**Validation & Test Report for R version <x.y>**

**Document Properties**

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| Company Name |  |
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| Approver |  |

**Document Approval**

|  |  |  |
| --- | --- | --- |
| Approver | Status | Approval Date |
|  | Pending |  |

**Document Change History**

|  |  |
| --- | --- |
| Version | Changes |
| 1 | Initial version |

# Introduction

The purpose of this document is to describe the activities and deliverables completed to validate R base installation version *insert full software version number:* *x.y.z* based on:

* *insert references to local policies/ SOPs, if applicable*
* SCTO CSV Policy for R
* insert link to system-specific Validation & Test Plan

It contains:

* a summary of testing activities and results, including any deviations and open defects accepted for Go Live
* a summary of executed validation activities and any open deviations
* a statement of acceptance for the software version in scope for productive use (with or without restrictions or “non-acceptance” for productive use)

# Summary of Installation Activities

## Installation on TEST Environment/ Machine used for Testing

R base installation version *insert full software version number:* *x.y.z* was installed

* on *insert unique ID/name of machine or server ID/ name*
* by *insert full name of person executing the installation*
* on *insert date and time of installation*

The following deviations were encountered during the installation on TEST:

|  |  |  |  |
| --- | --- | --- | --- |
| **Unique ID** | **Deviation** | **Impact Assessment and Further Actions** | **Classification** |
| TEST-DEV-01 | list any deviations encountered during the installationif no deviations were encountered, insert: n/a | insert a short impact assessment and a description of the further required actions or a rationale for acceptance without further actionsif no deviations were encountered, insert: n/a | Minor Major Criticaldelete the classifications that are not relevantif no deviations were encountered, insert: n/a |
| TEST-DEV-02 | … |  |  |

# Summary of Testing Activities

## Summary of User Acceptance Testing

**Example 1:**

The following report documents the results of testing activities and the traceability to requirements.

*insert reference to and attach copy of the R report generated during testing*

**Example 2:**

The following table summarizes the executed test protocols and the results of the execution:

|  |  |  |
| --- | --- | --- |
| **Unique ID** | **Test Protocol Title** | **Test Result** |
| UAT-01 | Data Import Test | PASS/FAILdelete the outcome that does not apply |
| UAT-02 | … |  |

## Summary of Defects & Deviations of User Acceptance Testing

The following defects and deviations were encountered during UAT Testing:

|  |  |  |  |
| --- | --- | --- | --- |
| **Unique ID** | **Deviation/ Defect** | **Impact Analysis and Further Actions/ Justification for Acceptance** | **Classification** |
| UAT-DEV-01 | list any defects/ deviations encountered during UAT testingif no defects/ deviations were encountered, insert: n/a | insert a short impact assessment and a description of the further required actions or a rationale for acceptance without further actionsif no defects/ deviations were encountered, insert: n/a | Trivial Minor Major Criticaldelete the classifications that are not relevantif no defects/ deviations were encountered, insert: n/a |
| UAT-DEV-01 | … |  |  |

# Summary of the Validation Activities

The following validation documentation was created or updated according to insert reference to Validation and Test Plan:

|  |  |  |
| --- | --- | --- |
| **Document Reference** | **Version** |  |
| insert document reference | insert latest approved document version | NEW/ UPDATEDremove the one not applicable |
| … |  |  |

The following validation documentation was NOT updated:

|  |  |  |
| --- | --- | --- |
| **Document Reference** | **Version** | **Rationale** |
| insert document reference | insert latest approved document version | *e.g., no changes to user requirements*  |
| … |  |  |

The following validation activities were performed:

* if applicable, list any validation activities that did not result in a document creation or update.
* if not applicable, delete this paragraph

## Deviations from the Plan

The following deviations from the Change Plan and Validation & Test Plan remain open with the approval of this Validation & Test Report

|  |  |  |  |
| --- | --- | --- | --- |
| **Unique ID** | **Deviation** | **Impact Analysis and Further Actions/ Justification for Acceptance** | **Classification** |
| VAL-DEV-01 | list any deviations from the Validation & Test Plan if no deviations occured: insert: n/a | insert a short impact assessment and a description of the further required actions or a rationale for acceptance without further actionsif no deviations occured: insert: n/a | Trival Minor Major Criticaldelete the classifications that are not relevantif no deviations occured: insert: n/a |
| VAL-DEV-02 | … |  |  |

# Installation and Testing Defects Summary

|  |  |
| --- | --- |
| **N°** | **Deviation / defect category** |
| 0 | Trivial |
| 0 | Critical |
| 0 | Major |
| 0 | Minor |

# Validation Deviation Summary

|  |  |
| --- | --- |
| **N°** | **Deviation / defect category** |
| 0 | Trivial |
| 0 | Critical |
| 0 | Major |
| 0 | Minor |

# Release Notes

|  |  |
| --- | --- |
| **Release Date** | ***Insert date from which on the R version can be used for productive purposes*** |
| **Version** | ***insert full software version number:* *x.y.z*** |
| **Notes** | ***Add a reference to the R release notes provided by CRAN*** |

# Acceptance Criteria

see insert link to Validation & Test Plan OR copy the acceptance criteria from the Validation & Test Plan here

# Conclusion & Acceptance for Productive Use

|  |  |
| --- | --- |
| [ ]  | The system validation was successfully completed **without deviations**.**The system can be accepted for Productive use without restrictions.** |
| [ ]  | The system validation was successfully completed **with deviations**.**The system can be accepted for Productive use with the following restrictions:*** list any restrictions here

OR:**The system can be accepted for Productive use without restrictions.** The deviations encountered during the validation are only minor and not GxP relevant. |
| [ ]  | The system validation was **not successful**.**The system can NOT be accepted for Productive.**There are open critical deviations encountered during the validation that are are GxP relevant. |

# References & Attachments

|  |  |  |
| --- | --- | --- |
| **Reference Title** | **Document Version** | **Link to document *(if applicable)*** |
| xxx |  | xxx |
| xxx |  | xxx |