|  |  |  |  |
| --- | --- | --- | --- |
| **Issue** | **Date** | **Author** | **Change description** |
| 1 | 05/05/23 | JF | Introduced |
| 2 | 29/02/24 | JF | Amendments to reflect practice |

# Purpose

This document captures the completion of the activities listed in SSI-QF-20 Software Maintenance Plan for the *<* *Software System/Software Item/ SOUP name>*.

# References

## *Doc. Ref. xxxxx: Document Title – Software Maintenance Plan*

## *Doc. Ref. xxxxx: Document title - Requirements Traceability Matrix*

## *Doc. Ref. xxxxx: Document Title – Software Development Plan*

## *Doc. Ref. xxxxx: Document Title – Software Safety Classification*

## SSI-SOP-20 Software Development

## SSI-SOP-13 Risk Management

## SSI-SOP-10 Design and Development

## SSI-QF-10P Problem Report

*Add / change as required*

# Maintenance Activities

The evaluation period for the software under consideration is *<start date>* to *<end date>*

Quality system procedures *<insert procedures as appropriate>* 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.

## 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. Nonconformities and issues that arise are recorded on **SSI-QF-10P Problem Report,** which is held within the Quality System as a Google Sheet. Problems are recorded by the CEO, Software Development Manager or Support Engineer as they arise. **SSI-QF-10P** is reviewed weekly by the same people and tracks the review, analysis, evaluation and resolution of each recorded problem.

*Add / change as required.*

## 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 are listed and evaluated below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Title** | **Configuration ID** | **Modified since last release? (Y/N)** | **Change Required (Y/N)** | **Change affect Software Safety Classification? (Y/N)** | **Change Request# (N/A if no change required)** |
|  | *Version number* |  |  |  |  |

## 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 are evaluated below.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Title** | **Configuration ID** | **Manufacturer** | **Licence type (if applicable)** | **Modified since last release? (Y/N)** | **Change Required (Y/N)** | **Change affect Software Safety Classification? (Y/N)** | **Change Request# (N/A if no change required)** |
|  | *Version, a release date, a patch number or an upgrade designation* |  |  |  |  |  |  |

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

Changes to development tools during the evaluation period are evaluated for effect on the software below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Title** | **Configuration ID** | **Manufacturer** | **Validation Status** | **Change Required (Y/N)** | **Change Request# (N/A if no change required)** |
|  | *Version, a release date, a patch number or an upgrade designation* |  | *Not Required (Include rationale). OR*  *Validation Required. See Doc. Ref. xx for results.* |  |  |
|  |  |  |  |  |  |

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

Changes to development tools during the evaluation period are evaluated for effect on the software below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Title** | **Configuration ID** | **Manufacturer** | **Validation Status** | **Change Required (Y/N)** | **Change Request# (N/A if no change required)** |
|  | *Version, a release date, a patch number or an upgrade designation* |  | *Not Required (Include rationale). OR*  *Validation Required. See Doc. Ref. xx for results.* |  |  |
|  |  |  |  |  |  |

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

*<Add as necessary>*

# Risk Management

*<Add as necessary> Risk is considered in each problem recorded on SSI-QF-10P Problem Report*

# Documentation

*<Add as necessary>*

| **Document Type** | **Template** | **Title** | **Document No.** |
| --- | --- | --- | --- |
| *Software Safety Classification* | *SSI-QF-20A* |  |  |
| *Software Development Plan* | *SSI-QF-20B* |  |  |
| *Software Requirement Traceability Matrix* | *SSI-QF-20C* |  |  |
| *Etc.* |  |  |  |
|  |  |  |  |
|  |  |  |  |
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|  |  |  |  |
|  |  |  |  |

# Approvals

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