

中華民國衛生福利部

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

Date: JUN 26 2015

No: 061630

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：雅登企業有限公司

Manufacturer: APOZA ENTERPRISE CO., LTD.

製造廠地址：新北市新莊區中正路 657、657-1、657-2、657-3、657-5、657-6 號 6 樓

Manufacturing Plant Location: 6F, No. 657、657-1、657-2、657-3、657-5、657-6, Chung-Cheng Road, Hsin-Chuang District  
242 New Taipei City, Taiwan, R.O.C.

醫療器材名稱：「雅登」根管充填器 (未滅菌)

Device Name: 「APOZA」 Root Canal Obturation Device (Non-sterile)

類別：第 F 類：牙科裝置

Classification: Category F: Dental Devices

許可證字號：衛署醫器製壹字第 002322 號 核准日期：97 年 12 月 18 日 有效日期：107 年 12 月 18 日

Registration Number: DOH-MD-(I)-No.002322 Date of Issue: Dec. 18, 2008 Date of Expiry: Dec. 18, 2018

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 Been-Huang Chiang, Ph.D.  
Minister  
Ministry of Health and Welfare,  
Republic of China (Taiwan)