檔　　號：
保存年限：

正本

# 衛生福利部　函

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受文者：中華民國西藥代理商業同業公會

發文日期：中華民國105年7月1日
發文字號：部授食字第1051605792號
速別：
密等及解密條件或保密期限：
附件：

主旨：「紅外線耳溫槍」等4項醫療器材臨床前測試資料切結書，業經本部於中華民國105年7月1日以部授食字第1051603544號公告，請查照並轉知所屬。

說明：旨揭公告及其附件請至衛生福利部食品藥物管理署(網址：http://www.fda.gov.tw)之「本署公告」自行下載。

正本：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、新北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、高雄市醫療器材商業同業公會、台北市歐洲商務協會、台北市日本工商會、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、台中市助聽器商業同業公會、高雄市助聽器商業同業公會、台灣省進出口商業同業公會聯合會、台北市進出口商業同業公會、新北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、社團法人中華無菌製劑協會、台灣口腔生物科技暨醫療器材產業發展促進協會、台北市生物技術服務商業同業公會、台灣區自行車輸出業同業公會、桃園縣儀器商業同業公會、高雄市儀器商業同業公會、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、南港軟體工業園區二期管理委員會、台灣科學工業園區科學工業同業公會、台灣先進醫療科技發展協會、經濟部工業局、中華民國生物產業發展協會、台灣橡膠暨彈性體工業同業公會、中華民國全國商業總會、中華民國全國工業總會、台灣醫院協會、台灣臨床檢驗標準協會、台灣藥物臨床研究協會、台灣區電機電子工業同業公會、台灣省橡膠製品商業同業公會聯合會、中華民國藥品行銷暨管理協會、台灣製藥工業同業公會、中華民國西藥代理商業同業公會、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、台北市西藥代理商業同業公會、中華民國開發性製藥研究協會、中華民國製藥發展協會、臺

北市醫療器材商業同業公會、臺中市醫療器材商業同業公會、台灣省醫療器材商業同業公會、臺南市醫療器材商業同業公會、高雄直轄市醫療器材商業同業公會(原高雄縣醫療器材商業同業公會)、台北市美國商會政府及公共事務部(美國商會醫療器材委員會)、台北市助聽器商業同業公會、桃園縣助聽器商業公會、彰化縣助聽器商業同業公會、桃園縣進出口商業同業公會、台北市國際工商協會、財團法人自行車暨健康科技工業研究發展中心、中華民國電動代步車協進會、臺北市儀器商業同業公會、臺中市儀器商業同業公會、台北市眼鏡商業同業公會、新竹科學工業園區管理局、南部科學工業園區管理局、財團法人金屬工業研究發展中心、財團法人塑膠工業技術發展中心、財團法人台灣電子檢驗中心、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、財團法人工業技術研究院量測技術發展中心

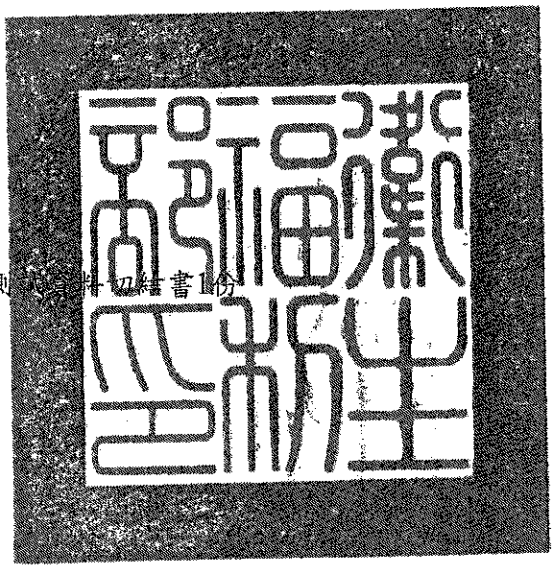
副本：

部長林奏延

正本

檔　號：
保存年限：

# 衛生福利部　公告



發文日期：中華民國105年7月1日
發文字號：部授食字第1051603544號
附件：「紅外線耳溫槍」等4項醫療器材臨床前測試資料切結書1份

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主旨：公告「紅外線耳溫槍」等4項醫療器材臨床前測試資料切結書。

訂

依據：藥事法第40條第3項及醫療器材查驗登記審查準則第12條第2項第2款。

公告事項：

一、公告「紅外線耳溫槍」等4項醫療器材臨床前測試資料切結書，如附件。

二、申請旨揭公告品項第二等級醫療器材查驗登記、變更規格或效能之登記，且製造廠曾有相同分類分級品項之類似品經本部核准上市者，得以臨床前測試資料切結書替代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；惟相關資料應留廠備查，並於必要時依本部食品藥物管理署之要求，於限期內提出供審核，未依限檢附或檢附資料內容與切結書所載不符者，該藥商日後申辦查驗登記，不得以切結書替代臨床

