

Audit Report: GAMP® 5 Software Categorisation

916 Ti-Touch

5.916.0045



Metrohm AG

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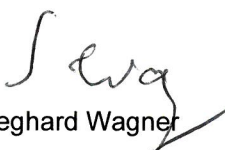
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- Date:** 02-May-2022
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- Objective:** Classification of *916 Ti-Touch* (version 5.916.0045) according to the GAMP® 5 software categories.
- Description:** *916 Ti-Touch* is a compact titration system for volumetric titration – in the class of stand-alone systems for routine analysis – with touch-sensitive display for processing methods, analysis (titration, measurements), data acquisition, evaluation, and reporting. *916 Ti-Touch* can be integrated in an automation system with Sample Processors.
- 916 Ti-Touch* was developed by the Metrohm AG in accordance with ISO 9001 requirements regarding design, manufacturing, and maintenance.
- Categorisation:** The *916 Ti-Touch* firmware is a “Non-Configured Product” – as such, it is categorized into **GAMP 5 software category 3**.
- Justification:
The firmware configuration is limited to:
- Customization of the system’s runtime environment, e.g.:
 - Maintenance of master data (methods, sample data, etc.)
 - Setup of technical parameters (connected devices, etc.)
 - Configuration of security settings
 - Definition of users and user groups (with pre-defined privileges).
- However, these are no structural modifications or customizations to adapt the firmware to customer-specific business processes.¹
- Creation of methods:
The creation and modification of methods is based on built-in standard system functionality. 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, settings, and reports included – if applicable. These measures are to be implemented as part of the operational controls in order to maintain the validated state.


Sieghard Wagner

¹ Please refer to the definition of Software Category 3: GAMP 5, Appendix M4