## 中華民國衛生福利部

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

Date: DEC 16'2020

No: 081113

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:泰博科技股份有限公司五股廠

Manufacturer: TaiDoc Technology Corporation Wugu Factory

製造廠地址:新北市五股區五工二路 127號 BI-7樓

Manufacturing Plant Location: B1-7F, No. 127, Wugong 2nd Rd., Wugu Dist., 24888 New Taipei City, Taiwan

醫療器材名稱:威創新型冠狀病毒抗原快速檢驗試劑

Device Name: VTRUST COVID-19 (SARS-CoV-2) Antigen Rapid Test

規格(型號): TD-4531 Model (Type): <u>TD-4531</u>

核准字號:防疫專案核准製造第1096034342號

Approval Number: Case-Specific Approval of Disease Control for Manufacture No. 1096034342

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 1096034342 號核准函內容辦理。

Please refer to the content of Approval Letter No. 1096034342 for other matters to be complied with.

Shou-Mei Wu

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)