Revision history

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| Revision | Date (ddmmmyyyy) | Project / Change Control / CAPA / Complaint | Change description |
| 00 | 19JAN2024 | Project | Creation |
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Written by

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# Abbreviations

IFU Instructions For Use

MD Medical Device

SOP Standard Operating Procedure

# Introduction

This Product Validation Plan supports the following objectives:

* Identification of hazard-related use scenarios that were selected for the summative evaluation and information for safety
* Recommended and described Test strategies to be employed
* Identification or required resources
* Estimation of the test effort
* List of deliverables for the test effort

# Intended Use

<Describe intended use as per IEC 82304 section 4.2-a>

# Scope

This document described the planned validation activities for the Software Project Name and version.

It includes:

* <list as per IEC 82304 section 6.1-a>

# Constraints potentially limiting the feasibility of validation activities

* <list the constraints as per IEC 82304 section 6.1-b>

# Validation Test Strategy

## Validation Methods Employed

<For the applicable test types, described how they are being employed and what the success criteria are and explain why these methods are used as per IEC 82304 section 6.1-c

Validation methods include: inspection, analysis, analogy/similarity, demonstration, simulation, peerreview, testing or certification. Relevant information: reference to standards and other publications such as compatibility standards, regulatory authority guidance documents, and clinical literature. >

## Tools used

|  |  |  |
| --- | --- | --- |
| Tool Name | Description | Purpose during Verification Activities |
|  |  |  |
|  |  |  |

# Acceptance Criteria

* <state the acceptance criteria as per IEC 82304 section 6.1-c>

# Operating environment

* <describe the operating environment including hardware and software platforms required for validation as per IEC 82304 section 6.1-d>

# Required IFU Documentation and Training

* <describe the required user training and availability of IFU documentation for the evaluation as per IEC 82304 section 6.1-c – d and e>

# Independence of Validation Team from Design Team

* <describe how the validation team is independent from the design team as per IEC 82304 section 6.1-f>

# Required Resources

## Staffing

This table shows the staffing assumptions for the project.

| Role | Names | Responsibilities |
| --- | --- | --- |
| Test Managers |  | Provides management oversight.  Responsibilities:   * provide technical direction * acquire appropriate resources * provide management reporting |
| Test Designers |  | Identifies, prioritizes, and implements test cases.  Responsibilities:   * generate test plan * generate test model * evaluate effectiveness of test effort |
| Testers, Users, Participates |  | Executes the tests.  Responsibilities:   * execute tests * log results * recover from errors * document change requests |

## 

## Validation Systems and Equipment

The following table sets forth the system resources for the testing project.

| Resource | Names / Type |
| --- | --- |
| Devices |  |
| Computers |  |
| Servers |  |

# Project Milestones

| Milestone Task | Effort | Start Date | End Date |
| --- | --- | --- | --- |
| Plan Test |  |  |  |
| Design Test |  |  |  |
| Implement Test |  |  |  |
| Execute Test |  |  |  |
| Evaluate Test |  |  |  |

# Deliverables

## Validation Test Cases

<describe how this is expected to be delivered>

## Validation Results and Objective Evidence

<describe how this is expected to be delivered>

## Defect Tracking and Reports

<describe how this is expected to be delivered>

## Deviations and Anomalies

The validation team SHALL perform the validation activities in the intended operational environment(s) according to this validation plan. Where deviations from the validation plan are deemed necessary, they shall be justified in the validation report.

When anomalies are found in the Health Software Product during validation, these SHALL be resolved through a problem resolution process according to <SOP Software Development>. Where this problem resolution process results in modification of the Health Software Product, the affected part of the validation shall be repeated, taking into account the extent of the modification.

## Residual risk

The validation report SHALL assess if the Residual Risk of the Health Software Product remains acceptable or not.

# References

## Internal references

Health Software Product use requirements as per IEC 82304 section 4.2

SOP Software Development

Software Development and Maintenance Plan

SOUP List

## External references

ISO 13485 Medical devices – Quality management systems

MDR 2017/745 (EU) Medical Device Regulation (GSPR 17.2)

ISO 14971 Application of risk management to medical devices

NF EN 62366-1/A1 Application of usability engineering to medical devices

IEC 82304 Health software – Part 1: General requirements for product safety

IEC 62304 Medical device software – Software life cycle processes

MDCG 2019-16 Guidance on Cybersecurity for medical devices

# Appendix 1

Diclaimer:

This tool is proposed for free by CSDmed. It gives the framework to build a robust Software Validation Plan. It is impossible to propose a SVP that could fit to each SOP or to each software. It must be tailored to your specific situation to be efficient. CSDmed is not responsible for the way the tool may be used. If you need help to build your Software Validation strategy, feel free to contact us, we will be happy to help.

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