

衛生福利部醫療器材製造許可證明書

醫療器材製造業者名稱：南六企業股份有限公司高雄總廠

醫療器材製造業者地址：高雄市燕巢區四林路 699、699-1 號

製造許可編號：QMS1774

許可項目及作業內容：1. 外科手術醫用口罩之設計、製造、包裝、貼標及最終驗放作業, 2. 醫用口罩之製造、包裝、貼標及最終驗放作業。



上述醫療器材製造業者係依醫療器材管理法第 22 條第 2 項經本部檢查符合醫療器材品質管理系統準則(等同於國際標準組織醫療器材品質管理系統 ISO13485:2016)。

本證明書係依據醫療器材品質管理系統檢查及製造許可核發辦法第 9 條規定核發。

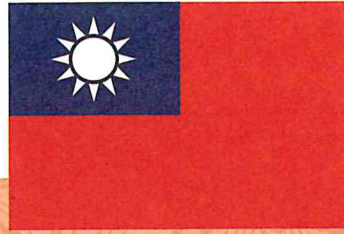
衛生福利部

部長 薛瑞元



發證日期：中華民國 113 年 2 月 2 日
有效日期：中華民國 116 年 1 月 25 日

ML 001751



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

Issue Date: February 2, 2024

No: MN001921



QMS Certificate

This is to certify that the quality management system of:

The Medical Device Manufacturer : NAN LIU ENTERPRISE CO., LTD. MAIN FACTORY
Address : NO.699, 699-1, SILIN RD., YANCHAO DIST., KAOHSIUNG CITY., TAIWAN
(R.O.C.)

QMS Number : QMS1774

Valid Until : January 25, 2027

This Certificate is applicable to : 1. Design, Manufacture, Packaging, Labeling, Final
Inspection and Release of Surgical Face Mask, 2. Manufacture, Packaging, Labeling,
Final Inspection and Release of Medical Face Mask.

The above-mentioned manufacturer, in accordance with Paragraph 2, Article 22 of the Medical Device Act, has been inspected and found to be in compliance with the Medical Device Quality Management System Regulations requirements (**based on ISO 13485:2016**). This certificate is hereby issued pursuant to Article 9 of the Regulations Governing the Inspection of the Medical Device Quality Management System and the Issuance of the Manufacturing license.

Shou-Mei Wu

Signed by _____

Director General
Food and Drug Administration
Under the delegated authority of
Jui-Yuan Hsueh, M.D., LL.M., Minister
Ministry of Health and Welfare
Republic of China (Taiwan)

MN001921