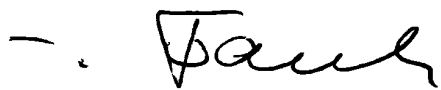



## Declaration of Conformity



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.

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|   |  |
|---|--|
| <i>Name of commodity</i>  | <b>830 IC Interface</b>  |
| <i>System software</i>  | Stored in ROMs   |
| <i>Name of manufacturer</i>   | Metrohm Ltd., Herisau, Switzerland   |
| <i>Description</i>  | PC controlled chromatography data system for remote control of IC instruments and for automatic evaluation of chromatograms. |
| <p>This Metrohm instrument has been built and has undergone final type testing according to the standards:</p> <p><i>Electromagnetic compatibility: Emission</i><br/>EN/IEC 61326, EN 55022 / CISPR 22</p> <p><i>Electromagnetic compatibility: Immunity</i><br/>EN/IEC 61326, EN/IEC 61000-4-2, EN/IEC 61000-4-3, EN/IEC 61000-4-4, EN/IEC 61000-4-5, EN/IEC 61000-4-6, EN/IEC 61000-4-8, EN/IEC 61000-4-11, EN/IEC 61000-4-14, NAMUR</p> <p><i>Safety specifications</i><br/>EN/IEC 61010-1, UL 3101-1 protection class I</p> <p>It has also been certified by ElectroSuisse, which is member of the International Certification Body (CB/IEC).</p> <p><i>The instrument meets the requirements of the CE mark as contained in the EU directives 89/336/EEC and 73/23/EEC and fulfils the following specifications:</i></p> |  |
| EN 61326  | Electrical equipment for measurement, control and laboratory use – EMC requirements  |
| EN 61010-1  | Safety requirements for electrical equipment for measurement, control and laboratory use                                     |
| Metrohm Ltd. is holder of the SQS-certificate of the quality system ISO 9001 for quality assurance in design/development, production, installation and servicing.   |  |
| <p>The system software, stored in Read Only Memories (ROMs) has been validated in connection with standard operating procedures in respect to functionality and performance.</p> <p>The technical specifications are documented in the instruction manual.</p>  |  |
| Herisau, May 28, 2003   |  |
|    |    |
| Dr. J. Frank<br>Development Manager   | Ch. Buchmann<br>Production and<br>Quality Assurance Manager  |

# Quality Management Principles

Metrohm Ltd., CH-9101 Herisau, Switzerland

 **Metrohm**  
Ion analysis  
CH-9101 Herisau/Switzerland  
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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.

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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.