

Audit Report: GAMP5® Software Categorisation

Mira Cal Software 3.1



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- Date:** 13.10.2017
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- Goal:** Classification of *Mira Cal Software 3.1* into one of the GAMP® software categories.
- Description:** *Mira Cal Software* is a control and database software for Raman spectroscopy devices, for creating operating procedures, libraries and training sets, data acquisition, data evaluation against libraries and/or training sets, and generating of reports.
- Mira Cal Software* was developed under the supervision of the Metrohm AG in accordance with its ISO 9001 requirements – Metrohm Raman USA itself developed *Mira Cal Software* based on an inhouse QMS which currently runs through the ISO 9001:2015 certification process.
- Categorisation:** The *Mira Cal 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 (training sets, libraries, 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, evaluation, barcodes). During normal system operation, operating procedures 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