Certificate

chemgineering

Audit Report: GAMP® 5 Software Categorisation

916 Ti-Touch

5.916.0043

Metrohm

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Objective: Classification of *916 Ti-Touch* (version 5.916.0043) according to the GAMP® 5 software categories.

Description: *916 Ti-Touch* is a compact titration system for volumetric titration titration – in the class of stand-alone systems for routine analysis – and operating unit for the Titrandos, USB Sample Processors, 856 Conductivity Modules, 867 pH Modules and 846 Dosing Interfaces 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.

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