MEDICAL SOFTWARE DOCUMENTATION

Kick-start the implementation of the requirements for software development in IEC 62304 "Medical device software – Software life cycle processes" with the extensive set of templates in this documentation package.

The documentation package is ideal for new products and companies:

- The package has a Class B CE approval track record and is prepared for Class C
- Focus your resources on product development rather than building a quality system
- Take advantage of the in-depth analysis of the requirements in IEC 62304 prepared by Prevas
- All templates are ready for printout in a physical documentation archive

The documentation package includes the following templates:

PLANNING AND SPECIFICATION	
Software Development Plan	Main entry point for the documentation. Describes processes, activities, and deliverables as required by the regulatory standards for medical device software
Software Configuration Management Plan	Describes processes of configuration, identification, control, status accounting, and verification
Software Risk Management Plan	Defines the risk processes and the risk management activities.
Software Risk Analysis	Documents and tracks the Software Risk Management Activities including identification of risks, and implementation of Risk Control Measures
Software Architectural Design	Breaks the software into SW Units. The description includes the relation between SW Units and SOUP, Risk Control Measures, and internal and external interfaces
Software Requirements Specification	Describes software requirements including interface to SOUP, HW and other external modules in detail.
Software Safety Classification	Assesses the Software Safety Classification and Level of Concern. The assessment is done before mitigation of any Software hazards
Terminology List	Documents the terminology and document references used across the project

Prevas
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With leading expertise in high-tech product development, embedded systems, and industrial IT & automation, Prevas contributes by providing innovative solutions and services that create growth. Prevas was founded in 1985 and is the main supplier and development partner to leading companies in industries such as life science, telecom, automotive, defense, energy, and engineering. Offices are located in Sweden, Denmark, Norway, and India. The company has just over 600 employees. Prevas has been listed on the NASDAQ exchange in Stockholm since 1998.
For more information, please visit www.prevas.com.

DESIGN AND IMPLEMENTATION	
Software Programming Style Guide	Describes the coding style to be used in C++ code developed from scratch
Software Build Manual	Specifies the steps necessary to build the Software
Software Tools Validation	Documents the tools used for software development and production
SOP for Issue Tracking	Describes the issue tracking during product development and maintenance of the Software
SOP for Software Review	Details the review procedure including requirements for documentation of formal Software reviews
Software Review Checklist	A supplement with some checks for the reviewer to consider during the Software review
Software List of Files	A list of files in the software – including source code files

VERIFICATION, RELEASE AND MAINTENANCE	
Software Verification Specification	Specifies the test cases needed to ensure verification coverage of all SW requirements
Software Verification Report	Documents the result of a software verification sequence
SOUP Documentation	Provide information on SOUP components to enable the use hereof in the system
SOP for Software Release	Describes the process of releasing the software including version scheme, release note and definition of release criteria
Software Release Note	A short form description of the software release including purpose, changes and verification
Software List of Anomalies	Lists the known anomalies in a specific release of the system
Software Revision Level History	A shortlist of software releases
Software Maintenance Plan	Uses the same processes as used for the development, but also describes Adverse Event an Urgent Release Processes
Bug Report Template	Documents, assesses, and tracks issues found.

The documentation package relies on the following typical external documentation for the development project, not included in this package.

Prevas has made another template package available to help establish the development project, Medical Device START-UP Templates package.

NAME
Configuration Item List
Documentation Plan
Master Quality and Project Plan
Product Risk Assessment – Hazard analysis
Requirements Traceability Matrix
Risk Management Plan
SOP for Complaint Handling
SOP for Control of Records
SOP for Engineering Change Control
SOP for Post Market Surveillance
System Architectural Design
System Design and Development Plan
System Requirements Specification
Terminology List
Verification and Validation Plan

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