Software-Development-Plan**[[1]](#footnote-2)**

**Version X of <YYYY-MM-DD>**

1. **Manufacturer Information**

|  |  |
| --- | --- |
| **Manufacturer Name** |  |
| **SRN** |  |
| **Responsible Person** |  |

1. **Description and Specification of the Medical Device**

|  |  |
| --- | --- |
| **Medical Device (Trade Name)** |  |
| **Basic UDI-DI** |  |
| **UDI (UDI-DI + UDI-PI)** |  |
| **CND Code(s)** |  |
| **General Description** |  |
| **Accessories** |  |

# Scope

## Motivation

This document describes planning and control of Software Development.

Goal is to achieve compliance to standard EN 62304AM1.

**(numbers in round brackets)** refer to clauses of the standard.

**[characters in square brackets]** refer to specific software-safety-classes; if omitted, the requirement applies to all classes.

# Software Development Planning

## Documentation Planning

*Provide description, based on the software safety classification.*

## Processes to be used (EN 62304, 5.1.1 a)); Software development plan reference to system design and development (5.1.3)

*Describe the used processes; may include reference to SOPs.*

## Software development standards, methods, and tools planning (EN 62304, 5.1.4, [Class C])

*The following standards, methods and tools are used:*

* *Standards*
* *Methods*
* *Tools*

## Identification and avoidance of common software defects (EN 62304, 5.1.12, [Class B, C])

*To develop the software-system, the following programming technology (such as: language) has been selected: (description).*

*This technology is prone to the following categories of defects:*

* ***Xxx***
* ***Yyy***
* ***…***

## Deliverables (includes documentation) of the Activities and Tasks (EN 62304, 5.1.1 b))

### Documents, based on Templates

| **Ref. No.** | **Document** | **Content** |
| --- | --- | --- |
| **1** |  |  |
| **2** |  |  |
| **3** |  |  |
| **4** |  |  |
| **5** |  |  |
| **6** |  |  |

### Documents, based on Tools

|  |  |  |
| --- | --- | --- |
| **Ref. No.** | **Document** | **Content** |
| **1** |  |  |
| **2** |  |  |

## Traceability between system requirements, software requirements, software system test, and risk control measures implemented in software (EN 62304, 5.1.1 c))

### General

*Provide a description how traceability is established.*

### AI/ML Components

*Provide a description how traceability for development and testing of the AI/ML components is established.*

## Software configuration and change management, including SOUP configuration items and software used to support development (EN 62304, 5.1.1 d)); Software configuration management planning, including list of items to be controlled (5.1.9); Supporting items to be controlled (5.1.10, [Class B, C])

*Provide a description of the Toolchain, used for configuration management.*

| **Ref. No.** | **Deliverable** | **Content** | **Means of configuration management** |
| --- | --- | --- | --- |
| **1** |  |  |  |
| **2** |  |  |  |
| **3** |  |  |  |
| **4** |  |  |  |
| **5** |  |  |  |
| **6** |  |  |  |
| **7** |  |  |  |

*Also consider configuration management of supporting items, such as IDEs!*

## Software problem resolution for handling problems detected in the medical device software, deliverables and activities at each stage of the life cycle (EN 62304, 5.1.1 e))

*Describe software problem resolution process.*

## Software integration and integration testing planning (EN 62304, 5.1.5) [Class B, C]

*Describe the integration process - as applicable. May also include hardware integration activities – as applicable.*

## Software verification planning (EN 62304, 5.1.6)

*Provide a description of the planned verification activities and how these activities will be performed.*

*Reference to the Toolchain may be added.*

## Software risk management planning (EN 62304, 5.1.7)

*Describe the risk management activities.*

I herewith approve the software development plan.

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Date Name and Function Sign

1. In accordance with section 5.1 „Software development planning“ in EN 62304 [↑](#footnote-ref-2)