

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) ☒ 國產 Manufactured Domestically
- ☐ 非體外診斷醫療器材 (Non- In Vitro Diagnostic Device) ☐ 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 家用血糖系統 “OO” Blood Glucose Monitoring System	XX 家用血糖測試系統 “XX” Blood Glucose System	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 000000 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.1345 葡萄糖試驗系統	A.1345 葡萄糖試驗系統	相同
5	產品敘述 效能/適應症/預期用途 Product Description Efficacy/Indication/Intended Use	本產品為體外診斷醫療器材，由血糖機與試紙組成，用來進行手指新鮮微血管血液中血糖的定量測定，提供糖尿病患者進行血糖監測。	本產品用來進行指尖、手掌及手臂微血管全血的血糖定量測定，可提供糖尿病患者量測及監控血糖值。	OO 血糖機測試檢體為手指採血；XX 血糖測試儀測試檢體為指尖、手掌及手臂採血。

6	工作/設計原理/方法 Work/Design Principle/Method	本產品運用電化學生物感測技術，當血糖試片上的葡萄糖氧化酶與血液中的血糖接觸時會產生微弱電流，電流值大小與血糖含量成正比，血糖機依電流的強弱計算出血糖值。	本產品運用電化學生物感測技術，透過試片中的葡萄糖氧化酵素與血液中葡萄糖反應，轉移到電極表面產生微電流，由血糖儀測量電流大小，進而精確地判讀血糖濃度值。	相同
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.)	N/A	N/A	相同
8	規格、型號 Model or Type	型號:OK-1S 1. 測試檢體: 微血管全血(手指採血) 2. 準確度: 血糖濃度<100 mg/dl，誤差度±15 mg/dl; 血糖濃度≥100 mg/dl，誤差度±15%。 3. 測試範圍: 20~600 mg/dL 4. 測試時間: 6 秒 5. 操作環境: 10-40°C，相對溼度 10~85%(含試片) 6. 儲存環境: 4-45°C，相對溼度 10~80%(含試片)	型號: BP-1050 1. 測試檢體: 指尖、手掌及手臂微血管全血 2. 準確度: 血糖濃度<100 mg/dl，誤差度±15 mg/dl; 血糖濃度≥100 mg/dl，誤差度±15%。 3. 測試範圍: 20~700 mg/dL 4. 測試時間: 6 秒 5. 操作環境: 10-40°C，相對溼度 10~85% 6. 機器保存溫度: 4-55°C 7. 試片保存溫度: 4-30°C	1. OO 血糖機測試檢體為手指頭採血；XX 血糖測試儀測試檢體為指尖、手掌及手臂採血。 2. 測試範圍及儲存環境略有差異
9	使用/操作人員資格 User/Operator Qualification	糖尿病患者	糖尿病患者	相同

10	<p>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</p> <p>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</p>	<p>OO 血糖機與 XX 血糖測試儀僅有測試檢體、測試範圍及儲存環境之差異，不影響新申請產品臨床使用安全及效能。</p>		

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 家用血糖機
Product Name in Chinese
產品英文名稱 “OO” Blood Glucose Monitoring System
Product Name in English
規格/型號 型號: OK-1S
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.	安全性與可靠度測試 Safety and Reliability Testing (1)基本要求(General requirements) (2)電擊的防護(Protection against electric shock) (3)機械危害的防護(Protection against mechanical hazards) (4)電磁相容性(Electromagnetic compatibility) (5)耐熱性(Resistance to heat)	ISO 15197:2013 IEC 60601-1:2020 IEC 61010-1:2019 IEC 61010-2-101:2018 IEC 60601-1-2:2020 IEC 61326-1:2020 IEC 61326-2-6:2020 IEC 60068-2-64:2019	SRT-001

	(6)防濕與防水性(Resistance to moisture and liquids) (7)排放氣體、爆炸與內爆的防護(Protection against liberated gases, explosion and implosion) (8)血糖機零組件(Meter components) (9)機械衝擊、震動、與撞擊之防護(Mechanical resistance to shock, vibration and impact) (10)設備儲存環境溫度限制(Equipment temperature exposure limits for storage) (11)設備儲存環境濕度限制(Equipment humidity exposure limits for storage)		
2.	軟體確效 Software validation	醫療器材軟體確效指引 US FDA Guidance: Content of Premarket Submissions for Device Software Functions (2023) IEC 62304:2015 US FDA Guidance- Radio Frequency Wireless Technology in Medical Devices (2013)	SW-001
3.	網路安全 Cybersecurity	適用於製造廠之醫療器材網路安全指引	CB-001
4.	清潔與消毒 Cleaning and Disinfection	US FDA Guidance: Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use (2020) Health Canada Notice: New Requirements for Medical Device Licence Applications for Lancing Devices and Blood Glucose Monitoring Systems (File Number: 14-111696-560) (2014)	CD-001

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	測試項目 Test Item	符合標準/製造廠規範 Conformity Standard /	報告編號 Report No.
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No.		Factory Specification	
1	精密度 Precision	ISO 15197:2013 CLSI EP05-A3 (2014)	PT-0001
2	準確度(方法比較) Accuracy (Method Comparison)	ISO 15197:2013 CLSI EP09c (2018)	AMC-0001
3	線性(Linearity)	CLSI EP06-Ed2 (2020)	LT-0001
4	干擾 Interference	ISO 15197:2013 CLSI EP07-Ed3 (2018)	IT-0001
5	系統追溯性 System Traceability	ISO 15197:2013 ISO 17511:2020	STT-0001
6	安定性 Stability	EN ISO 23640:2015 CLSI EP25-Ed2 (2023)	ST-0001
7	使用者操作評估	ISO 15197:2013	UPE-001

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
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<p>製造廠地址： Address of Manufacturer: 台北市南港區食藥路 1 號</p>	<p>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</p>
<p>製造廠權責人員（簽章）及日期： Authoritative and Responsible Person of Manufacturer (signature) and Date:</p>	<p>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:</p>