

Audit Report: Categorisation acc. to GAMP

StabNet 1.1



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Goal:	Classification of <i>StabNet 1.1</i> into one of the GAMP Software Categories.
Description:	<i>StabNet</i> is a control and database software for stability measurement devices. It features creating methods, performing single and multiple analyses, evaluating data (results, statistics, limit monitoring) and generating reports. <i>StabNet</i> is the successor of Rancimat. <i>StabNet</i> was developed by Metrohm Ltd. in accordance with ISO 9001 requirements regarding design, manufacturing and maintenance.
Categorisation:	The <i>StabNet</i> software is a "Non-Configured Product". Thus, it is categorized as GAMP Software Category 3. <i>Justification:</i> The software configuration is limited to: • Customization of the system's runtime environment, e. g.: - o Configuration of the connected instruments and sensors - o Definition of users and user groups (with pre-defined privileges) - o Configuration of security settings - o Maintenance of master data (methods, sample data, etc.). However, no structural modifications or customizations of the software concerning user-specific procedures are made¹. • Creation of methods: Methods can be grouped together to method groups. The methods themselves consist of measurement parameters and correction values. As part of the regular system operation, methods are adapted to specific analytical procedures on a case to case basis. The resulting method settings have to be approved accordingly. Therefore appropriate checks and verifications have to be included, especially as far as calculations and reports are concerned. 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