

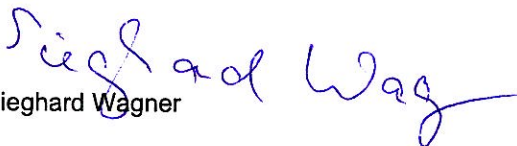
Audit Report: 21 CFR Part 11

MagIC Net 2.2 for ion chromatography



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Audit Date:	17.05.2010 ¹
Auditor:	Sieghard Wagner, mech. Engineer (grad.), Chemengineering Business Design GmbH
Audit Target:	Compliance check of <i>MagIC Net 2.2</i> software for controlling ion chromatography devices against the requirements of 21 CFR Part 11.
Description:	PC software for controlling ion chromatography devices. Creation of methods, carrying out determinations (chromatograms and measurements), data acquisition, evaluation, and archiving in a database. 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.
Investigation:	The functions and properties of the above software system are audited with the requirements of 21 CFR Part 11 and the 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:	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: • technical environment, data management • training • administration • SOP (Standard Operating Procedures)
Summary:	The software is compliant to the following 21 CFR Part 11 requirements: • 11.10 (b), (d), (e), (f), (g), (h) • 11.50, 11.70 • 11.200 (a) The software is compliant to the following 21 CFR Part 11 requirements with support of the operator. • 11.10 (a), (c), (i), (j), (k) • 11.100 (a), (b), 11.200(a) iii, 11.300 (a), (b), (c), (d), (e)


Sieghard Wagner

¹ This 21 CFR Part 11 certificate is based on an audit performed January the 13th 2009. Subject of this audit was the platform commonly used by MagIC Net 2.x and tiamo 2.x. This platform provides the functionality for electronic record and signature processing.