

Audit Report: GAMP® 5 Software Categorisation

917 Coulometer

5.917.0025



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Objective:	Classification of <i>917 Coulometer</i> (version 5.917.0025) according to the GAMP® 5 software categories.
Description:	<i>917 Coulometer</i> 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. <i>917 Coulometer</i> was developed by the Metrohm AG in accordance with ISO 9001 requirements regarding design, manufacturing, and maintenance.
Categorisation:	The <i>917 Coulometer</i> firmware is a “Non-Configured Product” – as such, it is categorized into GAMP 5 software category 3. <u>Justification:</u> 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