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前測試資料之方式辦理。

三、另為保障民眾健康安全，採用臨床前測試資料切結書替代臨床前測試及原廠品質管制資料者，其上市後檢驗將依據切結書表列之基準(或標準)進行測試及判定，不符合者將依藥事法相關規定論處。

四、本案另載於本部全球資源網(http://www.mohw.gov.tw)及衛生福利部食品藥物管理署網站(http://www.fda.gov.tw)之最新公告網頁。

衛生福利部食品藥物管理署收件章

副本：

部長林奏延

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# 醫療器材臨床前測試資料切結書
# Declaration of Pre-clinical Testing Conformity for Medical Device

**填寫前請注意 Instruction:**

1. 本切結書限**已有相同分級分類品項之類似產品經衛生福利部核准上市**之醫療器材製造廠簽署。

   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 declaration.

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**，並由製造廠權責人員及申請藥商共同簽署(如列印超出 1 頁請加蓋騎縫章戳)，**得以替代查驗登記申請案有關表列臨床前測試及原廠品質管制之檢驗規格、方法、成績書及原始檢驗紀錄**（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 declaration (In case the declaration 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，不符合者將依藥事法相關規定論處。**

   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 pharmaceutical Affairs Act.

4. **未檢附之臨床前測試資料應留廠備查，如有需要，衛生福利部得要求藥商/製造廠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，該藥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**

部可能要求藥商/製造廠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、醫療器材製造廠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<br>Medical device License Number | |
| 產品中文名稱<br>Product Name (Chinese) | |
| 產品英文名稱<br>Product Name (English) | |
| 規格/型號<br>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<br>Product Name (Chinese) | |
| 產品英文名稱<br>Product Name (English) | |
| 規格/型號<br>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，具結製造廠及藥商願受撤銷許可證及藥事法規定之處分，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.

| | |
|---|---|
| 製造廠名稱：Name of the manufacturer: | 申請藥商名稱(請蓋公司印鑑)：Name of the medical device dealer (with company stamp): |
| 製造廠地址：Address of the Manufacturer: | 申請藥商地址：Address of the medical device dealer: |
| 權責人員(簽章)及日期：<br>Manufacturer official representative signature and date: | 藥商負責人(請蓋負責人印鑑)及日期<br>Head of medical device dealer signature, stamp and date: |

# 附表、醫療器材品項及其應符合之臨床前測試基準或標準

105 年 07 月 01 日更新

## Conformity assessment of medical device to the recognized standards and guidance

| A. 品項名稱 Device name | B. 分級分類代碼 Classification Number | C. 臨床前測試基準 Guidance for pre-clinical testing | D. 採認標準 Recognized standards | |
|---|---|---|---|---|
| | | | 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 80601-2-56:2012 Medical electrical equipment. Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement；或<br>2. ASTM E1965 – 98:2009 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature；或<br>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. IEC 60601-1 :2005+AMD1:2012 Medical Electrical Equipment - Part 1: General Requirements for basic Safety and Essential Performance；及<br>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. |
| 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 1112-00(2011) Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature；或 | 1. IEC 60601-1 :2005+AMD1:2012 Medical Electrical Equipment - Part 1: General Requirements for basic Safety and Essential Performance；及<br>2. IEC 60601-1-2:2014 Medical electrical |

| | | | | |
|---|---|---|---|---|
| | | | 2. ISO 80601-2-56:2012 Medical electrical equipment. Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement；或<br>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) | equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. |
| 外科用覆蓋巾 (Surgical drape) | I.4370 | 外科用覆蓋巾臨床前測試基準 | 1. EN 13795:2011 +A1:2013 Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment — General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels. | 1. ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process (2009)；及<br>2. 進行滅菌確效 (Sterilization validation) (見備註)確保SAL (Sterility assurance level)小於 $10^{-6}$；及<br>3. ※重複使用產品：ANSI/AAMI ST65 Processing of reusable surgical textiles for use in health care facilities (2008), 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 | 1. EN 13795:2011+A1:2013 Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment — General requirements for manufacturers, processors and products, test methods, performance | 1. ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process (2009)；及<br>2. 進行滅菌確效 (Sterilization validation) (見備註)確保SAL (Sterility assurance level)小於 $10^{-6}$；及 |

| | | | | |
|---|---|---|---|---|
| | | | requirements and performance levels. | 3. ※重複使用產品：ANSI/AAMI ST65 Processing of reusable surgical textiles for use in health care facilities (2008), section 6-Laundry processing recommendations and section 7-Inspection, testing, and maintenance of laundered textiles. |

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. 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. Establishing the sterilization dose 及 ISO 11137-3:2006 Sterilization of health care products. Radiation. Guidance 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