第二等級醫療器材產品比較暨臨床前測試資料符合性聲明書
Class 2 Medical Devices Comparison and Preclinical Test Data Conformity Statement

☑體外診斷醫療器材 (In Vitro Diagnostic Device, IVD)
☐非體外診斷醫療器材 (Non- In Vitro Diagnostic Device)

☑國產 Manufactured Domestically
☐輸入 Imported

填寫須知：
Instructions for Filling In:

1. 本聲明書適用於第二等級醫療器材產品之查驗、變更登記，且與比較產品為相同醫療器材商、分級分類品項、製造廠、預期用途或效能或適應症、技術特點（如為體外診斷醫療器材，須具相同檢測標的、方法及臨床應用）之類似品，業經中央主管機關核准上市，且許可證仍於有效期間之產品，新申請產品內容範圍不得超過比較產品之範圍。

   This statement applies to the market approval registration and the change of registration for a Class 2 medical device, which is considered to be a similar product if its comparison product has the same medical device firm, risk class and classification item, actual manufacturing facility, intended use or effectiveness or indication, and technical characteristics (test objective, method and clinical application must be the same if it is an in vitro diagnostic device), has been approved for marketing by the central competent authority and has a license that is still within the validity period. The content scope of the new application product shall not exceed the scope of the comparison product.

2. 本聲明書各項資訊請依據醫療器材製造業者之技術性資料、安全及功能性檢驗資料據實填寫，由醫療器材製造業者之權責人員及申請醫療器材商共同簽署（如列印超出 1 頁請加蓋騎縫章戳），並保證該等資料的真實性、完整性及可追溯性。本聲明書得以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，包括為確保產品宣稱效能、結構、材質、設計及品質所進行之安全性及功能性檢測等資料。如有虛偽不實之情事，將依醫療器材管理法之相關規定論處，並應負相關法律責任。

   Please fill in each information item of this statement according to fact from the technical data, safety and performance test data of the medical device manufacturer, have it signed jointly by the medical device manufacturer's authoritative and responsible person and the medical device firm applicant (if printing more than 1 page, please stamp cross-page seal), and ensure the authenticity, integrity and traceability of those data.

   This statement may replace the preclinical testing and the test specifications and methods, the original test records, and the test reports for the quality control conducted by the original manufacturer, including documents of safety and performance testing for ensuring the claimed indication for use, structure, materials, design, and quality of the product.

If there are circumstances in which fraudulence or falsification is found, penalty shall be determined and enforced pursuant to relevant provisions of the Medical Devices Act and related legal responsibilities shall be imposed.

3. 以本聲明書申請之產品，其未檢附之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應留於申請醫療器材商處備查，中央衛生主管機關得要求醫療器材商於限期內提出，並依據本聲明書所載內容進行檢查判定。

   For a product applied using this statement, its preclinical testing and the test specifications and methods, the original test records, and the test reports for the quality control conducted by the original manufacturer that have not been submitted shall be kept for future reference at the premises of medical device firm. The central competent health authority may require the medical device firm to submit those documents within a prescribed period of time, and conduct inspection or make decision according to the contents declared in this statement.

4. 未依限檢附備查文件或經檢查文件內容與本聲明書所載內容不符者，視同使用虛偽不實之文件或資料申請查驗登記，將依醫療器材管理法第 69 條之規定處辦。

   Those who fail to submit within the prescribed period the documents for reference or contents of the documents have been inspected to be inconsistent with contents declared in this statement, they will be deemed as using fraudulent or falsified documents or data to apply for market approval registration, and shall be penalized and dealt with according to the provisions in Article 69 of the Medical Devices Act.

