Declaration of Conformity

Metrohm Ltd.
CH-9101 Herisau
Switzerland
Tel. +41 71 353 85 85
Fax +41 71 353 89 01
www.metrohm.com

for the instrument
716 DMS Titrino

Description
Compact general-purpose titrator.

The above instrument was developed and manufactured in accordance with the requirements demanded by the ISO 9001 quality system regarding the design, manufacture and servicing of Metrohm instruments.

The instrument was manufactured and tested according to the following standards:

Electromagnetic compatibility: emission

EN50081-1, EN50081-2, EN55011 class B, EN55022 class B	Generic emission

Electromagnetic compatibility: immunity

EN50082-1	Immunity
IEC801-2, IEC1000-4-2 (class 4)	Static discharge
IEC801-3, IEC1000-4-3, ENV50140+ENV50204 (class 2)	Radiated rf electromagn. field immunity
IEC801-4, IEC1000-4-4 (class 3)	Electrical fast transient requirements
IEC801-5, IEC1000-4-5, EN61000-4-5 (class 2/3)	«Surges» immunity
IEC801-6, IEC1000-4-6, ENV50141 (class 2)	Immunity to conducted disturbances
IEC1000-4-11	Voltage dips, short interruptions

Safety specifications

EN61010, IEC1010, UL3101

The instrument meets the requirements of the CE mark as contained in the EU directives 89/336/EWG and 73/23/EWG and fulfils the following specifications:

EN50081-1	Electromagnetic compatibility, basic specification «Emitted Interference»
EN50082-1	Electromagnetic compatibility, basic specification «Interference Immunity»
EN61010	Safety requirements for electrical laboratory measurement and control equipment

The technical specifications are documented in the instruction manual.

The instrument was validated with respect to functionality, analytical performance and accuracy of results. The instrument functions are documented in the instruction manual.

Herisau, 10th December 1997

Dr. J. Frank
Development Manager

Ch. Buchmann
Production and
Quality Assurance Manager

Quality Management Principles

Metrohm Ltd. holds the ISO 9001 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 quality system is described in Metrohm's QM Manual, which comprises detailed instructions on the following fields of activity:

Instrument development

The organisation 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 organisation 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.