

# Certificate

Audit Report: 21 CFR Part 11

## 917 Coulometer

chemengineering



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- Audit Date:** 08-May-2017<sup>1</sup>
- Auditor:** Sieghard Wagner, mech. Engineer (grad.), Chemengineering Business Design GmbH
- Audit Target:** Compliance check of the *917 Coulometer* software (Version 5.917.0020) against the 21 CFR Part 11 requirements.
- Description:** *917 Coulometer* is a stand-alone system 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.
- 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 to 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

<sup>1</sup> This 21 CFR Part 11 certificate is based on a remote audit performed May, 8<sup>th</sup> 2017. Subject of this audit was the software version 5.917.0020 with all compliance features enabled.