Pre-Validation Plan

Version: 1.0

Approval Details:

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Revision Details

Version	Date of release	Affected Sections	Reason for Change
0.1	20-AUG-2026	All	Initial Draft
1.0	21-AUG-2026	NA	Approved

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1 Introduction, Purpose and Scope

The Pre-Validation Plan outlines the various planning needs for effective execution of a release in accordance with the needs of Pre-Validation Process.

Product Name and version:	SPORIFY 2026.2.0.0
Purpose of the Release:	The purpose of this release is to enhance the application with new functionalities as mentioned in the AG_SPOR_URD (V6.0).
The base Validation kit used for this release is:	SPORIFY 2026.1.0.0
Configuration Management system for the release:	Sporify - Documents - 9. PRE VALIDATION - All Documents

Note: Configuration Management system Link is Internal to Aris Global.

The purpose is to define the requirements and acceptance criteria for installation and to provide documented evidence that the SPORIFY 2026.2.0.0 functionality meets its predefined specifications. This Plan details the activities and deliverables required to qualify the installation of SPORIFY 2026.2.0.0. The successful execution will establish documentary evidence that SPORIFY 2026.2.0.0 has been installed and configured correctly as per documented procedures and thus, fit for purpose. This document also includes the specific items in scope to be tested, the environment needs, and the acceptance criteria. The results of the execution of this document shall be summarized in the Pre-Validation Summary Report.

1.1 Scope

This section details the scope and out-of-scope items for this validation activity.

1.2 In scope

Listed below are the scopes of testing:

- Creation of SPORIFY 2026.2.0.0 Pre-validation environment.
- Requirements that were added, updated, and mapped as part of SPORIFY 2026.2.0.0 release as listed in Risk Analysis Document (AG_SPOR_RA (V6.0)) and whose RPN is equal or greater than 9.
- OQ AG_SPOR_2026.2.0.0_OQ_DataGovernance_Organisations_Source as part of issue fix SPRFY-4941 from previous release.
- Below mentioned existing OQs as part of regression testing.
    - AG_SPOR_2026.2.0.0_OQ_Security_Management
    - AG_SPOR_2026.2.0.0_OQ_Products_Overview
    - AG_SPOR_2026.2.0.0_OQ_Products_Comparison
    - AG_SPOR_2026.2.0.0_OQ_Products_Comparison_Target
    - AG_SPOR_2026.2.0.0_OQ_Admin_CFR_Part11

