Certificate

Audit Report: GAMP® 5 Software Categorisation
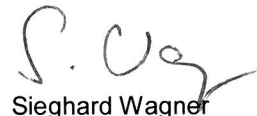
917 Coulometer
5.917.0023

chemgineering

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Objective:	Classification of *917 Coulometer* (version 5.917.0023) according to the GAMP® 5 software categories.
Description:	*917 Coulometer* is a compact titration system for coulometric Karl Fischer 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.
	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 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

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

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