Certificate TW18/10421

The management system of

Chroma ATE Inc.

88 Wenmao Road, Guishan District, Taoyuan City 333001, Taiwan

has been assessed and certified as meeting the requirements of

ISO 13485:2016/EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes

For the following activities
Design and manufacturing of IVD equipment for PCR/qPCR amplification, fluorescence detection, and nucleic acids hybridization.
Design and manufacturing of IVD equipment for nucleic acid purification and microtiter diluting and dispensing.
Manufacturing of PCBA for IVD Medical Devices.

This certificate is valid from 15 September 2026 until 15 September 2029 and remains valid subject to satisfactory surveillance audits.
Issue 8. Certified since 13 October 2018
Certified activities performed by additional sites are listed on subsequent pages.

L. Moran

Authorised by
Liz Moran
Business Manager

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Chroma ATE Inc.

ISO 13485:2016/EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes

Issue 8

Sites

Chroma ATE Inc.
88 Wenmao Road, Guishan District, Taoyuan City 333001, Taiwan
Design and manufacturing of IVD equipment for PCR/qPCR amplification, fluorescence detection, and nucleic ac-ids hybridization.
Design and manufacturing of IVD equipment for nucleic acid purification and microtiter diluting and dispensing.

Chroma ATE Inc.
99 Wenxin Road, Guishan District, Taoyuan City 333001, Taiwan
Manufacturing of PCBA for IVD Medical Devices.

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