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).

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□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: