869 Compact Sample Changer

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1 Declaration of Conformity

This is to certify the conformity to the standard specifications for electrical appliances and accessories, as well as to the standard specifications for security and to system validation issued by the manufacturing company.

Name of commodity

869 Compact Sample Changer

Sample changer for automated processing of small sample series in analytical laboratories.

CE

This instrument meets the requirements of the CE mark as contained in the EU directives 2006/95/EC (LVD), 2004/108/EC (EMC). It fulfils the following specifications:

Safety specifications	EN 61010-1: 2001	Safety requirements for electrical equipment for measurement, control and laboratory use, protection class I
	EN 61010-2-081: 2003	Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
	EN 60529: 2013	Degrees of protection provided by enclosures, IP 20
Electromagnetic compatibility	EN 61326-1: 2013	Electrical equipment for measurement, control and laboratory use – EMC requirements - Part 1: General requirements
	Emission:	EN 61000-6-3: 2011, EN 55011 / CISPR 11: 2010
	Immunity:	EN 61000-6-2: 2005, EN 61000-4-2: 2009, EN 61000-4-3: 2010, EN 61000-4-4: 2010, EN 61000-4-5: 2006, EN 61000-4-6: 2009, EN 61000-4-11: 2004, EN 61000-4-14: 2009

This instrument meets the requirements of the ETL Listed Mark for the North American market. It conforms to the electrical safety standards UL 61010-1 and CSA-C22.2 No. 61010-1. This product is listed in Intertek's Directory of Listed Products.

Manufacturer

Metrohm Ltd., CH-9100 Herisau/Switzerland

Metrohm Ltd. is holder of the SQS certificate ISO 9001:2000 Quality management system for development, production and sales of instruments and accessories for ion analysis.

Herisau, February 23, 2015

P. Hunziker

Vice President,
Head of Development

M. Matter

Head of Quality Management

2 Quality Management Principles

Metrohm Ltd. holds the ISO 9001:2000 Certificate, registration number 10872-02, issued by SQS (Swiss Association for Quality and Management Systems). Internal and external audits are carried out periodically to assure that the standards defined by Metrohm's QM Manual are maintained.

The steps involved in the design, manufacture and servicing of instruments are fully documented and the resulting reports are archived for ten years. The development of software for PCs and instruments is also duly documented and the documents and source codes are archived. Both remain the possession of Metrohm. A non-disclosure agreement may be asked to be provided by those requiring access to them.

The implementation of the ISO 9001:2000 quality management system is described in Metrohm's QM Manual, which comprises detailed instructions on the following fields of activity:

Instrument development

The organization of the instrument design, its planning and the intermediate controls are fully documented and traceable. Laboratory testing accompanies all phases of instrument development.

Software development

Software development occurs in terms of the software life cycle. Tests are performed to detect programming errors and to assess the program's functionality in a laboratory environment.

Components

All components used in the Metrohm instruments have to satisfy the quality standards that are defined and implemented for our products. Suppliers of components are audited by Metrohm as the need arises.

Manufacture

The measures put into practice in the production of our instruments guarantee a constant quality standard. Production planning and manufacturing procedures, maintenance of production means and testing of components, intermediate and finished products are prescribed.

Customer support and service

Customer support involves all phases of instrument acquisition and use by the customer, i.e. consulting to define the adequate equipment for the analytical problem at hand, delivery of the equipment, user manuals, training, after-sales service and processing of customer complaints. The Metrohm service organization is equipped to support customers in implementing standards such as GLP, GMP, ISO 900X, in performing Operational Qualification and Performance Verification of the system components or in carrying out the System Validation for the quantitative determination of a substance in a given matrix.