

Audit Report: Categorisation according to GAMP 5

*tiamo 2.5*



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- Date:** 07.07.2015
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- Goal:** Classification of *tiamo 2.5* 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 by Metrohm AG in accordance with the ISO 9001 requirements regarding design, manufacturing and maintenance.
- Categorisation:** The *tiamo software* is a “Non-Configured Product” – as such, it is categorized into **GAMP software category 3**.
- Justification:*  
The software configuration is limited to:
- Customization 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 customizations of the software concerning user-specific procedures are made<sup>1</sup>.
- Creation of methods:  
The creation and modification of methods is based on built-in standard system functionality (methods are compiled of tracks, which are composed of pre-defined commands). During normal system operation, methods are adapted to specific analytical procedures on a case by case basis. This has to include appropriate checks and verifications, especially of all calculations and reports included – if applicable. These measures are to be implemented as part of the operational controls in order to maintain the validated state.

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<sup>1</sup> see definition of Software Category 3: GAMP 5, Appendix M4