



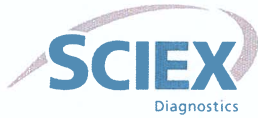
SCIEX Topaz™ SYSTEM LIQUID CHROMATROGRAPHY-MASS SPECTROMETER/MASS SPECTROMETER IN VITRO DIAGNOSTIC ANALYSER SYSTEM

DECLARATION OF CONFORMITY

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DECLARATION OF CONFORMITY

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



We
of

AB SCIEX LP
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 Diagnostics Topaz™ SYSTEM**
Equipment Components: **SCIEX Diagnostics Topaz™ mass spectrometer with Turbo V Ion Source, Turbo Ion Spray (TIS) and Atmospheric Pressure Chemical Ionization (APCI) probes, Oerlikon Leybold SV28Bi roughing pump, Dell T3600 personal computer, Dell U2312HM or P2214H display monitor, SCIEX ClearCore™ MD V.1.1.x software, SCIEX DX Liquid Chromatography system consisting of SCIEX DX sampler, two SCIEX DX pumps, SCIEX DX oven w/valves, SCIEX DX controller, SCIEX DX degasser.**
Product Options: **Peak Scientific Gas Generator, Model AB-3G or Infinity 1031; Peak Scientific MS Table, Model Table*-1B or Table*-1N.**

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	Canada: CAN/CSA C22.2 No. 61010-1-12	IVD Equipment Class I, Pollution Degree 2
	CAN/CSA C22.2 No. 61010-2-61-16	
	CAN/CSA C22.2 No. 61010-2-101-16	
	EU: EN 61010-1:2010	
USA:	EN 61010-2-061:2015	IVD Equipment Class I, Pollution Degree 2
	EN 61010-2-101:2015	
	ANSI/UL 61010-1 (Ed. 3),	
EMC	UL 61010-2-061 (Ed. 3),	IVD Equipment Class I, Pollution Degree 2
	UL 61010-2-101 (Ed. 2)	
	Canada: ICES-001	
EU: EN 61326-1:2013		
U.S.A.: FCC Part 15		

Notes: The product was tested in a typical configuration

Year Mark First Applied: **2016**

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

Chris Lock
on behalf of

Chris Lock
Vice President, LCMS
Research and Development

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

2018-06-08
Date



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