

Project 0.2.0.263.786

Audit Report: Categorisation acc. to GAMP 4

tiamo 1.3



Metrohm

Metrohm Ltd.

CH-9101 Herisau

Switzerland

Tel. +41 71 353 85 85

Fax +41 71 353 89 01

www.metrohm.com

Audit Date: 08.05.2008¹

Auditor: Yvonne Zurbuchen, Chemist FH, Chemgineering AG

Goal: Classification of *tiamo 1.3* in software categories according to GAMP 4

Description: *tiamo* is a control and database software for titrators, dosing devices and sample processors for creating methods, carrying out determinations, data evaluation and generating reports. *tiamo* is the successor of TiNet and Workcell software. *tiamo* was developed and manufactured by Metrohm Ltd. in accordance with the requirements of ISO 9001 quality system regarding design, manufacturing and maintenance.

Categorisation: *tiamo* is a standard - software according to GAMP 4 category 3.

Justification:

The software configuration is limited to:

- Adaptation of the system's runtime environment, e.g.:
 - Configuration of the connected instruments,
 - Installation of databases
 - Definition of users and user groups (with pre-defined privileges)
 - Configuration of security settings.

However, no structural modifications or customisations of the software concerning user-specific procedures are done.

- Creation of *methods*:
Methoden are compiled of tracks, which are composed of pre-defined commands. As a consequence, methods are adapted to user-specific analytical procedures and have to be approved accordingly. That applies also and in particular to calculations and reports.