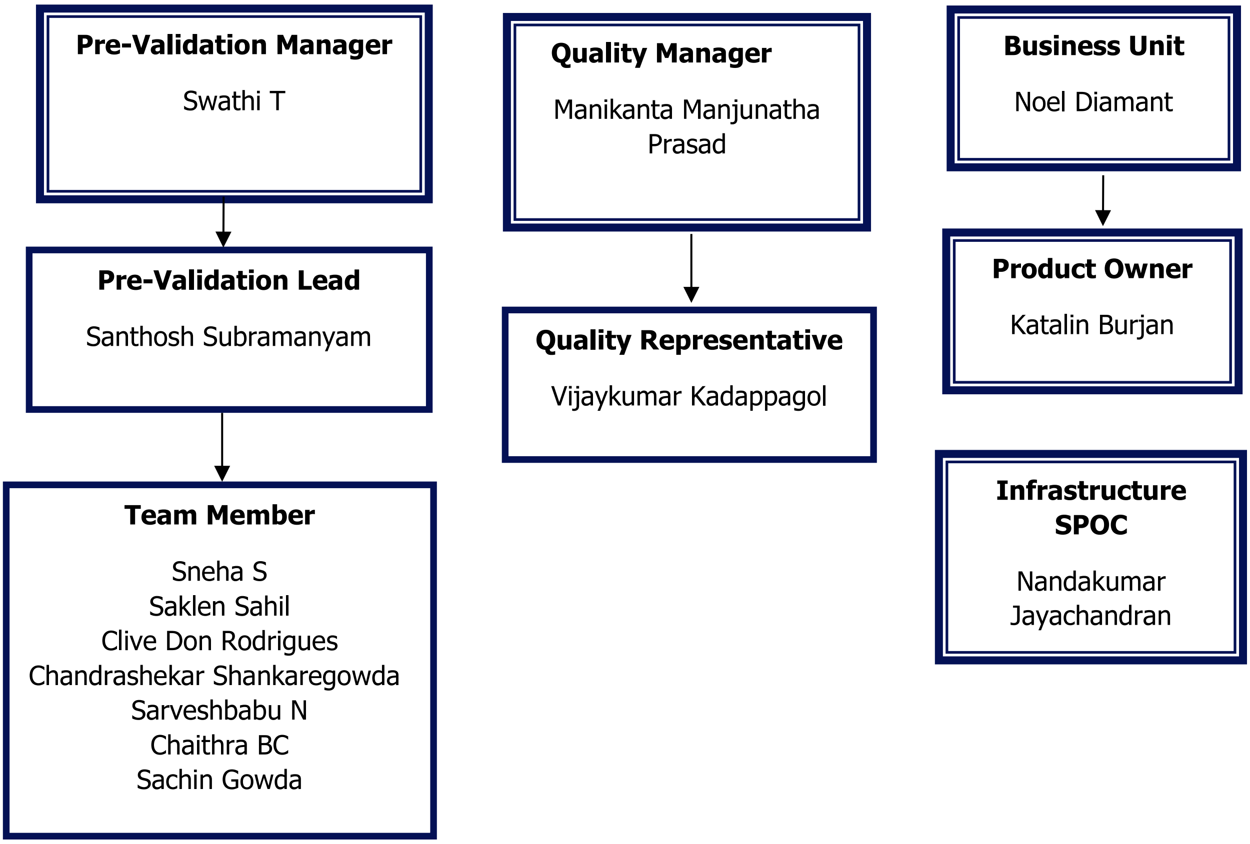
1.3 Out of Scope

Listed below are the out of scope of this IQ/OQ testing:

- Data migration, User interface, Customization, Upgrade Data, Security and Performance specific issues/functionalities are out of scope for Pre-Validation.

2 Organizational Structure/Roles and Responsibilities for Pre-Validation

2.1 Org Chart



#.	Name of the Team Member	Role
1.	Swathi T	Pre-Validation Manager
2.	Santhosh Subramanyam	Pre-Validation Lead
3.	Sneha S	Pre-Validation Team Member
4.	Saklen Sahil	Pre-Validation Team Member
5.	Clive Don Rodrigues	Pre-Validation Team Member
6.	Chandrashekar Shankaregowda	Pre-Validation Team Member
7.	Sarveshbabu N	Pre-Validation Team Member
8.	Chaithra BC	Pre-Validation Team Member
9.	Sachin Gowda	Pre-Validation Team Member
10.	Katalin Burjan	Product Owner
11.	Noel Diamant	Business Unit
12.	Nandakumar Jayachandran	Infrastructure SPOC
13.	Manikanta Manjunatha Prasad	Quality Manager
14.	Vijaykumar Kadappagol	Quality Representative

2.2 Responsibilities

The table below describes the roles and responsibilities of team member involved in the Pre-Validation activity.

Department/ Individual	Responsibility
Pre-Validation Team	▪ Prepare and execute the approved IQ, OQ scripts. ▪ Raise defects / test incidents encountered during IQ and OQ execution. ▪ Prepare Pre-Validation Summary Report.
Pre-Validation Lead	▪ Prepare Pre-Validation plan and Traceability Matrix. ▪ Review the adequacy of IQ, OQ scripts pre and post the test script execution. ▪ Perform defect and deviation management. ▪ Provide technical support. ▪ Review the adequacy of User Requirement Document and Risk Analysis. ▪ Review the adequacy of Pre-Validation Summary Report. ▪ Coordinate and secure resources (personnel, equipment, materials, etc.) needed to execute the IQ and OQ scripts.

Department/ Individual	Responsibility
Pre-Validation Manager	▪ Approve adequacy of IQ scripts, OQ scripts pre and post execution and Defects. ▪ Review and Approve the Pre-Validation plan. ▪ Approve the User Requirement Document and Risk Analysis ▪ Review and approve Traceability Matrix. ▪ Approve adequacy of Pre-Validation Summary Report.
Product Owner	▪ Prepare User Requirement Document and Risk Analysis
Business Unit	▪ Review and Approve User Requirement Document and Risk Analysis Document. ▪ Review Pre-Validation Summary Report.
Quality Representative	▪ Review User Requirement Document, Risk Analysis and Traceability Matrix document. ▪ Approve adequacy of Pre-Validation plan and Pre-Validation Summary Report.

