

915 KF Ti-Touch

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| Audit Date: | 08-May-2017 ¹ |
| Auditor: | Sieghard Wagner, mech. Engineer (grad.), Chemengineering Business Design GmbH |
| Audit Target: | Compliance check of the <i>915 KF Ti-Touch</i> software (Version 5.915.0040) against the 21 CFR Part 11 requirements. |
| Description: | <p><i>915 KF Ti-Touch</i> is a stand-alone system with touch-sensitive display for processing methods, analysis (titration, measurements), data acquisition, evaluation and reporting</p> <p><i>915 KF Ti-Touch</i> was developed by the Metrohm AG in accordance with ISO 9001 requirements regarding design, manufacturing and maintenance.</p> |
| Investigation: | <p>The functions and properties of the above software system are audited against the requirements of 21 CFR Part 11 and its current interpretations.</p> <p>During the audit the following items were examined:</p> <ul style="list-style-type: none">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: | <p>Compliance with 21 CFR Part 11 requires an appropriate operational environment. It is the operations responsibility to provide a compliant environment regarding:</p> <ul style="list-style-type: none">• Technical environment, data management• Training• Administration• Standard Operating Procedures (SOP). |
| Summary: | <p>The software is compliant to the following 21 CFR Part 11 requirements:</p> <ul style="list-style-type: none">• 11.10 (b), (d), (f), (g)• 11.50, 11.70• 11.300 (a) <p>The software is compliant to the following 21 CFR Part 11 requirements with support of the operator:</p> <ul style="list-style-type: none">• 11.10 (a), (c), (e), (h), (i), (j), (k)• 11.100 (a), (b), 11.200 (a), 11.300 (b), (c), (d), (e) <p>The software supports electronic signature.</p> |



Sieghard Wagner

¹ This 21 CFR Part 11 certificate is based on a remote audit performed May, 8th 2017. Subject of this audit was the software version 5.915.0040 with all compliance features enabled.