# 衛生福利部醫療器材製造許可證明書

醫療器材製造業者名稱：尚品醫療器材股份有限公司

醫療器材製造業者地址：新北市中和區立德街 170 號 7 樓

製造許可編號：QMS1909

許可項目及作業內容：1.椎弓螺釘系統之設計、製造、包裝、貼標及最終驗放作業,2.椎體間融合裝置(滅菌)之設計、包裝、貼標及最終驗放作業,3.單一或多重之金屬類骨固定裝置及附件之設計、包裝、貼標及最終驗放作業,4.手動式骨科手術器械之設計、包裝、貼標及最終驗放作業。

上述醫療器材製造業者係依醫療器材管理法第 22 條第 2 項經本部檢查符合醫療器材品質管理系統準則(等同於國際標準組織醫療器材品質管理系統 ISO13485:2016)。

本證明書係依據醫療器材品質管理系統檢查及製造許可核發辦法第 9 條規定核發。

衛生福利部

部長 邱泰源

發證日期：中華民國 113 年 7 月 18 日

有效日期：中華民國 116 年 4 月 30 日

ML 001883

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

Issue Date: July 18, 2024 No: MN002058

## QMS Certificate

This is to certify that the quality management system of:

The Medical Device Manufacturer：CHANPIN MEDTAK CO., LTD.
Address：7F., No. 170, Lide St., Zhonghe Dist., New Taipei City 23512, Taiwan (R.O.C.)
QMS Number：QMS1909
Valid Until：April 30, 2027
This Certificate is applicable to：1.Design, Manufacture, Packaging, Labeling, Final Inspection and Release of Pedicle Screw Spinal System, 2.Design, Packaging, Labeling, Final Inspection and Release of Intervertebral Disc Prosthesis(Sterile), 3.Design, Packaging, Labeling, Final Inspection and Release of Single/Multiple Component Metallic Bone Fixation Appliance and Accessories, 4.Design, Packaging, Labeling, Final Inspection and Release of Orthopedic Manual Surgical Instrument.

The above-mentioned manufacturer, in accordance with Paragraph 2, Article 22 of the Medical Device Act, has been inspected and found to be in compliance with the Medical Device Quality Management System Regulations requirements (**based on ISO 13485:2016**). This certificate is hereby issued pursuant to Article 9 of the Regulations Governing the Inspection of the Medical Device Quality Management System and the Issuance of the Manufacturing license.

Shin-Hun Juang

Signed by _____
Director General
Food and Drug Administration
Under the delegated authority of
Tai-Yuan Chiu, M.D., LL.M., Minister
Ministry of Health and Welfare
Republic of China (Taiwan)

MN 002058