中華民國衛生福利部

MINISTRY OF HEALTH AND WELFARE, REPUBLIC OF CHINA (TAIWAN)

Date: JUL 3 0 '2021

No: 083254

證明書

Certificate

茲證明下述醫療器材係為因應緊急公共衛生情事之需要, 經衛生福利部核准,准予產銷及輸出。 Ministry of Health and Welfare, Republic of China (Taiwan) hereby certifies that for responding to the necessity of emergency public health circumstances, the medical device as described below is legally approved in the Republic of China (Taiwan) and may be manufactured, exported, and freely sold.

製造廠名稱:寶齡富錦生技股份有限公司汐止廠 Manufacturer:<u>Panion & BF Biotech Inc. Xizhi Factory</u>

製造廠地址:新北市汐止區大同路一段 306 號 6F 之 3

Manufacturing Plant Location: 6F.-3, No.306, Sec. 1, Datong Rd., Xizhi Dist., New Taipei City 22146, Taiwan

醫療器材名稱:飛確RV2家用新型冠狀病毒抗原快速檢驗試劑 Device Name:<u>Vstrip RV2 COVID-19 Antigen Rapid Test Home Use</u>

規格(型號):IG13002S01(2 Tests/Kit)、IG13004S01(4 Tests/Kit)、IG13020S02(20 Tests/Kit) Model(Type):<u>IG13002S01(2 Tests/Kit)、IG13004S01(4 Tests/Kit)、IG13020S02(20 Tests/Kit)</u>

核准字號:防疫專案核准製造第1106810589號

Approval Number: Case-Specific Approval of Disease Control for Manufacture No.1106810589

核准有效日期:至中央流行疫情指揮中心解散日止

Expiry Date: until the Central Epidemic Command Center is dissolved

其他應配合事項請參照衛授食字第 1106810589 號核准函內容辯理。

Please refer to the content of Approval Letter No.1106810589 for other matters to be complied with.

Signed by_

Shou-Wei Wu
Director General

Food and Drug Administration

for Shih-Chung Chen, D.D.S. Minister

Ministry of Health and Welfare, Republic of China (Taiwan)