APPROVAL

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PURPOSE

The purpose of this procedure is to describe and define responsibilities, requirements, methods, and phases in the software configuration management process at ASPIVIX SA with the intent to identify and define software items (including documentation) in a system, control modifications, and releases of the items and document and report the status of the items and change requests. Software configuration management is necessary to recreate a software item, to identify its constituent parts, and to provide a history of the changes that have been made to it.

SCOPE

This procedure applies to the configuration management of medical software in ASPIVIX SA.

RESPONSIBILITIES

Responsible for implementing and maintaining this SOP is the is the Regulatory Affairs and Quality Assurance Manager (RAQM). All parties participating must respect the defined procedure.

DOCUMENT HISTORY

Description of Changes	Version
Initial version	A

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1. PROCEDURE

The procedure defines rules for the software configuration management in the ASPIVIX SA. The procedure conforms to IEC 62304 and contains all activities and tasks required for medical software

1.1. Establishing Means to Identify Configuration Items

This activity (8.1.1)[1] requires the ASPIVIX SA to uniquely identify software configuration items and their versions. This identification is necessary to identify the software configuration items and the versions that are included in the medical device software.

ASPIVIX SA uses semantic versioning in the software development process for uniquely identifying software items.

A version number shall take the form X.Y.Z where X, Y, and Z are non-negative integers, and shall not contain leading zeroes. X is the major version, Y is the minor version, and Z is the patch version. Each element MUST increase numerically. For instance: 1.9.0 -> 1.10.0 -> 1.11.0.

Rules for increasing version number:

X- MAJOR version when you make incompatible API (Application Programming Interface) or hardware changes (software not backward compatible)

Y- MINOR version when you add functionality in a backwards-compatible manner, and

Z- PATCH version when you make backwards-compatible bug fixes or development sprints

1.2. Identifying Configuration Items

When the medical software is released, configuration items shall be identified and listed in the T-208-3 Software Configuration Record and maintained by the Project Manager.

1.3. Software Architecture Design

The Project Manager shall track Software of Unknown Provenance (SOUPs) (8.1.2) used in software projects by listing them in the configuration record. All used 3rd-party libraries shall be listed including the following SOUP data:

- The title
- The manufacturer
- The unique SOUP designator (version)

1.4. Software Implementation

A detailed description of methods and tools for managing configuration items is described in Table 2. System Configuration documentation (8.1.3) will be identified and listed in the record based on the T-200-1 Design Development Plan for each project and maintained by the Project Manager.

Configuration Item	Methods/Tools
Tracking and management of SOUP and associated risks	SOUP items used shall be described in the software architecture document. Each SOUP item shall be assessed for risk of impact on the device and patient/user safety.

[1] This procedure contains references in brackets (i.e. (5.2.1)) which are a direct reference to the requirements of EN 62304:2005/A1:2016

Source Code Management	Source code shall be managed as described in the Software Development Plan. The source code location used is GitHub, Bitbucket or similar tools.
Software Testing Tools Management	Shall be managed in accordance with Software test (e.g. Jira X-Ray test plugin). These documents shall be controlled using Documents and Record Control SOP-300.
Software Testing Scripts Management	Automated tests shall be stored alongside the source code (GitHub, Bitbucket or similar tools)
Identification	Software Requirements shall be listed and described in User Requirements Specifications (T-200-3) Software Items are described in software architecture records. These documents shall be controlled in accordance with the Document and Record Control SOP.
Document Management	Documents shall be managed in accordance with Document and Record Control SOP.

1.5. Software Configuration Management – Change Control

This activity requires controlling changes of the software configuration items and documenting information identifying change requests and providing documentation about their disposition. This activity is necessary to ensure that unauthorized or unintended changes are not made to the software configuration items and to ensure that approved change requests are fully implemented and verified.

1.5.1. Approve change request

Requests for changes to the Configuration Items are initiated by the Project Manager based on inputs from both internal and external sources and are classified into the following categories:

- Requirement Change,
- Software design change (without requirement change),
- Software Error Correction.

The RAQM oversees approving or rejecting the change requests (8.2.1). The change request process is managed according to the procedure SOP-303 Change Request. Prior to approving any change request, the Project Manager needs to review the Risk Assessment for the software and perform an update that may be required.

If a client-initiated change request must be rejected, or if the change severely impacts the schedule, or if it is a change in scope, then it will be brought to the attention of the CEO.

1.5.2. Implement changes

Only approved change requests with updated Risk Assessment will move to software implementation.

Project Manager is responsible for implementing the change request (8.2.2). Once a change is accepted, the software development process begins at the appropriate stage according to the type of change being requested. A requirement change begins with a revision to the User Requirement Specifications (T-200-3). A software design change (without requirement change) begins with a revision to the Design Input Requirement (T-200-12). A software error correction begins with a revision to the source code. All software development process reviews will be performed, as required in SOP-208 Software Development.

1.5.3. Verify & Release changes

Any changes made to the software system will go through software system verification and validation testing (8.2.2). and software release process as per SOP-208 Software Development.

1.5.4. Provide means for traceability of change

Requirements traceability (8.2.4) will be performed through the software development process per SOP-208 Software Development.

1.5.5. Configuration Status Accounting

For each released software version, a record based on the T-208-3 Software Configuration Record is prepared in order to determine when and why changes were made.

The Project Manager is responsible for tracking the status of Configuration Items, the status of the requested changes, and the implementation of the approved changes. (8.3).

2. REFERENCE

2.1. Procedures, instructions, and guidelines

- SOP-208 Software Development
- SOP-300 Documents and Record Control
- SOP-303 Change Request.

2.2. Templates and forms

- T-200-1 Design Development Plan
- T-208-3 Software Configuration Record
- T-200-3 User Requirements Specifications
- T-200-12 Design Input Requirement

2.3. External

- IEC 62304:2006/A1:2015 - Medical device software – Software life cycle processes
- ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes
- EN ISO 13485:2016/A11:2021 - Medical devices - Quality management systems - Requirements for regulatory purposes
- FDA QSR 21 CFR Part 820, Medical Devices - Quality System Regulation
- IEC 82304-1 Ed. 1.0 - Health Software - Part 1: General requirements for product safety
- Medical Device Regulation - Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
- EN ISO 14971:2019/A11:2021 - Medical devices - Application of risk management to medical devices

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