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1 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.

The responsibility for issuing this EU declaration of conformity lies solely with the manufacturer.

1.1 Product validity

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

Misa

Metrohm Instant SERS Analyzer (Misa) is a high performance, portable analyzer system used for rapid, trace level detection / identification of illicit materials, food additives and food contaminants.

1.2 Directives

The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:



2014/35/EU – Low Voltage Directive, LVD

Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits; Official Journal of the EU L96, 29 March 2014, p. 357-374

2014/30/EU – EMC Directive, EMC

Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility; Official Journal of the EU L96, 29 March 2014, p. 79-106

Safety specifications

2011/65/EU – Directive for certain hazardous substances,

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment; Official Journal of the EU L174, 1 July 2011, p. 88-110

- 2015/863/EU Amendment Annex II RoHS Commission delegated directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances; Official Journal of the EU L137, 4 June 2015, p. 10-12
- 2012/19/EU Disposal and recycling of electrical and electronic equipment, WEEE
 Directive 2012/19/EU of the European Parliament and of the Council

of 4 July 2012 on waste electrical and electronic equipment (WEEE); Official Journal of the EU L197, 24 July 2012, p. 38-71

1.3 Safety specifications

This instrument fulfills the following safety requirements:

Design and type testing

- EN 61010-1: 2019
 Safety requirements for electrical equipment for measurement, control, and laboratory use
- EN 60529: 2013 degree of protection IP40
 Degrees of protection provided by enclosures (IP Code)
- EN 60825-1: 2014
 Safety of laser products Part 1: Instrument classification and requirements
- ISO 12100: 2010
 General principles for design Risk assessment and risk reduction
- EN 61140: 2016 protection class III
 Protection against electric shock Common aspects for installation and equipment

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1.4 Electromagnetic compatibility (EMC)

Design and type testing

EN 61326-1: 2013

Electrical equipment for measurement, control and laboratory use - General EMC requirements

1.4.1 Emission

Standards fulfilled

EN 61000-6-3: 2011

EN 55011 / CISPR 11: 2017EN 55032 / CISPR 32: 2020

EN 61000-3-2: 2019EN 61000-3-3: 2019

1.4.2 Immunity

Standards fulfilled

EN 61000-6-2: 2019

■ EN 61000-4-2: 2009

■ EN 61000-4-3: 2010

■ EN 61000-4-4: 2012

■ EN 61000-4-5: 2017

EN 61000-4-6: 2014EN 61000-4-8: 2010

■ EN 61000-4-11: 2020

1.5 Radio equipment

Standards fulfilled:

EN 300 328: 2016 V2.1.1

EN 301 489-1: 2019 V2.2.1

EN 301 489-17: 2017 V3.2.0

1.6 Manufacturer

Metrohm AG, Ionenstrasse, CH-9100 Herisau/Switzerland

Metrohm AG holds the SQS certificate ISO 9001 – Quality management system for the development, production and sale of instruments and accessories for analyses.

Herisau, June 26, 2020

P. Hunziker

Vice President, Head of Development Dr. M. Saba

Vice President,
Head of Quality Management
& Regulatory Affairs