IQ, OQ script execution or portions thereof may be performed by trained personnel from any of the Departments listed in the table above.

3 References

#	Document Name
[1]	Guidelines - Validation Testing (V7.0)
[2]	Computerized System Validation (V8.0)
[3]	Guidelines - Risk Management (V5.0)
[4]	AG_SPOR_URD (V6.0)
[5]	AG_SPOR_RA (V6.0)
[6]	Pre-Validation Process (V15.0)
[7]	SPORIFY_2026.2.0.0_HW_SW_Requirements (V1.0)

Note: Refer to the eQMS Portal for the latest approved versions of the process documents.

4 Definitions and Abbreviations

Abbreviations	Definitions
ALM	Application Lifecycle Management
API	Application Programming Interface
CFR	Code of Federal Regulations
FHIR	Fast Healthcare Interoperability Resources
HW_SW	Hardware Software

Abbreviations	Definitions
IDMP	Identification of Medicinal Product
IQ	Installation Qualification
OQ	Operation Qualification
PMS	Product Management Service
PVSR	Pre-Validation Summary Report
RA	Risk Analysis
RPN	Risk Priority Numbering
SDLC	Software Development Life Cycle
SPOR	Substances Products Organisations Referentials
System	SPORIFY 2026.2.0.0
TM	Traceability Matrix
URD	User Requirement Document
XML	Extensible Markup Language

5 System Description

SPORIFY provides a Simple, Secure, Single Solution to enable Mapping, Synchronisation and Notification services between your systems and SPOR master data with a streamlined workflow process.

