



**SCIEX Triple Quad™ 4500MD LC/MS/MS and
SCIEX QTRAP® 4500MD LC/MS/MS for IN VITRO DIAGNOSTIC USE**

DECLARATION OF CONFORMITY

5072386

↑
↓

↓



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 Triple Quad™ 4500MD LC/MS/MS and SCIEX QTRAP® 4500MD LC/MS/MS**
 Equipment Components: **SCIEX Triple Quad™ 4500MD or SCIEX QTRAP® 4500MD atomic mass spectrometer with Turbo V Ion Source, Oerlikon Leybold SV28Bi roughing pump, Dell XE2 or SCIEX Alpha Workstation 2020 (Del T3630) personal computer, Dell P2217H or P2219H display monitor, 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 Cliquant® 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) 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	Canada: CAN/CSA C22.2 No. 61010-1-12 CAN/CSA C22.2 No. 61010-2-61-15 CAN/CSA C22.2 No. 61010-2-101-15	IVD Equipment Class I, Pollution Degree 2
	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
	Japan: JIS C 1010-1:2014 IEC 61010-2-061:2005 IEC 61010-2-101:2002	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	Canada: ICES-001	Class A
	EU: IEC 61326-1: 2012 / EN 61326-1:2013 IEC 61326-2-6: 2012 / EN 61326-2-6:2013	EN 55011, Class A
	U.S.A.: 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: **2014** Replaces: **5060930**

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

		2019/05/13	<table border="1"> <tr> <td>EC</td> <td>REP</td> </tr> </table>	EC	REP
EC	REP				
Chris Lock Vice President, LCMS Research and Development	Penelope Ernould Senior Manager, Quality Management Systems and CDT&R	Date	AB Sciex Netherlands B.V. 1e Tochtweg 11, 2913LN Nieuwerkerk aan den IJssel Netherlands		