

Audit Report: Categorisation acc. to GAMP

MagIC Net 3.1



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

www.metrohm.com

- Date:** 28.07.2014
- Author:** Sieghard Wagner, mech. Engineer (grad.), Chemengineering Business Design GmbH
- Goal:** Classification of *MagIC Net 3.1* into one of the GAMP software categories.
- Description:** *MagIC Net* is a control and database software for ion chromatography devices, dosing devices and sample processors for creating methods, performance of analyses, data evaluation and generating reports. *MagIC Net* is the successor of IC Net.
MagIC Net was developed by Metrohm AG in accordance with the ISO 9001 requirements regarding design, manufacturing and maintenance.
- Categorisation:** The *MagIC Net software* is a “Non-Configured Product” – as such, it is categorized into **GAMP software category 3**.
Justification:
The software configuration is limited to:
- Customization of the system’s runtime environment, e. g.:
 - Configuration of the connected instruments,
 - Definition of users and user groups (with pre-defined privileges),
 - Configuration of security settings,
 - Maintenance of master data (methods, standards, system settings, etc).
- However, no structural modifications or customizations of the software concerning user-specific procedures are made¹.
- Creation of methods:
The creation and modification of methods is based on built-in standard system functionality (device arrangement, time program and evaluation parameters). During normal system operation, methods are adapted to specific analytical procedures on a case by case basis. This has to include appropriate checks and verifications, especially of all calculations and reports included – if applicable. These measures are to be implemented as part of the operational controls in order to maintain the validated state.

Sieghard Wagner

¹ see definition of Software Category 3: GAMP 5, Appendix M4