

中華民國衛生福利部

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

Date: JUL 18 2017

No: 069158

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：亞登仕生物科技股份有限公司(新竹縣竹北市復興二路 229 號 2 樓之 7)委託 旭諾生物科技股份有限公司(新北市新莊區新樹路 207-4 號 5 樓)製造

Manufacturer and Manufacturing Plant Location: Manufactured by ShiNeo Technology Corporation Ltd. (5F., No.207-4, Xinshu Rd., Xinzhuang Dist., New Taipei City 242, Taiwan, R.O.C.) for tYDS Biotech Incorporation (2F.-7, No.229, Fuxing 2nd Rd., Zhubei City, Hsinchu County 30271, Taiwan, R.O.C.)

醫療器材名稱：“髓福定”牙科根管封填材

Device Name: "SavDen MTA" root canal filling materials

許可證字號：衛部醫器製字第 005455 號
License Number: MOHW-MD-No. 005455

許可證有效日期：
License Expiry Date: Oct. 14, 2021

規格（型號）

Model (Type):

MTA-1-P04-L0, MTA-1-P04-L1, MTA-1-P04-L2, MTA-1-P08-L0, MTA-1-P08-L1, MTA-1-P08-L2, MTA-1-P12-L0, MTA-1-P12-L1, MTA-1-P12-L2, MTA-3-P04-L0, MTA-3-P04-L3, MTA-3-P04-L4, MTA-3-P08-L0, MTA-3-P08-L3, MTA-3-P08-L4, MTA-3-P12-L0, MTA-3-P12-L3, MTA-3-P12-L4, MTA-5-P04-L0, MTA-5-P04-L5, MTA-5-P04-L6, MTA-5-P08-L0, MTA-5-P08-L5, MTA-5-P08-L6, MTA-5-P12-L0, MTA-5-P12-L5, MTA-5-P12-L6, 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)