

Certificate

Audit Report: 21 CFR Part 11

tiamo 3.0

chemengineering



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Audit Target: Proof that the *tiamo* software, used for control of titration devices, complies with 21 CFR Part 11.

Description: *tiamo* is a PC software for control of titration devices. It features creating methods, performing determinations (titrations and measurements), data acquisition, evaluation and archiving in a database.
The software was developed by 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 with the requirements of 21 CFR Part 11 and the current interpretations.
During the audit the following items were examined:
Validation, password, documentation, audit trail, electronic copies, access rights, user access, access violation, sequence of steps, plausibility, device check, data encryption, electronic signature.

Operator Responsibility: Compliance with the requirements of 21 CFR Part 11 can only be met in connection with the operational environment. The requirements for such an environment encompass:

- 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), (e), (f), (g)
- 11.50, 11.70
- 11.300 (a)

The software is compliant to the following 21 CFR Part 11 requirements with support of the operator:

- 11.10 (a), (c), (h), (i), (j), (k)
- 11.100 (a), (b), 11.200 (a), 11.300 (b), (c), (d)

The software supports electronic signature.

Sieghard Wagner

¹ This 21 CFR Part 11 assessment is based on an on-site audit performed January the 13th 2009 based on the *tiamo* 2.0 version. 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 requirements, or compliant with 21 CFR Part 11 (see Release Notes 8.101.8017EN, 8.101.8027EN, 8.101.8039EN, 8.101.8055EN, 8.101.8072EN and 8.101.8080EN). Therefore, this update does not require an on-site re-audit.