PREVAS PRODUCTS

MEDICAL SYSTEM SOFTWARE

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 that are carried out
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 details.
Software Safety Classification	This document assesses the Software Safety Classification and Level of Concern. The assessment is done before mitigation of any Software hazards

Prevas

Innovation for Growth

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	Documents the tools used for software development and production
Software Defect Tracking	Describes the defect tracking during product development and maintenance of the Software
Software Review Process	Details the review procedure including requirements for documentation of formal Software reviews
Software Code 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 Plan	Defines verification activities and methods of verification including acceptance criteria for all Software systems, SOUP and Tools
Software verification specification	Specifies the test cases needed to ensure test coverage of all SW requirements
Software verification Report	Documents the result of a software test sequence
Unit Verification Report	Documents the result of unit verification activities
SOUP Documentation	Provide information on SOUP components to enable the use hereof in the system
SOUP Bug Report	Documents the assessment of SOUP bugs
Software Release Procedure	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	Basically uses the same processes as used for the development, but also describes Adverse Event an Urgent Release Processes
Tools Bug Report	Documents the assessment of tool bugs
Test Tools	Documents the special tools used in software testing

The documentation package relies on the following typical external documentation, not included in the package:

NAME
SOP for Change Control
SOP for Complaint Handling
System Design and Development Plan / Master Quality and Project Plan
Documentation Plan / Document overview
SOP for Post Market Surveillance
Product Risk Assessment / Hazard Analysis
SOP for Control of Records
Risk Management Plan
System Requirements Specification
System Architectural design
Terminology List
Verification and Validation Plan

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