General Compliance Statement

Mira Handheld Raman Spectrometers

Metrohm Instant Raman Analyzers (Mira) are handheld, powerful Raman spectrometers designed for the rapid, nondestructive identification of chemical and pharmaceutical samples, both liquid and solid. Barely larger than a smartphone, Mira spectrometers are the only handheld Raman spectrometers currently on the market with Orbital Raster Scan (ORS) technology.

This document references global regulatory, safety, and commercial requirements relevant to Mira applications and operation. Specific standards, chapters, or articles are included. Unless otherwise noted, the Mira family of products meets or exceeds the requirements.

This declaration is valid for the following products or product versions:

Mira DS/ Mira P

American National Standards Institute (ANSI)/National Conference Of Standards Labs (NCSL)

ANSI/NCSL Z540.1	General Requirements for Calibration Laboratories and Measuring and Test Equipment
ANSI Z136.1	Safe Use of Lasers

ASTM International Standards

E 1840-96(2014)	Raman Shift Standards for Spectrometer Calibration
E 2529-06(2014)	Standard Guide for Testing the Resolution of a Raman Spectrometer
E 2911-13	Standard Guide for Relative Intensity Correction of Raman Spectrometers
E 131-10 (2015)-	Standard Terminology Relating to Molecular Spectroscopy

Electromagnetic Compatibility (EMC)

EN 61326-1: 2013	General Standards
EN 61000-6-3: 2011	Emission Standards
EN 55011 / CISPR 11: 2017	
EN 61000-6-2: 2005	Immunity Standards
EN 61000-4-2: 2009	
EN 61000-4-3: 2010	
EN61000-4-8:2010	

European Pharmacopeia (EP)

Chapter 2.2.48	Raman Spectrometry Statement of Compliance

EU declaration of conformity

This declaration attests the compliance of the instrument with the standard specifications for electrical instruments and accessories and with the standard specifications for safety and system validation of the manufacturing company.

2014/35/EU	Low Voltage Directive, LVD
2014/30/EU	Electromagnetic Compatibility Directive, EMC
2011/65/EU	Restriction of Hazardous Substances Directive, RoHS
2015/863/EU	Amendment Annex II RoHS
2012/19/EU	Waste Electrical And Electronic Equipment Directive (WEEE)

Federal Communications Commission (FCC)

47 CFR Part 15	Device has been tested and found to comply with the limits for a Class B digital device

International Conference on Harmonization (ICH)

Q2(R1)	Validation of Analytical Procedures: Text and Methodology

International Electrotechnical Commision (IEC)

EN 61010-1: 2019	Safety requirements for electrical equipment for measurement, control, and laboratory use
EN 60529: 2013	Degree of protection = IP67 • 6 = No ingress of dust • 7 = immersed 1 meter in water for 30 minutes
EN 60825-1: 2014	Safety of laser products
EN 61140: 2016	Protection against electric shock = protection class III

International Organization for Standardization (ISO)

ISO 12100: 2010	Safety Of Machinery-Design Risk Assessment & Reduction
ISO 9001: 2015	Quality Management System

Japanese Pharmacopoeia (JP)

2.26	Raman Spectrophotometry

National Institute of Standards and Technology (NIST)

Standard Reference Material (SRM) 2241	Relative intensity correction standard for Raman spectroscopy: 785 nm

United States Department of Defense (DoD)

MIL-STD-810H	Test Method Standards: Environmental Engineering Considerations and Laboratory Tests
Method 514.8	Restrained cargo/truck/trailer/vehicle vibration exposure = Category 4
Method 516.8	Shock drop along all applicable faces, edges, and corners at 1 m
Method 516.6	Bench handling shock along all applicable sides
Method 501.7	High temperature exposure
Method 502.7	Low temperature exposure
Method 512.6	Immersion, IP67

United States Food and Drug Administration (FDA)

Laser Safety for Class IIIb device

21 CFR 1040.10	Performance standard for light emitting products
21 CFR 1040.11	Specific purpose laser products

United States Pharmacopeia (USP)

USP 41- NF 36 <1039>	Chemometrics
USP 40-NF 35 <1058>	Analytical Instrument Qualification
USP 39–NF 34 <1225>	Validation of Compendial Procedures
USP 29-NF 24 <1120>	**to be replaced by <858> and <1858>
USP 39-NF 34 <858>	Raman Spectroscopy
USP 43-NF 38 <1858>	Raman Spectroscopy- Theory and Practice

Software Compliance

Mira Cal P

ALCOA	MiraCal P adheres to ALCOA+ and ALCOA, which are used by the FDA, WHO, PIC/S and GAMP to ensure data integrity.
FDA 21 CFR Part 11	Electronic Records, Electronic Signatures

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