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

DECLARATION OF CONFORMITY

5072387
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

This product 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 Directive
2012/19/EU - Waste Electrical and Electronic Equipment Directive
2011/65/EU - Restriction of Hazardous Substances Directive

and conforms with the following product standards:

<table>
<thead>
<tr>
<th>Category</th>
<th>Standard</th>
<th>Classification</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>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</td>
<td>IVD Equipment Class I, Pollution Degree 2</td>
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<tr>
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<td>USA: UL 61010-1 (Ed.3), UL 61010-2-061 (Ed.3), UL 61010-2-101 (Ed. 2)</td>
<td>IVD Equipment Class I, Pollution Degree 2</td>
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<td>EMC</td>
<td>EU: IEC 61326-1; 2012 / EN 61326-1:2013 IEC 61326-2-6; 2012 / EN 61326-2-6:2013</td>
<td>EN 55011, Class A</td>
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<td>Canada: ICES-001 (CISPR 11:2004)</td>
<td>Class A ISM</td>
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<td>USA: FCC Part 15</td>
<td>Class A</td>
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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 Luck
Vice President, LCMS Research & Development

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

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