

Audit Report: GAMP5® Software Categorisation

MagIC Net 4.2



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

<https://www.metrohm.com>

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

Goal: Classification of *MagIC Net 4.2* 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 "Standard Product" – as such, it is categorized into **GAMP software category 3**.

Justification¹:
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 business processes are made.

- 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 and Chapter 4.2.6.1 "Example of a Standard Product"