

Project 0.2.0.263.786

Audit Report: Categorisation acc. to GAMP

tiamo 1.0



Metrohm Ltd.

CH-9101 Herisau

Switzerland

Tel. +41 71 353 85 85

Fax +41 71 353 89 01

www.metrohm.com

Date: 21.02.2005

Author: Dr. Gerald Schwarzenbacher, Chemengineering Planung GmbH

Goal: Classification of *tiamo 1.0* in software categories according to GAMP

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 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*:

Methods are compiled of *tracks*, which are composed of pre-defined *commands*. Consequently, methods are adapted to user-specific procedures ("GAMP category 4") and have to be validated accordingly. That applies also and in particular to calculations and reports.

Note:

It is recommended to validate the *methods* and the software separately!