

Audit Report: Categorisation acc. to GAMP

MagIC Net 2.0



Metrohm Ltd.
CH-9101 Herisau
Switzerland
Tel. +41 71 353 85 85
Fax +41 71 353 89 01

www.metrohm.com

Date: 29.06.2009

Author: Sieghard Wagner, mech. Engineer (grad.), Chemengineering Business Design GmbH

Goal: Classification of *MagIC Net 2.0* in software categories according to GAMP

Description: *MagIC Net* is a control and database software for ion chromatography devices, dosing devices and sample processors for creating methods, carrying out determinations, data evaluation and generating reports. *MagIC Net* is the successor of IC Net.

MagIC Net was developed and manufactured by Metrohm Ltd. in accordance with the requirements of ISO 9001 quality system regarding design, manufacturing and maintenance.

Categorisation: *MagIC Net* is a standard - software according to GAMP category 3.

Justification:

The software configuration is limited to:

- Adaptation of the system's runtime environment, e.g.:
 - Configuration of the connected instruments,
 - Installation of databases
 - Definition of users and user groups (with pre-defined privileges)
 - Configuration of security settings.

However, no structural modifications or customisations of the software concerning user-specific procedures are done.

- Creation of *methods*:
Methods are consisting of a *device arrangement*, a *time program* and *evaluation parameters*. As part of the regular system operation, methods are adapted to specific analytical procedures on a case by case bases. The resulting method settings have to be approved accordingly. That applies also and in particular to calculations and reports.

A handwritten signature in blue ink, reading "Sieghard Wagner".

Sieghard Wagner