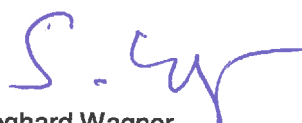


916 Ti-Touch



Metrohm AG
CH-9100 Herisau
Switzerland
Tel. +41 71 353 85 85
Fax +41 71 353 89 01
www.metrohm.com

Audit Date:	08-May-2017 ¹
Auditor:	Sieghard Wagner, mech. Engineer (grad.), Chemengineering Business Design GmbH
Audit Target:	Compliance check of the <i>916 Ti-Touch</i> software (Version 5.916.0040) against the 21 CFR Part 11 requirements.
Description:	<p><i>916 Ti-Touch</i> is a stand-alone system unit with touch-sensitive display for processing methods, analysis (titration, measurements), data acquisition, evaluation and reporting.</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>
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 5.916.0040 with all compliance features enabled.