

中 華 民 國 衛 生 福 利 部

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

Date: SEP 09 2016

No: 066088

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。  
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.

製造廠名稱：新駿實業股份有限公司  
Manufacturer: Sturdy Industrial Co., Ltd.

製造廠地址：新北市五股區中興路一段 168 號  
Manufacturing Plant Location: No.168, Sec. 1, Zhongxing Rd., Wugu Dist., New Taipei City, Taiwan

醫療器材名稱：“新駿”非呼吸用醫藥噴霧器(未滅菌)  
Device Name: “Topster” Medicinal Nonventilatory Nebulizer (Atomizer) (Non-sterile)

類別：第 D 類：麻醉學科用裝置  
Classification: Category D: Anesthesiology Devices

許可證字號：衛署醫器製壹字第 003478 號 核准日期：100 年 5 月 12 日 有效日期：110 年 5 月 12 日  
Registration Number: DOH-MD-(I)-No. 003478 Date of Issue: May 12, 2011 Date of Expiry: May 12, 2021

處方、規格(型號)  
Formula、Model (Type): All Models.

效 能  
Intended Use: Blank.

Signed by

*Chiang Yu-Mei*

Director General  
Food and Drug Administration

for Tzou-Yien Lin, M.D.  
Minister  
Ministry of Health and Welfare,  
Republic of China (Taiwan)



台灣醫療暨生技器材工業同業公會 Taiwan Medical and Biotech Industry Association

## **DECLARATION**

No. FSC-10549

Date: Sep. 12, 2016

### **TO WHOM IT MAY CONCERN:**

The undersigned, of the Taiwan Medical and Biotech Industry Association, State of Taiwan, refer to the Certificate No. 066088 dated Sept. 9, 2016 issued by Ministry of Health and Welfare, Republic of China (Taiwan) for Registration No. DOH-MD-(I)-No. 003478, we hereby certify that "All Models" for "Topster" Medicinal Nonventilatory Nebulizer (Atomizer) (Non-sterile) is refer to Model No. listed below.

SNB-030A  
SNB-030B  
SNB-030C  
SNB-031

Taiwan Medical and Biotech Industry Association

*Frank Huang*

Chairman

