

Certificate

Audit Report: GAMP5® Software Categorisation

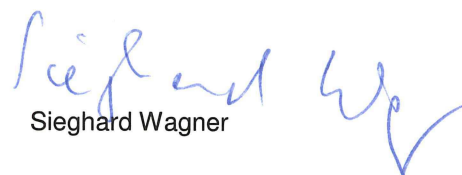
Vision Air 2.0



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- Date:** 13.01.2017
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- Goal:** Classification of *Vision Air 2.0* into one of the GAMP® software categories.
- Description:** *Vision Air* is a control and database software for NIR spectroscopy devices, for creating operating procedures, project databases and libraries, data acquisition, data evaluation against libraries, and generating of reports.
Vision Air was developed by Metrohm AG in accordance with the ISO 9001 requirements regarding design, manufacturing and maintenance.
- Categorisation:** The *Vision Air 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 (libraries, project database, system settings, etc).
- However, no structural modifications or customizations of the software concerning user-specific business processes are made.¹
- Creation of operating procedures:
The creation and modification of operating procedures is based on built-in standard system functionality (settings for: header data, acquisition, external reference, output, product order...). During normal system operation, 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