therapy apparatus))	O.5500	紅外線燈(治療器) 臨床前測試基準	JIS T 0601-2-203:2015 Medical electrical equipment - Part 2-203: Particular requirements for the basic safety and essential performance of infrared therapy equipment	1. IEC 60601-1:2005+Amd 1:2012 Medical Electrical Equipment – Part 1: General Requirements for basic Safety and Essential Performance；及 2. IEC 60601-1-2:2014 Medical electrical Equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

備註：滅菌確效需視滅菌方法，以對應之國際公定標準進行—

1. EO 滅菌- ISO 11135:2014 Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices
2. 輻射滅菌- ISO 11137-1:2015 Sterilization of health care products- Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices 及 ISO 11137-2:2015 Sterilization of health care products- Radiation - Part 2: Establishing the sterilization dose 及 ISO 11137-3:2017 Sterilization of health care products- Radiation - Part 3Guidance on dosimetric aspects
3. 濕熱滅菌- ISO 17665-1:2006 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices