

中華民國衛生福利部

MINISTRY OF HEALTH AND WELFARE, REPUBLIC OF CHINA

(TAIWAN)

Date: MAR 11 2024

No: 090996

證明書

Certificate

茲證明下述醫療器材製造廠符合衛生福利部醫療器材管理法規定，亦符合衛生福利部施行之醫療器材品質管理系統準則，其所產製之醫療器材，准予銷售及輸出。

It is hereby certified that the medical device manufacturer as described below is in compliance with the provisions of Medical Devices Act governed by the Ministry of Health and Welfare, Republic of China (Taiwan), and also in compliance with Regulations Governing Medical Device Quality Management System enforced by the Ministry of Health and Welfare, Republic of China (Taiwan). The medical devices it has manufactured may be freely sold and exported.

製造廠名稱：拉法生醫股份有限公司中和廠

Manufacturer: RBC BIOSCIENCE CORP.

製造廠地址：新北市中和區橋和路 15 號 15 樓

Manufacturing Plant Location: 15F, No. 15, Qiaohe Rd. Zhonghe Dist., New Taipei City, Taiwan (R.O.C.)

產品列表：見附件

Products List: See Attached List.

*Shou-Mei Wu*

Signed by

Director General  
Food and Drug Administration

for Jui-Yuan Hsueh, M.D., LL.M.  
Minister  
Ministry of Health and Welfare,  
Republic of China (Taiwan)

許可證字號/登錄字號 License Number / Listing Number	醫療器材名稱 Device Name	規格 (型號) Model (Type)	有效日期 Expiry Date
衛部醫器製壹字第 009685 號 MOHW-MD-(I)-No. 009685	“拉法生醫”核酸純化 儀(未滅菌) “RBC Bioscience” Automated DNA/RNA Purification Analyzer (Non-Sterile)	MagCore HF16 Plus、 MagCore Super、MagCore Plus II、MagCore Plus II LITE、MagCore EDA MGB400-01、MGB400-02、 MGB400-03、MGB400-04、 MGB1200、MPD1200、 MGB400-07、MGB400-08、 MCC-01、MCC-02、 MPD4000-01、 MDP4000-03、MVN400-01、 MVN400-02、MVN400-03、 MVN400-04 MVN400-05、MVN400-06、 MVN1200、MVN2401、 MGP-01、MGP-02、 MGT-01、MGT-02、 MGF-01、MGF-03、 MFC-03、MBB-01、 MBB-02、MGM-01、 MGM-02、MRF-01、 MRF-03、MMR-01、 MMR-03、MRX-01、 MRX-03、MRM-01、 MRM-03、MNC-01、MNC-02	Sep. 27, 2027

End of Products List.