

Project 90921500

Audit Report: Categorisation acc. to GAMP 5

tiamo 2.1



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Audit Date: 06.07.2009

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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