

Audit Report: GAMP5® Software Categorisation

MiraCal P Software 4.2.x



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- Date:** 2020-05-29
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- Objective:** Classification of *MiraCal P Software 4.2.x*¹ into one of the GAMP® software categories.
- Description:** *MiraCal P Software* is a control and database software for Raman spectroscopy devices. It is used for creating operating procedures, libraries and training sets, data acquisition, data evaluation against libraries and/or training sets, and generating of reports.
- Categorisation:** The *MiraCal P 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.²
- 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, and 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.

Sieghard Wagner

¹ Version numbers below 4.1 are used for bug fixing only

² see definition of Software Category 3: GAMP 5, Appendix M4