壹、新申請產品及比較產品之異同處比對表：

I. Comparative table of differences and similarities between the new application product and the comparison product

	產品資訊 **Product Information**	**新申請產品** **New Application Product**	**比較產品** **Comparison Product**	**異同處比對說明** **Comparative Explanation for Differences and Similarities**
1	中英文品名 Chinese and English Name of Product	OO 真空採血管 “OO” Vacuum Blood Collection Tube	XX 真空採血管 “XX” Vacutainer Blood Collection Tubes	中英文品名差異
2	衛生福利部核准字號 License Number Approved by Ministry of Health and Welfare		衛部醫器製字第 OOOOOO 號	衛生福利部核准字號差異
3	製造廠名稱/地址 Manufacturer Name/Address (註：請填寫製造廠) (Note: Please fill in the actual manufacturing facility.)	食藥股份有限公司 (台北市南港區食藥路 1 號)	食藥股份有限公司 (台北市南港區食藥路 1 號)	相同
4	產品類別 Product Category	A.1675 血液樣本收集設備	A.1675 血液樣本收集設備	相同
5	產品敘述 效能/適應症/預期用途 Product Description Efficacy/Indication/Intended Use	本產品用來採集靜脈血液進行血清生化檢測用。	本產品用於收集靜脈血液以供臨床實驗室測試血清生化檢驗使用。	相同
6	工作/設計原理/方法 Work/Design	促凝劑成分為 2.5%矽藻土懸浮	血清真空採血管塗有矽酮和二	OO 真空採血管添加物為 2.5%

	Principle/Method	液。	氧化矽。	矽藻土懸浮液，XX 真空採血管添加物為矽酮和二氧化矽，功能皆為促進血液的凝集。
7	材料/成分配方 Material/Ingredient Formula (註：適用體外診斷試劑及接觸人體之醫療器材) (Note: Applicable to medical devices that are IVD reagents and contact human body.)	添加物為二氧化矽	添加物為矽酮和二氧化矽	OO 真空採血管添加物為二氧化矽，XX 真空採血管添加物為矽酮和二氧化矽，功能皆為促進血液的凝集。
8	規格、型號 Model or Type	1. 型號: 524050606 2. 採血管種類:塑膠採血管 3. 採血管容量: 4/5/7ml 4. 操作溫度: 15-25°C 5. 保存溫度:室溫	1. 型號:535075 2. 採血管種類: PET 試管 3. 採血管容量: 10ml 4. 操作溫度: 25 °C 5. 保存溫度: 4-25°C	採血管容量、操作及保存溫度略有差異
9	使用/操作人員資格 User/Operator Qualification	專業人員	專業人員	相同
10	新申請產品與比較產品之差異處，不影響新申請產品臨床使用安全及效能之**說明** **Explanation** that differences between the new application product and the comparison product do not affect safety and effectiveness for clinical use of the new application product	OO 真空採血管與 XX 真空採血管之添加物、採血管容量、操作及保存溫度略有差異，不影響新申請產品臨床使用安全及效能。		

填寫說明：申請產品如為中央衛生主管機關已公告臨床前測試基準之品項，得參考臨床前測試基準所列之參考方法做比較。

Explanatory Note for Filling In: If the new application product is a product that has a preclinical testing guidance announced by the central health competent authority, reference methods listed in the preclinical testing guidance may be consulted for making the comparison.

貳、新申請產品之臨床前測試符合性聲明：
II. Conformity statement on preclinical testing of the new application product

產品中文名稱 OO 真空採血管
Product Name in Chinese
產品英文名稱 “OO” Vacuum Blood Collection Tube
Product Name in English
規格/型號 型號: 524050606
Model/Type

臨床前測試符合性聲明
Conformity Statement on Preclinical Testing

填寫說明:
Explanatory Note for Filling In:

1. 請列舉擬新申請產品符合之安全及功能性標準，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。
   Please list and enumerate the safety and performance standards that the new application product conforms to. If there are no specifications in a standard, factory specifications or comparison data with similar products shall be provided separately.
2. 請列舉新申請產品符合之功能性試驗項目摘要
   Please list and enumerate performance test items in a summary that the new application product conforms to.

