API 3200MD™ and 3200MD QTRAP® LC/MS/MS System for In Vitro Diagnostic Use

DECLARATION OF CONFORMITY

5072385
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: API 3200MD™ LC/MS/MS System and 3200MD QTRAP® LC/MS/MS System

Equipment Components: API 3200MD™ LC/MS/MS System or 3200MD QTRAP® LC/MS/MS System mass spectrometer with Turbo V™ Ion Source, Agilent HS-602-2000 roughing pump, Dell Optiplex XE2 or SCIEX Alpha workstation 2020 (Dell T3630) personal computer, Dell P2217H or P2219H display monitor with Analyst® MD Instrument Control and Data Processing Software Version 1.6.x, MultiQuant™ MD Software for High-throughput Quantitative Analysis Version 3.0.x and CliquidB MD software Version 3.2.x or 3.3.x, where x may or may not be present and represents maintenance changes not impacting safety.

Product Options: TurbolonSpray® (TIS) or 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 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>
</thead>
<tbody>
<tr>
<td></td>
<td>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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<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>Global: IEC 61326-1:2012, IEC 61326-2-6:2012</td>
<td>CISPR 11, Class A</td>
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<td>Canada: ICES-001</td>
<td>Class A</td>
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<td>EU: EN 61326-1:2013, EN 61326-2-6:2013</td>
<td>EN 55011, Class A</td>
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<td>USA</td>
<td>FCC Part 15</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: 2013

Replaces: 5060925

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

Chris Lock
Vice President, LCMS, Research and Development

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

Date: 2019/05/15

EC REP

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Netherlands

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