

MINISTRY OF HEALTH AND WELFARE REPUBLIC OF CHINA (TAIWAN)

Issue Date: December 3, 2025

QMS Certificate

No: MN002392

This is to certify that the quality management system of:

The Medical Device Manufacturer: Mouldex Co., Ltd.

Address: No. 22, Guang Fu South Rd., Hukou Township, Hsinchu County, Taiwan (R.O.C.)

QMS Number: QMS0786 Valid Until: December 22, 2028

This Certificate is applicable to : Design, Manufacture, Packaging, Labeling, Final Inspection

and Release of Intravascular Administration Set and

Accessories.

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.

Chih-Kang Chiang

Signed by_

Chih-Kang Chiang, M.D., Ph.D.
Director General
Food and Drug Administration

Under the delegated authority of Chung-Liang Shih, M.D., Ph.D.

Minister

Ministry of Health and Welfare Republic of China (Taiwan)