



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

Issue Date: January 17, 2023

No: MN001623

**QMS Certificate**

This is to certify that the quality management system of:

The Medical Device Manufacturer : **Mouldex Co., Ltd.**

Address : No. 22, Guangfu S. Rd., Hukou Township, Hsinchu County, Taiwan (R.O.C.)

QMS Number : QMS0786

Valid Until : December 22, 2025

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.

Signed by

**Shou-Mei Wu**

Director General  
Food and Drug Administration  
Under the delegated authority of  
Jui-Yuan Hsueh, M.D., LL.M., Minister  
Ministry of Health and Welfare  
Republic of China (Taiwan)

**MN 001623**