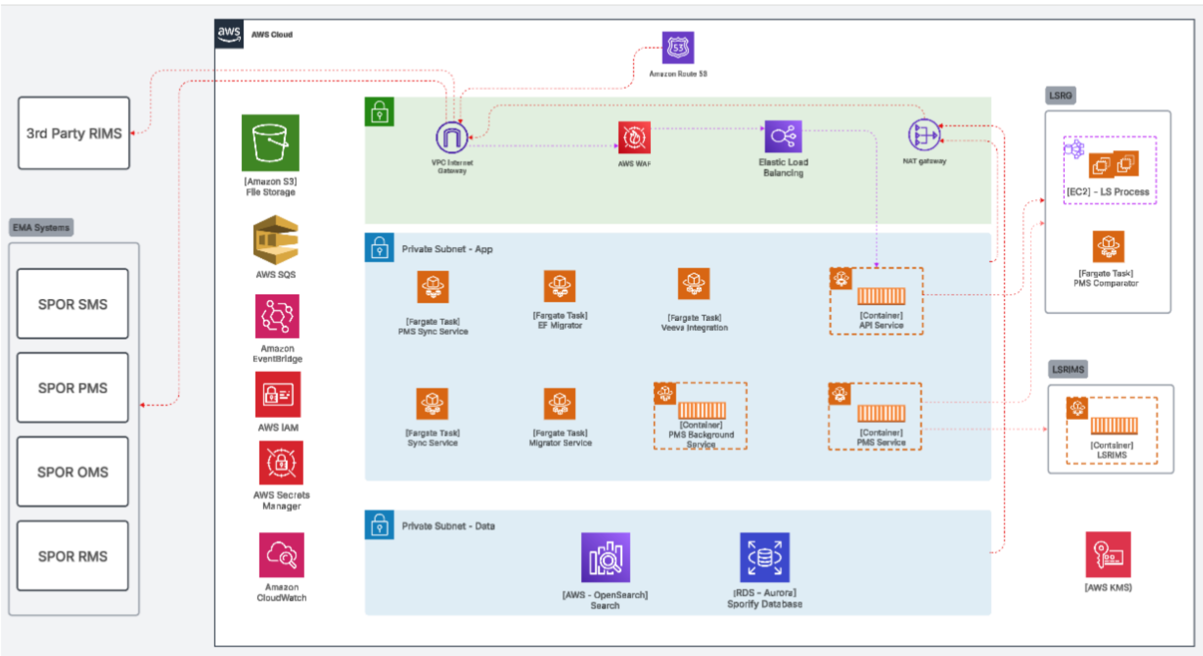
6 Pre-Validation Deliverables

#.	Deliverables Phase	Deliverables
1.	Initial Planning and Design Phase	User Requirements Document (URD) AG_SPOR_URD
2.	Initial Planning and Design Phase	Risk Analysis (RA) AG_SPOR_RA
3.	Initial Planning and Design Phase	Pre-Validation Plan (PVP) AG_SPOR_2026.2.0.0_Pre-Validation Plan
4.	Reporting	Traceability Matrix (TM) AG_SPOR_TM
5.	Installation Qualification	IQ Test Script AG_SPOR_2026.2.0.0_IQ_<Feature/Functionality/>

#.	Deliverables Phase	Deliverables
6.	Operational Qualification	OQ Test Script AG_SPOR_2026.2.0.0_OQ_<Feature/Functionality>
7.	Reporting	Pre-Validation Summary Report (PVSR) AG_SPOR_2026.2.0.0_PVSR
8.	Defect naming convention for non-functional defect	AG_SPOR_2026.2.0.0_DEF_<IQ/OQ>_<positive_integer>
9.	Defect naming convention for functional defect	SPRFY-<positive_integer>

7 Deployment Architecture

Below diagram depicts the high-level deployment architecture of SPORIFY application.



8 Pre-Validation Strategy

The Pre-Validation activity is carried out in accordance with activities narrated in the Pre validation process. This section describes the test strategy of the SPORIFY 2026.2.0.0 on AWS Cloud Validation environments

- Update the User Requirement Document (URD) for SPORIFY 2026.2.0.0 requirements. The URD will be reviewed and approved.
- Update, review and approve Risk Analysis (RA) document for SPORIFY 2026.2.0.0 requirements.
- Create a Pre-Validation Plan. The Pre-Validation Plan shall be reviewed and approved.
- Create, review, and approve the IQ document.
- There is no CS CV document for this product hence it is not applicable for this product.

- Create, review, and approve the OQ scripts.
- Manually execute the approved IQ scripts in ALM tool.
- Installation would be done through automated DevOps pipeline to create a Multi-Tenant Validation environment on AWS environment. SPORIFY application will be installed for 2026.2.0.0 version.
- Resolve any issues or defects resulting from testing.
- Execute the approved OQ scripts in Validation environment in Tenant schemas.
- All the OQ scripts will be executed manually through ALM tool.
- Review and approve the OQ test results.
- Resolve any issues or defects resulting from test execution.
- Update, Review, and Approve the Traceability Matrix (TM) to display the linkage between the requirements and test script. Only requirements for whose RPN are equal or greater than 9 would be mapped in Traceability Matrix.
- Create, Review, and Approve the Pre-Validation Summary Report (PVSR).

8.1 IQ/OQ Protocol and Strategy

- The Pre-Validation Plan (this document) should be approved before commencement of IQ Phase execution.
- Create, review, and approve the IQ.
- The IQ script shall be executed in the Validation environment as defined in the Section 11, Table 11-1. The executed IQ script document shall be reviewed and approved as per Pre-Validation Process[6]. The results of the Validation IQ activity shall be summarized in the PVSR.
- Application shall be deployed for SPORIFY 2026.2.0.0.
- The OQ scripts as mentioned in Section 11 Table 11-2 shall be executed for SPORIFY 2026.2.0.0 in the Pre-Validation environment.
- The results of the OQ execution shall be captured in PVSR.
- Defects that occurred during the execution shall be logged in the Defects Management module of ALM Tool.

8.1.1 Dependencies/Prerequisites

- Pre-Validation Plan, User Requirement Document and Risk Analysis must be approved before IQ execution commences.
- IQ script is reviewed and approved by the identified stakeholders prior to the execution.
- Executed IQ script document is reviewed and approved.
- Each OQ script is reviewed and approved by the identified stakeholders prior to the execution.
- Executed OQ script is reviewed and approved.

8.1.2 Hardware Software Description

Hardware Software configuration would be as per the Hardware Software Requirement document SPORIFY_2026.2.0.0_HW_SW_Requirements [7] available in below repository.

