

Audit Report: GAMP® 5 Software Categorisation

916 Ti-Touch

5.916.0046



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Objective:	Classification of <i>916 Ti-Touch</i> (version 5.916.0046) according to the GAMP® 5 software categories.
Description:	<p><i>916 Ti-Touch</i> is a compact titration system for volumetric 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>916 Ti-Touch</i> can be integrated in an automation system with Sample Processors.</p> <p><i>916 Ti-Touch</i> was developed by the Metrohm AG in accordance with ISO 9001 requirements regarding design, manufacturing, and maintenance.</p>
Categorisation:	<p>The <i>916 Ti-Touch</i> firmware is a “Standard System Components” – as such, it is categorized into GAMP 5 software category 3.</p> <p><u>Justification:</u> The firmware configuration is limited to:</p> <ul style="list-style-type: none">▪ Customization of the system’s runtime environment, e.g.:<ul style="list-style-type: none">▫ 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). <p>However, these are no structural modifications or customizations to adapt the firmware to customer-specific business processes.¹</p> <p>▪ 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.</p>

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