

Audit Report: Categorisation acc. to GAMP



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MagIC Net 1.1

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Goal: Classification of *MagIC Net 1.1* 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*. Consequently, methods are adapted to user-specific analytical procedures and have to be verified accordingly. That applies also and in particular to calculations and reports.

A handwritten signature in blue ink, appearing to read 'Y. Zurbuchen', with a horizontal line underneath it.
Yvonne Zurbuchen