



**SCIEX Citrine Triple Quad™ LC/MS/MS and SCIEX Citrine
QTRAP® LC/MS/MS for IN VITRO DIAGNOSTIC USE**

DECLARATION OF CONFORMITY

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DECLARATION OF CONFORMITY

(According to EN ISO/IEC 17050-1:2004)



We

AB SCIEX LP

of

71 Four Valley Drive, Concord, ON, Canada L4K 4V8

declare under sole responsibility that the product as originally delivered

Equipment: **Liquid Chromatography/Mass Spectrometer/Mass Spectrometer for In Vitro Diagnostic Use**

Product Name: **SCIEX Citrine Triple Quad™ LC/MS/MS and SCIEX Citrine QTRAP® LC/MS/MS**

Equipment Components: **SCIEX Citrine Triple Quad™ or SCIEX Citrine QTRAP® atomic mass spectrometer with IonDrive Turbo V Ion Source, two Agilent MS40+ roughing pumps, Dell XE2 or SCIEX Alpha Workstation 2020 (Dell T3630) personal computer, Dell P2217H or P2219H display monitor, Analyst® MD Instrument Control and Data Processing Software Version 1.6.x and MultiQuant™ MD Software for High-throughput Quantitative Analysis Version 3.0.x, where x may or may not be present and represents maintenance changes not impacting safety.**

Product Options: **TurbolonSpray® (TIS) and Atmospheric Pressure Chemical Ionization (APCI) probes**

complies with the essential requirements of the following applicable European Directives, and carries the CE marking accordingly:

- 98/79/EC - In Vitro Diagnostic Medical Devices Directive¹**
- 2012/19/EU - Waste Electrical and Electronic Equipment Directive**
- 2011/65/EU - Restriction of Hazardous Substances Directive**

and conforms with the following product standards:

Category	Standard	Classification
Safety	EU: IEC 61010-1:2010 / EN 61010-1:2010 + Corrigendum 1:2011 IEC 60101-2-061: 2015 / EN 61010-2-061:2015 IEC 61010-2-101:2015 / EN 61010-2-101:2017	IVD Equipment Class I, Pollution Degree 2
	Canada: CAN/CSA C22.2 No. 61010-1-12 CAN/CSA C22.2 No. 61010-2-061-15 CAN/CSA C22.2 No. 61010-2-101-15	IVD Equipment Class I, Pollution Degree 2
	USA: UL 61010-1 (Ed.3), UL 61010-2-061 (Ed.3), UL 61010-2-101 (Ed. 2)	IVD Equipment Class I, Pollution Degree 2
EMC	EU: IEC 61326-1; 2012 / EN 61326-1:2013 IEC 61326-2-6: 2012 / EN 61326-2-6:2013	EN 55011, Class A
	Canada: ICES-001 (CISPR 11:2004)	Class A ISM
	USA: FCC Part 15	Class A

Notes: 1 Evaluated as a component where the suitability of the integrated system is to be determined. The product was tested in a typical configuration.

Year Mark First Applied: **2018**

Replaces: **5064640**

We, the undersigned, hereby declare that the equipment specified above conforms to the above Directives and Standards.

Chris Lock
Vice President, LCMS
Research & Development

Penelope Ernould
Senior Manager,
Quality Management Systems
and CDT&R

2019/05/13

Date



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