



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

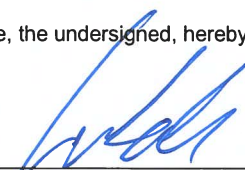
Category	Standard	Classification
Safety	Global: IEC 61010-1:2010	IVD Equipment Class I, Pollution Degree 2
	IEC 61010-2-061:2015	
	IEC 61010-2-101:2015	
	Canada: CAN/CSA C22.2 No. 61010-1-12,	IVD Equipment Class I, Pollution Degree 2
	CAN/CSA C22.2 No. 61010-2-061-15,	
	CAN/CSA C22.2 No. 61010-2-101-15	IVD Equipment Class I, Pollution Degree 2
	EU: EN 61010-1:2010	
	EN 61010-2-061:2015	
	Japan: JIS C 1010-1:2014	IVD Equipment Class I, Pollution Degree 2
	IEC 61010-2-061:2005	
IEC 61010-2-101:2002		
USA: UL 61010-1 (Ed. 3)	IVD Equipment Class I, Pollution Degree 2	
UL 61010-2-061 (Ed. 3)		
UL 61010-2-101 (Ed. 2)		
EMC	Global: IEC 61326-1:2012	CISPR 11, Class A
	IEC 61326-2-6:2012	
	Canada: ICES-001	Class A
	EU: EN 61326-1:2013	
	EN 61326-2-6:2013	
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: **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 Ernould
 Senior Manager,
 Quality Management Systems
 and CDT&R

2019/05/13
Date



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