



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

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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](http://www.prevas.com).

## DESIGN AND IMPLEMENTATION

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

## VERIFICATION, RELEASE AND MAINTENANCE

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

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

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