





MINISTRY OF HEALTH AND WELFARE REPUBLIC OF CHINA (TAIWAN)

Issue Date: March 14, 2022

No: MN001440

QMS Certificate

This is to certify that the quality management system of:

The Medical Device Manufacturer: Fortune Medical Instrument Corp.

Address: No. 256, Changchun 2nd Rd., Jhongli Dist., Taoyuan City, Taiwan (R.O.C.)

QMS Number: QMS0555

Valid Until: February 24, 2025

This Certificate is applicable to: Medical Devices Listed in the Attachment of QMS

Certificate (QMS0555/No: MN001440).

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.

Signed by_

Shou-Mei Wu

Director General
Food and Drug Administration
Under the delegated authority of
Shih-Chung Chen, D.D.S., Minister
Ministry of Health and Welfare
Republic of China (Taiwan)