Certificate

Audit Report: 21 CFR Part 11

916 Ti-Touch

5.916.0041

chemgineering

Ω Metrohm

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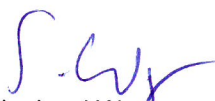
Audit Date:	2019-02-08[1]
Auditor:	Sieghard Wagner, mech. Engineer (grad.), Chemgineering Business Design GmbH
Audit Target:	Compliance check of the *916 Ti-Touch* software (Version 5.916.0041) against the 21 CFR Part 11 requirements.
Description:	*916 Ti-Touch* is an operating unit for the Titrandos, 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.
	916 Ti-Touch was developed by the Metrohm AG in accordance with ISO 9001 requirements regarding design, manufacturing, and maintenance.
Investigation:	The functions and properties of the above software system are audited against the requirements of 21 CFR Part 11 and its current interpretations. During the audit the following items were examined: Validation, documentation, audit trail, electronic copies, access rights, user access, password, access violation, sequence of steps, plausibility, device check, data encryption, electronic signature.
Operator Responsibility:	Compliance with 21 CFR Part 11 requires an appropriate operational environment. It is the operations responsibility to provide a compliant environment regarding: • Technical environment, data management • Training • Administration • Standard Operating Procedures (SOP).

Summary:

The software is compliant to the following 21 CFR Part 11 requirements:
- 11.10 (b), (d), (f), (g)
- 11.50, 11.70
- 11.300 (a)

The software is compliant with the following 21 CFR Part 11 requirements with support of the operator:
- 11.10 (a), (c), (e), (h), (i), (j), (k)
- 11.100 (a), (b), 11.200 (a), 11.300 (b), (c), (d), (e)

The software supports electronic signature.

Sieghard Wagner

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[1] This 21 CFR Part 11 assessment is based on a remote audit performed on May 8, 2017. Subject of this audit was the firmware version 5.900.0040 with all compliance features enabled. According to Metrohm AG management (development and QA) all implemented changes in the following versions – including the current version – are not relevant with regard to 21 CFR Part 11 or 21 CFR Part 11 compliant (see Release Notes 8.916.8009 EN). Therefore, this update does not require a formal re-audit.

8.916.3010 EN