Certificate

chemgineering

Audit Report: GAMP5® Software Categorisation

917 Coulometer

5.917.0021

Metrohm

Metrohm AG
CH-9100 Herisau
Switzerland
Tel. +41 71 353 85 85
Fax +41 71 353 89 01

https://www.metrohm.com/en

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Author: Sieghard Wagner, mech. Engineer (grad.), Chemgineering Business Design GmbH

Objective: Classification of *917 Coulometer* (version 5.917.0021) according to the GAMP5® software categories.

Description: *917 Coulometer* 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.

917 Coulometer was developed by the Metrohm AG in accordance with ISO 9001 requirements regarding design, manufacturing, and maintenance.

Categorisation: The *917 Coulometer* 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