



MINISTRY OF HEALTH AND WELFARE  
REPUBLIC OF CHINA (TAIWAN)

Issue Date: December 11, 2023

No: MN001876



QMS Certificate

This is to certify that the quality management system of:

The Medical Device Manufacturer : Chroma ATE Inc. (LIN-KOU FACTORY)

Address : 1F-3F, No. 68, Huaya 1st Rd., Guishan Dist., Taoyuan City 33383, Taiwan  
(R.O.C.)

QMS Number : QMS1581

Valid Until : November 17, 2026

This Certificate is applicable to :

- 1.Design, Manufacture, Packaging, Labeling, Final Inspection and Release of RNA Preanalytical Systems,
- 2.Design, Manufacture, Packaging, Labeling, Final Inspection and Release of Microtiter Diluting and Dispensing Device,
- 3.Design, Manufacture, Packaging, Labeling, Final Inspection and Release of Instrumentation for Clinical Multiplex Test Systems,
- 4.Design, Manufacture, Packaging, Labeling, Final Inspection and Release of Colorimeter, Photometer, or Spectrophotometer for Clinical Use.

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.

*Shou-Mei Wu*

Signed by \_\_\_\_\_

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)

MN001876