SPORIFY_2026.2.0.0_HW_SW_Requirements.docx

8.1.3 Execution of the Test Scripts

- Testing activities shall be conducted according to the requirements defined in Guidelines - Validation Testing [1].
- The Pre-approved IQ script document shall be executed for SPORIFY 2026.2.0.0 in the validation environment.
- The executed IQ script document shall be reviewed by Pre-Validation Lead and approved by Pre-Validation Manager.

- If any script failed, the Pre-Validation team shall follow the corrective actions, re-execute the test script as required and Pre-Validation Manager shall re-approve the Script.
- The test script manual execution is performed through Application Lifecycle Management tool.
- The pre-approved OQ scripts shall be executed for SPORIFY 2026.2.0.0 in the Validation environment. The results of execution, defects, and deviations, if any, will be summarized in the PVSR.
- All the executed IQ and OQ script(s) shall be reviewed and approved as per the approval matrix defined in the Section [2.2] - Responsibilities of the Pre-Validation Plan.

9 Criteria for Assessing Test Results

Test Step Result Assessment Criteria (for assessment by Tester):

Result Assessment	Criteria
Execution by using Test Management tool	
Pass	The expected result as per the script is attained. All the evidence has been captured, annotated and delivered. The objective evidence demonstrates that the test objective is met.
Fail	The expected result is not achieved. The system performed differently than expected.
N/A	The step is Not Applicable.

NOTE: The overall execution result of the test shall be concluded by the approver based on the above criteria.

Test Execution Approval / Rejection Criteria (for assessment by Reviewer / Approver):

Execution Assessment	Criteria
Approved	All the test steps have passed, and the test objective is met. A failed test step has a defect linked and the defects raised have been adequately documented and current status of the defects is indicated
Rejected	The test objective is not met by the executor due to execution error/ tool error. The objective evidence do not demonstrate the successful completion of test execution. The defects raised are not linked with appropriate test scripts. The defects do not indicate the current status of its resolution.

10 Defect Management

- Defects encountered during the test script executions and test script errors/post execution review findings shall be logged in the Test Management and bug tracking tool ALM with necessary details.
- Any Test Script/ Test Executor errors identified during execution shall be logged in the Test Management and bug tracking tool ALM with necessary details.
- The Pre-Validation Lead shall coordinate the evaluation of the defect and set proper Severity and assign the defect to the appropriate team for resolution.
- The member/team responsible shall investigate the defect and propose corrective action. The corrective action shall be executed, and the impacted test scripts and other validation documents shall

be revised and re-executed, as applicable.

- The Pre-Validation manager shall evaluate the defect for completeness of the data and approve/close the defect.
- In the event the documentation of the Severity level requires modification later to initial assignment, the Pre-Validation Lead shall document the rationale for the modification made.
- Any Open defects or test incidents shall be tracked in the PVSR with the rationale.
- Any deviations from the execution of this plan shall be documented in the PVSR and approved by the Quality representative and Pre-Validation Manager

11 Qualification Scripts

The following table lists Installation Qualification scripts and the test objectives:

Table 11-1: Installation Qualification

S. No.	Name of the IQ Script	Test Objective
1.	AG_SPOR_2026.2.0.0_IQ_Upgrade	The purpose of this IQ is to provide the steps to ensure the installation of SPORIFY 2026.2.0.0 is completed

The following table lists Operational Qualification scripts and the test objectives:

