



Certificate TW18/10421

The management system of

Chroma ATE Inc.

68 Huaya 1st Road, Guishan, Taoyuan 33383, Taiwan

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

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.

This certificate is valid from 13 October 2024 until 13 October 2027 and remains valid subject to satisfactory surveillance audits.

Issue 6. Certified since 13 October 2018

Certified activities performed by additional sites are listed on subsequent pages.

L. Moran

Authorised by

Liz Moran

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Certificate TW18/10421, continued

Chroma ATE Inc.

SGS

ISO 13485:2016

EN ISO 13485:2016

Issue 6

Sites

Chroma ATE Inc.

68 Huaya 1st Road, Guishan, Taoyuan 33383, Taiwan

Manufacturing of IVD equipment for PCR/qPCR amplification, fluorescence detection, and nucleic acids hybridization.
Manufacturing of IVD equipment for nucleic acid purification and microtiter diluting and dispensing.

Chroma ATE Inc.

88 Wenmao Road, Guishan, Taoyuan 333001, Taiwan

Design of IVD equipment for PCR/qPCR amplification, fluorescence detection, and nucleic acids hybridization.
Design of IVD equipment for nucleic acid purification and microtiter diluting and dispensing.



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