# Purpose

Stowood maintains its software through the use of **SSI-QF-10P Problem Report** on which all software issues arising from any source are recorded, analysed, assessed for risk, usability and other issues, verified and resolved. This Software Maintenance Plan (SMP) derives from **SSI-SOP-20 Software Development**  to define the activities and tasks of the maintenance process for the *<project name/ code>*.

*<In case of SOUP or software items that are independently managed, this plan may be used to document their configuration management and review process. Add verbiage as necessary>*

# References

## SSI-QF-20A Software Safety Classification

## SSI-QF-20B Software Development Plan

## SSI-QF-20C Software Requirements Specification and Traceability Matrix

## SSI-QF-20I Software Summary Report

## SSI-SOP-10 Design and Development

## SSI-SOP-13 Risk Management

## SSI-SOP-20 Software Development

## VISI-006 Risk Management Assessment and Control Implementation

# Maintenance Activities

*<*Provide a brief overview of the maintenance process e.g.:

*The software system under consideration has been assigned a Safety Class of* <class>*. Based on this, the following shall be evaluated at a frequency of* <x months> *to ensure that the safety and effectiveness of the software. OR*

*The highest safety classification of the software system that utilizes this* <SOUP or software item> *is* <class>*. Based on this, the following shall be evaluated at a frequency of* <x months> *to ensure that the safety and effectiveness of the software.*

Additionally make reference to how review of software shall be documented e.g.

*The results of this evaluation shall be documented on* ***SSI-QF-10P Problem Report*** *and referenced in* ***SSI-QF-20I Software Summary Report****.*

*Quality system procedures shall be used for receiving, documenting, evaluating, resolving and tracking feedback arising after release of the medical device software, and for criteria for determining whether feedback is considered to be a problem.>*

## Maintenance Responsibilities

The Software Management process will be managed by *<NAME>*. This includes management of design changes associated with software as a result of identified software problems. Quality system personnel *<NAME>* will be involved in reviewing and verifying problems associated with software and ensuring they are adequately recorded and resolved in line with non-conformance and CAPA procedures *<insert procedures as appropriate>*. *<insert other responsibilities as required>.*

## Problem Resolution

The software problem resolution process described in **SSI-SOP-20** is used for analysing and resolving problems arising after release of this software. Any nonconformities or issues that have arisen during this evaluation period shall be listed and evaluated.

## Software Items *(Optional: Remove section if not applicable as plan is for SOUP/software item)*

Changes during this evaluation period in the software items whose configuration is independently controlled shall be listed and evaluated.

## SOUP *(Optional: Remove section if not applicable as plan is for SOUP/software item)*

Upgrades, bug fixes, patches and obsolescence of SOUP during this evaluation shall be evaluated and implemented if necessary.

## Development Tools *(Optional: Remove section if not applicable as plan is for SOUP/software item)*

Changes to development tools during the evaluation period shall be evaluated for effects on the software.

## Production Tools *(Optional: Remove section if not applicable as plan is for SOUP/software item)*

Changes to development tools during the evaluation period shall be evaluated for effects on the software.

## Other Configuration Items *(Optional: Remove section if not applicable as plan is for SOUP/software item)*

Changes during the evaluation period to other configuration items that were documented in the Software Development Plan shall be evaluated for affects on the software.

# Risk Management

Changes to the architecture are reviewed for effects on existing risk controls. The final safety classification is reviewed and revised, if necessary. The design risk assessment will be reviewed and updated as necessary throughout the lifecycle of the software. See **SSI-SOP-13** for details on the risk management process.

# Cyber Security

Review cyber security activities and report on any cyber security incidents

# Documentation

All documentation associated with the maintenance of the software during the evaluation period, i.e. periodic review reports, software summary reports, nonconformance reports, change requests and other associated documentation that might have undergone updates shall be listed here.

# Preparation/Amendments and Approvals

|  |  |  |  |
| --- | --- | --- | --- |
| **Role** | **Name** | **Signature** | **Date** |
| **Software Engineer** |  |  |  |
| **Project Lead** |  |  |  |

# Document Change Control

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| --- | --- | --- | --- |
| **Version umber** | **Date** | **Author(s)** | **Brief Description of Change** |
| <<###>> | <<###>> | <<###>> | <<###-###>> |