

中華民國衛生福利部

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

Date: SEP 11 2017

No: 069787

證明書
Certificate

茲證明下述醫療器材經衛生福利部核准許可登記，准予產銷及輸出。

該醫療器材之製造廠亦經評定已實施衛生福利部公布推行之

醫療器材優良製造規範，並接受定期與不定期之稽查。

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

that the medical device as described below is subject to its jurisdiction and is legally

approved in the Republic of China (Taiwan) to be manufactured, exported and freely sold.

It is also certified that the manufacturing establishment has been in compliance with the

requirements for Good Manufacturing Practices as promulgated by the Ministry of Health and Welfare,

Republic of China (Taiwan) and is subject to inspections at appropriate intervals.

製造廠名稱及地址：博錄生技股份有限公司(台北市內湖區陽光街351號6樓之1)委託 緯創資通股份有限公司(新竹市東區新竹市科學園區新安路5號)製造

Manufacturer and Manufacturing Plant Location : Manufactured by Wistron Corporation (No. 5 Hsin Ann Rd. Science-Based Industrial Park., Hsinchu 300, Taiwan, R.O.C.) for PlexBio Corporation (6F-1, No. 351, Yangguang St., Neihu District, Taipei City 11491, Taiwan, R.O.C.)

醫療器材名稱：“博錄”螢光分析儀(未滅菌)

Device Name : PlexBio 100 Fluorescent Analyzer (Non-sterile)

許可證字號：衛部醫器製壹字第006602號

License Number : MOHW-MD-(I)-No. 006602

許可證有效日期：111年02月21日

License Expiry Date : Feb. 21, 2022

規格(型號)

Model (Type) : All Models.

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)

Shou-Mei Wu