

Audit Report: GAMP5® Software Categorisation

## MagIC Net 3.3



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**Goal:** Classification of *MagIC Net 3.3* 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.

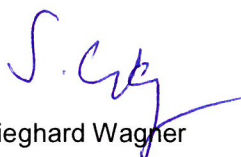
**Categorisation:** The *MagIC Net* software is a "Non-Configured Product" – as such, it is categorized into **GAMP software category 3**.

*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 business processes are made.<sup>1</sup>

- 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

<sup>1</sup> see definition of Software Category 3: GAMP 5, Appendix M4