Table 11-2: Operational Qualification

S. No	Name of the OQ Script	Test Objective
1.	AG_SPOR_2026.2.0.0_OQ_VeevaSync	The purpose of this OQ is to verify the veeva sync based on specific domain, veeva sync for all domains and the sync logs.
2.	AG_SPOR_2026.2.0.0_OQ_Security_Management	The purpose of this OQ is to verify the system security settings management.
3.	AG_SPOR_2026.2.0.0_OQ_DataGovernance_Organisations_Source	The purpose of this OQ is to verify the Governance actions for the Organisations from Source screen.
4.	AG_SPOR_2026.2.0.0_OQ_Products_Overview	The purpose of this OQ is to verify the Product overview details like marketing authorisation, products per marketing authorisation, connectivity details.
5.	AG_SPOR_2026.2.0.0_OQ_Products_SourceList	The purpose of this OQ is to verify the Products source list upload and managing source products.
6.	AG_SPOR_2026.2.0.0_OQ_Products_SourceLists_Actions	The purpose of this OQ is to verify the different actions on Products source lists and source products.
7.	AG_SPOR_2026.2.0.0_OQ_Products_TargetLists	The purpose of this OQ is to verify the Products Target lists.
8.	AG_SPOR_2026.2.0.0_OQ_Products_Comparison	The purpose of this OQ is to verify the initiation of products comparison from compare products screen and verify the comparison data for each records.
9.	AG_SPOR_2026.2.0.0_OQ_Products_Comparison_Target	The purpose of this OQ is to verify the initiation of products comparison from target products screen

S. No	Name of the OQ Script	Test Objective
		and verify the comparison data for each records.
10.	AG_SPOR_2026.2.0.0_OQ_Admin_CFR_Part11	The purpose of this OQ is to verify the CFR requirements and system compliance with the CFR rules.
11.	AG_SPOR_2026.2.0.0_OQ_Products_API	The purpose of this OQ is to verify the PMS APIs that are exposed through Gravitee and access APIs only through the authorized users using m2m authentication.

The results of execution, defects, and deviations, if any, will be summarized in the Pre-Validation Summary Report.

12 Acceptance Criteria

For the Installation and Operational Qualification to be considered successful, the following acceptance criteria must be met:

- For closure of the protocol, all test results must be reviewed, approved, and successfully completed and all defects and deviations must be addressed and resolved.
- There are no open issues without rationale provided.
- In addition, the Pre-Validation Summary Report shall be developed, reviewed, and approved. Once these steps have been accomplished, the IQ and OQ phase will be considered completed and closed.

13 Training

All individuals responsible for executing this protocol are trained on all the processes and plans listed in the references section.

14 Exceptions and Deviations

Exceptions and/or deviations to this Plan shall be documented in the Pre-Validation Summary Report, with the evaluation of their impact on the validation status of the System and approved by the Delivery Manager/Pre-Val Manager and Quality Team.

15 Change Management

There is upgrade involved from SPORIFY 2026.1.0.0 to SPORIFY 2026.2.0.0. As part of the new Vanilla image creation for a release, the Pre-Validation team shall need access to existing Validation images of base versions along with existing documentation.

This Pre-Validation plan will be extended to include necessary approvals for above stated activities.

Client/Customer Name	SPORIFY 2026.2.0.0 Pre-Validation
Description of Change	Validation images would be taken from SPORIFY 2026.1.0.0 and will be upgraded to SPORIFY 2026.2.0.0. The validation base kit for this release is SPORIFY 2026.1.0.0.
	Assessment of Change
Technical Assessment:	**Requirements**: Upgrade SPORIFY 2026.1.0.0 application to SPORIFY 2026.2.0.0 **System Impact Assessment:** Overall system impact is Medium. **Severity of System Failure:** High – System will be upgraded by executing approved IQs, but in case of failure it will affect the product quality. **Detectability of System Failure:** High – This will be verified by launching application URL and logging into application. In case of failure, the user will not be able to login to an application. **Risk Assessment**: Risk assessments have been performed, and the risk level is marked as Low. **Risk Involved**: If the system is not bundled with all the components, upgrade deployment will not be successful. The following parameters/assessments were used to ascertain the risk level. **Probability of Risk occurrence**: Low – There were no errors or issues observed during Testing phase as part of this upgrade. Approved IQ will be executed to carry out the installation. Hence the probability of risk occurrence is Low. **Severity of impact**: High – In case of failure, will have an impact on customer's business and it will affect the product quality and submissions of registrations to authority which is critical. **Detectability**: High - The failure can be identified with the logs generated after upgrade execution.
Functional Assessment:	**System Impact Assessment:** The System Impact assessment has been performed, and the impact is marked as medium. Following parameters were used for the assessment. **Severity of the System Failure:** • **High**: If this upgrade fails, the SPORIFY 2026.2.0.0 system will not work as expected and result in degraded system usability. Failure of the System impacts SPOR data sync and Source Data creation.

