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1 Introduction

The purpose of the **Validation report** is to summarize and document the found differences that require corrective actions from the validation activities performed.

The scope of the validation tasks performed are described in paragraph 2.1 in the Validation plan.

This partial validation complements the full validation of SIMCA 18 (version 18.0.0.372).

1.1 Notation and Notes

'US' followed by a number refers to a User Story in Azure DevOps.

'WI' followed by a number refers to a Work Item in Azure DevOps. May be Defect, User Story, Feature etc.

Note: Approving this document includes approval of all subdocuments and results referred to in this document.

2 Validation Report Summary

The Validation plan defines the validation tasks to perform. The results from the validation tasks are included in the validation package and all found difference requiring a corrective action are listed under paragraph 3.

The numerical validation of SIMCA 18.0.1 was done versus SIMCA 18.0.0 and specification using CompareSimcaData.

The CompareSimcaData report was saved and included in the validation package.

2.1 Validation Package Content

The validation package includes files and folders as follows:

- Validation Report - This document
- Validation Plan – Scope of the validation
- Risk Assessment – Risks and mitigations
- Work item folder – Details for defects fixed, and other work items included in the release
- Numerical validation folder – The results from the numerical comparisons

3 Validation Task Results

The numerical validation of SIMCA 18.0.1 was done versus the specification, using Python scripts and CompareSimcaData under Windows 10. The outcome is included in the validation package.

No differences that require a corrective action were found. Differences due to rounding are not listed.

Regression tests were completed as listed in the table in paragraph 3. Testing and validation tasks in the Risk assessment document.

4 Verification of Installed Software

To verify that your license of the software has been correctly installed follow the instruction here:

1. In SIMCA, click **File | Help** and under About SIMCA, verify that the version is SIMCA 18.0.1.507.
2. Open one of the .pdfs in the Graphical validation folder in the full validation of SIMCA (18.0.0.372).
3. Open the corresponding project in the software, found in the Verification of installed software folder of the full release.
4. Create and compare one of the 2D plots (column, line, or scatter) and one 3D plot (3D scatter, response surface, or wavelet power spectrum). The plots should content wise be identical.

5 Source Code

All source code for the final version of a full release is transferred to electronic media and kept in a safe storage externally.



6 Routines

The relevant routines are stored in Azure DevOps in the QualityManual and QualityManagementSystem folders.

7 Defect Handling

Work items describing defects found are stored electronically in Azure DevOps. Defects that require a corrective action are listed in the tables in paragraph 3.

8 Validation Conclusion

All defects found during this development life cycle that remain unsolved were considered noncritical to the user of the system and therefore remain open. None of the deviations found are serious.

The performed quality activities throughout the life cycle of the software development, in accordance with the outlined testing and validation strategy in the Quality Management System (QMS), secures that the requirements perform according to specification and that SIMCA 18.0.1 gives correct results and is reliable.