新申請產品符合之安全性及功能性標準、功能性測試摘要:
Safety and performance standards that the new application product conforms to and summary of performance tests:

表1. 新申請產品符合之安全性標準：
Table 1. Safety standards that the new application product conforms to:

序號 Order No.	評估項目 Evaluation Item	符合標準/製造廠規範 Conformity Standard / Factory Specification	報告編號 Report No.
1.	滲漏試驗 Test for leakage of container	ISO 6710:2017	LC-001
2.	離心力試驗 Test for robustness of container	ISO 6710:2017	RC-001
3.	滅菌確效 Sterilization validation	ISO 11137-1:2018 ISO 11137-2:2013 ISO 11137-3:2017	SV-001 SV-002 SV-003

表2. 新申請產品符合之功能性標準及功能性試驗項目摘要：
Table 2. Performance standards that the new application product conforms to and summary

of performance test items:

序號 Order No.	測試項目 Test Item	符合標準/製造廠規範 Conformity Standard / Factory Specification	報告編號 Report No.
1	標稱容量及體積標示測試 Test for nominal capacity and graduation marks	CLSI GP39-A6 (2010) ISO 6710:2017	NCGM-0001
2	抽吸體積測試 Test for negative pressure draw volume	CLSI GP39-A6 (2010) ISO 6710:2017	NPDV-0001
3	添加劑的容許量 Additive tolerance	CLSI GP39-A6 (2010) ISO 6710:2017	AT-0001
4	空白值分析 Blank analysis	CLSI GP34-A (2010)	BA-0001
5	精密度 Precision	CLSI GP34-A (2010) CLSI EP05-A3 (2014)	PT-0001
6	與同類產品之比對測試 Method comparison	CLSI GP34-A (2010) CLSI EP09c (2018)	MC-0001
7	安定性 Stability	CLSI GP39-A6 (2010) ISO 6710:2017 CLSI GP34-A (2010) EN ISO 23640:2015 CLSI EP25-Ed2 (2023)	ST-0001

新申請產品如屬體外診斷醫療器材，符合之功能性標準應至少包括以下項目：靈敏度、線性、特異性、干擾性研究、準確性、精密度/再現性、閾值確認、安定性、追溯性。
If the new application product is an in vitro diagnostic medical device, the performance standards it conforms to shall include at least the following items: sensitivity, linearity, specificity, interference study, accuracy, precision/reproducibility, threshold confirmation, stability, and traceability.

前列符合標準/製造廠規範中未訂有允收規格者，應另提供評估方法、允收規格等資料。
For the above listed conformity standards / factory specifications that do not have established acceptance specifications, information on evaluation methods, acceptance specifications, and so forth, shall be provided separately.

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醫療器材商處備查，如有錯誤或不實，具結醫療器材商願受許可證撤銷及醫療器材管理法規定之處分，絕無異議。
We, the undersigned, hereby declare to the Ministry of Health and Welfare, Republic of China, that information filled out in the above is all truthful and accurate, and preclinical test data that have not been submitted are all kept for future reference at the premises of medical device firm. If there is inaccuracy or falsification, the undersigned medical device firm agrees without any objection to be

subject to license revocation and penalty provisions of the Medical Devices Act.

製造廠名稱： Name of Manufacturer: 食藥股份有限公司	申請醫療器材商名稱（請蓋公司印鑑）： Name of Medical Device Firm (please stamp company seal): 食藥股份有限公司
製造廠地址： Address of Manufacturer: 台北市南港區食藥路 1 號	申請醫療器材商地址： Address of Medical Device Firm: 台北市南港區食藥路 1 號
製造廠權責人員（簽章）及日期： Authoritative and Responsible Person of Manufacturer (signature) and Date:	醫療器材商負責人(請蓋負責人印鑑)及日期： Responsible Person of Medical Device Firm (please stamp seal of the responsible person) and Date:

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