	Detectability of the System Failure: • **High**: Once the upgrade activity is completed, the application will be verified through necessary test scripts for functionality and performance. Any failures will be detected during the IQ and OQ phase thus preventing it getting into the Live Environment. **Risk Assessment:** Risk assessments have been performed, and the risk level is marked as low. Following parameters/assessments were used to ascertain the risk level. **Risk Involved:** If these upgrades fail, the enhancements will not work as intended. **Probability of Risk occurrence**: Low – These upgrade patches have been run through the SDLC life cycle. There were no errors or issues observed or documented during these phases. A risk analysis for this upgrade has been documented and is available with the pre-validated kit. **Severity of impact:** High - If these upgrade fails; the enhancements will not work as intended and thus resulting in degraded system quality and usability. In-order to mitigate any unforeseen risks database schema backup will be taken. **Detectability of Risk**: High - In case of any error, it can be identified with the logs generated. Necessary testing will be conducted through test scripts on the Validation Environment prior to promoting it in implementation phase.
Validation Assessment	SPORIFY Database including all Tenants will be upgraded from SPORIFY 2026.1.0.0 to SPORIFY 2026.2.0.0 level. Pre validation team will execute IQ documents followed by OQ scripts to validate the enhancements.
Change Roll back procedure	The Database RDS- snapshot and Application server- machine AMI image back up of the current environment will be taken before the upgrade and the same will be restored in case of any failures

16 Pre-Validation Completion Criteria

The system can be accepted as validated once the Pre-Validation Summary Report is drafted, reviewed, and approved.

AG_SPOR_2026.2.0.0_Pre-Validation Plan

Final Audit Report 2026-08-21

Created:	2026-08-21 (India Standard Time)
By:	Santhosh Subramanyam (Santhosh.Subramanyam@arisglobal.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAADthxYjwU88ykBrQKfh8wluUftGsUuQiF

"AG_SPOR_2026.2.0.0_Pre-Validation Plan" History

Document created by Santhosh Subramanyam (Santhosh.Subramanyam@arisglobal.com)

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Document emailed to Santhosh Subramanyam (Santhosh.Subramanyam@arisglobal.com) for signature

2026-08-21 - 6:03:43 PM GMT+5.5

Santhosh Subramanyam (Santhosh.Subramanyam@arisglobal.com) authenticated with Email OTP by verifying one-time code sent via email

Challenge: The user completed the signing ceremony.

2026-08-21 - 6:04:58 PM GMT+5.5

Document e-signed by Santhosh Subramanyam (Santhosh.Subramanyam@arisglobal.com)

Signing reason: I am the author of this document

Signature Date: 2026-08-21 - 6:04:59 PM GMT+5.5 - Time Source: server - Signature Appearance Selected: TYPE

Document emailed to swathi.t@arisglobal.com for signature

2026-08-21 - 6:05:01 PM GMT+5.5

Email viewed by swathi.t@arisglobal.com

2026-08-21 - 6:08:53 PM GMT+5.5

Signer swathi.t@arisglobal.com entered name at signing as Swathi T

2026-08-21 - 6:15:33 PM GMT+5.5

swathi.t@arisglobal.com authenticated with Email OTP by verifying one-time code sent via email

Challenge: The user completed the signing ceremony.

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Document e-signed by Swathi T (swathi.t@arisglobal.com)

Signing reason: I approve this document

Signature Date: 2026-08-21 - 6:15:35 PM GMT+5.5 - Time Source: server - Signature Appearance Selected: IMAGE

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2026-08-21 - 6:15:37 PM GMT+5.5

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2026-08-21 - 6:18:57 PM GMT+5.5

Signer vijaykumar.kadappagol@arisglobal.com entered name at signing as Vijaykumar Kadappagol

2026-08-21 - 6:20:27 PM GMT+5.5

vijaykumar.kadappagol@arisglobal.com authenticated with Email OTP by verifying one-time code sent via email

Challenge: The user completed the signing ceremony.

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Signing reason: I approve this document

Signature Date: 2026-08-21 - 6:20:29 PM GMT+5.5 - Time Source: server - Signature Appearance Selected: MOBILE_TYPE

Agreement completed.

2026-08-21 - 6:20:29 PM GMT+5.5