



MINISTRY OF HEALTH AND WELFARE  
REPUBLIC OF CHINA (TAIWAN)

Issue Date: May 14, 2026

No: MN002512

QMS Certificate

This is to certify that the quality management system of:

The Medical Device Manufacturer : Chroma ATE Inc. (Chan-Zhuan factory)

Address : 1, 2, 3, 4, 6, 7F, 88 Wenmao Road, Guishan District, Taoyuan City 333001,  
Taiwan(R.O.C.)

QMS Number : QMS2420

Valid Until : April 22, 2029

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 Instrumentation for Clinical  
Multiplex Test Systems.

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)