

Audit Report: GAMP5® Software Categorisation

915 KF Ti-Touch

5.915.0041



Metrohm AG

CH-9100 Herisau

Switzerland

Tel. +41 71 353 85 85

Fax +41 71 353 89 01

<https://www.metrohm.com/en>

- Date:** 2019-02-08
- Author:** Sieghard Wagner, mech. Engineer (grad.), Chemengineering Business Design GmbH
- Objective:** Classification of *915 KF Ti-Touch* (version 5.915.0041) according to the GAMP5® software categories.
- Description:** *915 KF Ti-Touch* is an 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.
915 KF Ti-Touch was developed by the Metrohm AG in accordance with ISO 9001 requirements regarding design, manufacturing, and maintenance.
- Categorisation:** The *915 KF Ti-Touch* firmware is a “Non-Configured Product” – as such, it is categorized into **GAMP 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 see definition of Software Category 3: GAMP 5, Appendix M4