

中華民國衛生福利部

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

Date: SEP 10 2020

No: 080266

證明書  
Certificate

茲證明下述醫療器材經衛生福利部依據藥事法第 48-2 條規定，  
為因應緊急公共衛生情事之需要，准予產銷及輸出。

Ministry of Health and Welfare, Republic of China (Taiwan) hereby certifies  
that according to Article 48-2 of the Pharmaceutical Affairs Act 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: Panion & BF Biotech Inc. Xizhi Factory

製造廠地址：新北市汐止區大同路一段 306 號 6 樓之 3  
Manufacturing Plant Location: 6F-3, No. 306, Sec 1, Datong Rd. Xizhi Dist. New Taipei City, 221 Taiwan

醫療器材名稱及規格（型號）：飛確 新型冠狀病毒抗原快速檢驗試劑 & IG10020S(20tests/kit)  
Device Name and Model (Type): Vstrip COVID-19 Antigen Rapid Test & IG10020S(20tests/kit)

核准字號：防疫專案核准製造第 1096813815 號  
Approval Number: Case-Specific Approval of Disease Control for Manufacture No. 1096813815

核准有效日期：110 年 12 月 31 日  
Expiry Date: Dec. 31, 2021

其他應配合事項請參照衛授食字第 1096813815 號核准函內容辦理。  
Please refer to the content of Approval Letter No. 1096813815 for other matters to be complied with.

Signed by \_\_\_\_\_

Director General  
Food and Drug Administration

for Shih-Chung Chen, D.D.S.  
Minister  
Ministry of Health and Welfare,  
Republic of China (Taiwan)