FOR-DND-015

Software Development Plan <Name of the Device>

Template revision	Version	Brief description or reason for the revision	Approved by <@name>, <function>, on yyyy/mm/dd
	x		

Only use validated templates from the QMS active space.

Status of the record	Version history of the record
State: Review	**Change History**

Approvals	Reviewer	Status	Date	Comment
Approval		PENDING		

Page Version	Date	Comment
Current Version (v. x)	<Date>	QA Manager

Signatures required for the record

Meaning (Prepared by, Reviewed by, Approved by, Read and understood)	Function of signatories	Name of signatories

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This Software Development Plan is established and maintained in accordance with the applicable design and development planning procedures.

1-Relevant Processes and Documents

[Class A,B,C]

Processes applicable to software development and maintenance are identified below. Detailed procedures are defined at QMS level

Note: The plan can reference existing processes or define new ones.

Document	Scope

2-Introduction

The software development plan aims to establish a framework for conducting software development activities tailored to the software system's scope, scale, and safety requirements to be developed. It seeks to define or reference the software development life cycle model, outline processes to be used, specify deliverables including documentation, ensure traceability between system and software requirements, manage software configuration and changes, and facilitate resolution of software issues throughout the life cycle of medical device software products.

This Software Development Plan defines the planned framework, processes, responsibilities, and deliverables applicable to software development and maintenance activities.

It does not document execution results, which are recorded in the corresponding design, verification, validation, and maintenance records.

2.1 Purpose (IEC 62304 §5.1.1)

The purpose of this Software Development Plan for `<PRODUCT NAME>` is to define the framework applicable to software development and maintenance activities.
This plan describes:

- the software development processes to be applied;
- the planned activities, tasks, and associated deliverables, including required documentation;
- the approach used to establish and maintain traceability between system requirements, software requirements, software verification activities, and software-related risk control measures;
- the principles for software configuration management and software change management;
- the software tools used to support software development activities;
- the approach for the identification, assessment, and management of Software of Unknown Provenance (SOUP);
- the process for the identification, tracking, and resolution of software-related problems throughout the software life cycle.

2.2 Software development plan update (IEC 62304 §5.1.2)

[Class A,B,C]

The project manager maintains the development plan, which is reviewed at least during Design Reviews as per the appropriate DND SOPs. It covers the development of the new software and its maintenance (Minor/Major versions).

The complete template is included in ReadySet

ISO 13485 QMS framework for Confluence – azbc.be