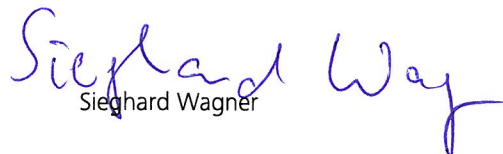


## PC Control 6.0 for Titrandos

<b>Audit Date:</b>	30.06.2009 <sup>1</sup>
<b>Auditor:</b>	Sieghard Wagner, mech. Engineer (grad.), Chemengineering Business Design GmbH
<b>Audit Target:</b>	Compliance check of PC Control 6.0 software for controlling Titrandos against the requirements of 21 CFR Part 11.
<b>Description:</b>	<p>PC software for controlling Titrandos. Creation of methods, carrying out determinations (titrations and measurements), data acquisition, and evaluation.</p> <p>The mentioned software was developed and manufactured in accordance with the requirements demanded by the ISO 9001 quality system regarding the design, manufacture and servicing of Metrohm instruments.</p>
<b>Investigation:</b>	<p>The functions and properties of the mentioned software system are audited with the requirements in 21 CFR Part 11 and the current interpretations.</p> <p>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, digital signature.</p>
<b>Operator Responsibility:</b>	<p>The compliance with the requirements of 21 CFR Part 11 can only be met together with the operational environment. The requirements for such an environment are:</p> <ul style="list-style-type: none"><li>• technical environment, data management</li><li>• training</li><li>• administration</li><li>• SOP (Standard Operating Procedures)</li></ul>
<b>Summary:</b>	<p>The software is compliant to the following 21 CFR Part 11 requirements:</p> <ul style="list-style-type: none"><li>• 11.10 (b), (d), (f), (g), (h)</li><li>• 11.50, 11.70</li><li>• 11.200 (a), 11.300 (a)</li></ul> <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"><li>• 11.10 (a), (c), (e), (i), (j), (k)</li><li>• 11.100 (a), (b)</li><li>• 11.200 (a) iii, 11.300 (b), (c), (d), (e).</li></ul>

  
Sieghard Wagner

<sup>1</sup> A physical audit has been performed on the base of the Version 3.0 on the 02.03.2004. According to Metrohm Ltd., the implemented changes in the current version are not relevant regarding 21 CFR Part 11 (see Release Notes 8.840.8009EN). Therefore this update was carried out without a physical audit.