

**Audit Report: Categorisation acc. to GAMP**

## ***Mag/C Net 2.3***



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**Goal:** Classification of *Mag/C Net 2.3* into one of the GAMP software categories.

**Description:** *Mag/C 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. *Mag/C Net* is the successor of IC Net.

*Mag/C Net* was developed by Metrohm Ltd. in accordance with the ISO 9001 requirements regarding design, manufacturing and maintenance.

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

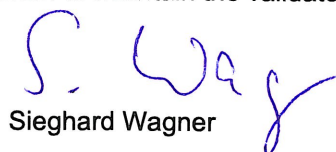
**Justification:**

All functions required for operation are available in the product – no configuration is necessary in order to conform to user-site business processes<sup>1</sup>.

The existing configuration is limited to adaptation 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).

The creation and modification of methods in particular, 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

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<sup>1</sup> see definition "Categories of Software": GAMP 5, appendix M4