

Audit Report: GAMP5[®] Software Categorisation

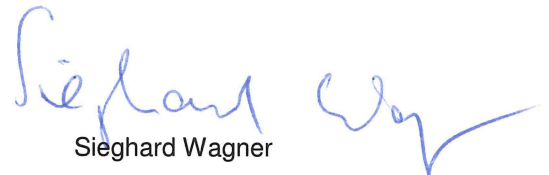
Vision 4.1 Patch 1



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- Date:** 13.01.2017
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- Goal:** Classification of *Vision 4.1 Patch 1* into one of the GAMP[®] software categories.
- Description:** *Vision* is a control and database software for NIR spectroscopy devices, for creating operations methods, project databases and libraries, data acquisition, data evaluation against libraries, and generating of reports.
Vision was developed by Metrohm AG in accordance with the ISO 9001 requirements regarding design, manufacturing and maintenance.
- Categorisation:** The *Vision 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, libraries, databases, system settings...).
- However, no structural modifications or customizations of the software concerning user-specific business processes are made.¹
- Creation of methods:
The creation and modification of the different methods is based on built-in standard system functionality (e. g. settings for: qualification method, sample selection, operations method...). During normal system operation, methods may be adapted to specific analytical procedures on a case by case basis. This has to include appropriate checks and verifications, especially of all calculations, settings and reports included – if applicable. These measures are to be implemented as part of the operational controls in order to maintain the validated state.



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