# Revision History

|  |  |  |  |
| --- | --- | --- | --- |
| **ISSUE NUMBER** | **DATE** | **AUTHOR** | **CHANGE DESCRIPTION** |
| 1 | 05/23 | JF | Introduced as part of EUMDR |
| 2 | 04/11/24 | JF | Integration of existing forms, etc with new procedure |

# Purpose

This report summarizes the software testing and verification that was performed on the <*Project Name / Build No. yyddmm>* according to **SSI-QF-20E Software Test Protocol**. Any deviations from the Protocol, failures in the software, unusual events (anomalies) and limitations in software performance are noted herein.

# References

## SSI-QF-10C Design Review

## SSI-QF-10P Problem Report

## SSI-QF-20C Software Requirements Specification

## SSI-QF-20B Software Development Plan

## SSI-QF-20E Software Test Protocol

## SSI-QF-20J Software Release version control

## SSI-QF-20K Software Checklist

## SSI-QF-20L Software Build no. Summary of Changes

## SSI-QF-20M Firmware Programmable Part Release

## SSI-QF-20P Software Requirement Specification

## SSI-QF-20Q Software Functional Specification

## SSI-QF-20R Software User Requirements

## SSI-QF-20S Software Analysis Verification

## SSI-SOP-20 Software Development

# Test Hardware

The following test hardware was used for software verification.

|  |  |  |
| --- | --- | --- |
| **Test Hardware Serial Number** | **Board PCB P/N** | **Identification/Description** |
|  |  |  |

*List STP ID – Software test protocol unique identifier STP-yymmdd + [letter a, b, etc]*

*Test Title – Brief description of the software test protocol.*

*Record Result – Outcome of the software test protocol:*

*Fail - if any software requirements not met*

*Pass - if all software requirements met*

*Pass with Deviation - if software performs as expected and software requirements are met, but there is a functional or other deviation shown up in the test execution. Record and justify*

# Test Procedure Results

The table below lists the executed software test procedures and the results of testing.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ***Test ID*** | ***Iss no.*** | ***Test Name*** |  | ***Result – Pass / Fail*** | ***Further action – Y/N, Describe if Y*** | ***Notes - Record and justify any accepted test functional deviation*** |
| SSI-QF-10C |  | Design Review (relevant to this project/build |  |  |  |  |
| SSI-QF-1OP |  | Problem Report  Have all problems included in this project /build been fully documented? |  |  |  |  |
| SSI-QF-20C |  | Software Requirements Traceability Matrix.  Are all outputs traceable to inputs? |  |  |  |  |
| SSI-QF-20J |  | Software release version control dated yymmdd  Are all tests met? |  |  |  |  |
| SSI-QF-20K |  | Software Checklist  Is checklist complete? |  |  |  |  |
| SSI-QF-20L |  | Software Build no. Summary of Changes  Is this complete? |  |  |  |  |
| SSI-QF-20M |  | Firmware Programmable Part Release  Is this complete |  |  |  | *n/a if not applicable* |
| SSI-QF-20P |  | Software Requirements Specification  Have all SRS been met? |  |  |  |  |
| SSI-QF-20Q |  | Software Functional Specification  Have all SRS been met? |  |  |  |  |
| FSI-QF-20R |  | Software User Requirements  Are all SUR met? |  |  |  |  |
| SSI-QF-20S |  | Software Analysis Verification  Is Verification complete? |  |  |  |  |
| VISI-003 |  | Risk Management Report  Has this been completed? |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  | ***OVERALL PROTOCOL TEST RESULT*** |  |  |  |  |
|  |  | Is new Build [yymmdd] approved for release? |  | Y / N |  |  |
|  |  | Are release notes for the new Build no. ready for end users? |  | Y / N |  |  |
|  |  |  |  |  |  |  |

Significant anomalies or deviations found in the testing process should be recorded. A significant anomaly is one which if not corrected would lead to a new or greater risk for the patient or end user.

*Failed SRS Requirement – SRS ID(s) as listed in the SRS or N/A*

*Anomaly ID – Software change request and deviation report unique identifier(s)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **STP ID** | **Test Title** | **Failed SRS Requirement** | **Anomaly ID** | **Result** |
| *STP-yymmdd + letter* |  | *N/A* | *N/A* | *Pass* |

# Software Anomalies

*<For Regression testing, each software change request in the regression plan should be verified. If not verified and still open, then list here and note it.*

Software anomalies include software not performing as expected, software not meeting a requirement and for when the software performs as expected but the software requirement is in error. If it is determined that the software requirement is in error, then the corrections shall be made and a minor rev checked into the configuration management repository; reference the minor rev in the description.>

|  |  |
| --- | --- |
| **Software Change Request ID Per SSI-QF-10P Problem Report** | **Description** |
| *PR number* |  |

# Deviations

*<* *Any of the following problems result in creating a Deviation Report OR*

*No deviations were found>*

## Hardware Issues

*<It is expected that the hardware testing would catch these, but it could happen during STP execution. OR*

*No hardware issues were found.>*

## Procedure Errors

*<* *If the steps cannot be executed as described in the procedure, then document the deviation>*

|  |  |  |
| --- | --- | --- |
| **Deviation ID** | **Description** | **Document** |
|  |  |  |

## Test Execution Deviations

*<*T*he test execution did not follow the protocol, then document the deviation. These result in*

*Pass with Deviation result of the test procedure. OR*

*No test execution deviations were found>*

# Evaluation and Conclusion

*<The Software Test Results summarized above provide objective evidence that the Project Name / Software Build yymmdd is fit for release.*

# Approval – either the Software Manager *or* the CEO must sign

|  |  |  |  |
| --- | --- | --- | --- |
| **Role** | **Name** | **Signature** | **Date** |
| **Software Manager** |  |  |  |
| **CEO** |  |  |  |
|  |  |  |  |
|  |  |  |  |