

中 華 民 國 衛 生 福 利 部

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

Date: MAY 30 2018

No: 072156

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：新駿實業股份有限公司(新北市五股區中興路一段 168 號)委託遠貿企業股份有限公司民族廠(臺中市神岡區昌平路 5 段 257 號)製造

Manufacturer and Manufacturing Plant Location : Manufacture by Foremount Enterprise Co., Ltd. Minzu Factory (No.257, Sec. 5, Changping Rd., Shengang Dist., Taichung City, Taiwan) for Sturdy Industrial Co., Ltd. (No.168, Sec. 1, Zhongxing Rd., Wugu Dist., New Taipei City, Taiwan)

醫療器材名稱：“新駿”非重吸入式呼吸面罩(未滅菌)

Device Name : “Sturdy” Nonrebreathing Mask (Non-sterile)

許可證字號：衛署醫器製壹字第 004306 號

License Number : DOH-MD-(I)-No. 004306

許可證有效日期：111 年 9 月 24 日

License Expiry Date : Sep. 24, 2022

規格 (型號)：

Model (Type)：

SP-007

End of Products List.

Signed by Shou-Mei Wu

Director General

Food and Drug Administration

for Shih-Chung Chen, D.D.S.

Minister

Ministry of Health and Welfare,

Republic of China (Taiwan)