

Project 90921500  
Audit Report: Categorisation acc. to GAMP 5



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## *tiamo 2.1*

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**Goal:** Classification of *tiamo 2.1* 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