

Project 0.2.0.263.786

Audit Report: Categorisation acc. to GAMP

tiamo 1.1



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Goal: Classification of *tiamo 1.1* 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!

¹ The audit was carried out with *tiamo* version 1.0. The current software version does not contain any modifications regarding GAMP. (01. September 2005)