

**Audit Report: 21 CFR Part 11**

## ***MagIC Net 2.0* for ion chromatography**



Metrohm Ltd.

CH-9101 Herisau

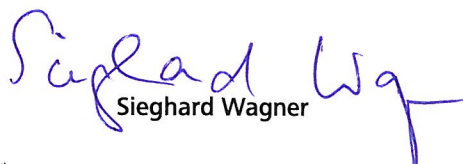
Switzerland

Tel. +41 71 353 85 85

Fax +41 71 353 89 01

www.metrohm.com

<b>Audit Date:</b>	29.06.2009 <sup>1</sup>
<b>Auditor:</b>	Sieghard Wagner, mech. Engineer (grad.), Chemengineering Business Design GmbH
<b>Audit Target:</b>	Compliance check of <i>MagIC Net 2.0</i> software for controlling ion chromatography devices against the requirements of 21 CFR Part 11.
<b>Description:</b>	<p>PC software for controlling ion chromatography devices. Creation of methods, carrying out determinations (chromatograms and measurements), data acquisition, evaluation, and archiving in a database.</p> <p>The above 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 Ltd.</p>
<b>Investigation:</b>	<p>The functions and properties of the above software system are audited with the requirements of 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, electronic 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), (e), (f), (g), (h)</li><li>• 11.50, 11.70</li><li>• 11.200 (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), (i), (j), (k)</li><li>• 11.100 (a), (b), 11.200(a) iii, 11.300 (a), (b), (c), (d), (e)</li></ul>

  
Sieghard Wagner

<sup>1</sup> This 21 CFR Part 11 certificate is based on an audit performed January the 13<sup>th</sup> 2009. Subject of this audit was the platform commonly used by MagIC Net 2.0 and tiamo 2.0. This platform provides the functionality for electronic record and signature processing.