



衛生福利部藥品優良製造證明書

衛部藥廠證字第(G)0012005 號

製造廠名稱：三福氣體股份有限公司西盛廠

製造廠地址：新北市新莊區新樹路 293 巷 11 號

核定劑型及作業內容：

- 一、劑型：醫用氣體（液態/氣態）— 灌注/充填廠。
- 二、作業內容：灌注/充填作業、貼標作業、實驗室作業。
- 三、GDP 作業項目（DA0305）：儲存、供應及運輸。

本證明書係依據藥事法第五十七條符合藥物優良製造準則之規定發給。

本部係依據藥物優良製造準則第二編第一章西藥藥品優良製造規範及國際醫藥品稽查協約組織（PIC/S）GMP 及 GDP 之標準進行查核。

部長陳時中

原發證日期：101 年 11 月 28 日

發證日期：107 年 2 月 13 日

有效期限：109 年 8 月 14 日



CERTIFICATE OF GOOD MANUFACTURING PRACTICE

Issue Date: February 13, 2018

Issued following an inspection in accordance with Article 57 of the Pharmaceutical Affairs Law and relevant Regulations of the Republic of China (Taiwan).

The competent authority of the Republic of China confirms the following:

The manufacturer: Air Products San Fu ShiCheng Plant

Site address: No.11, Ln.293, Xinshu Rd., Xinzhuang Dist., New Taipei City 24262, Taiwan
(R.O.C.)

Manufacturer's licence number: (G) 0012005

is the manufacturer of medicinal products for human use that has been inspected with the following pharmaceutical dosage form:
Medicinal gas (filling operation)

From the knowledge gained during inspection performed on September 27-28, 2017, it is considered that the manufacturer complies with the Pharmaceutical Inspection Convention/Co-operation Scheme Guide to Good Manufacturing Practice (PIC/S GMP) and Good Distribution Practice (PIC/S GDP) for medicinal products.

This certificate is valid until August 14, 2020.

This certificate may be revoked at anytime as warranted.

Signed by

Shou-Mei Wu

Shou-Mei Wu, Ph.D.

Director-General

Food and Drug Administration

(<http://www.fda.gov.tw/TC/index.aspx>)

Under the delegated authority of

Shih-Chung Chen, D.D.S.

Minister

Ministry of Health and Welfare

Republic of China (Taiwan)

