

Project 2501800
Audit Report: Categorisation acc. to GAMP 5

tiamo 2.3



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Goal: Classification of *tiamo 2.3* in software categories according to GAMP 5

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 5 category 3.

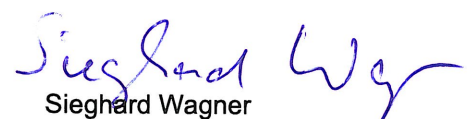
Justification:

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. As part of the regular system operation, methods are adapted to specific analytical procedures on a case by case bases. The resulting method settings have to be approved accordingly. That applies also and in particular to calculations and reports.


Sieghard Wagner