

Evidence Product Checklist

For Standard
IEC 62304:2015* *Medical device
software – Software life
cycle processes*

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*(IEC 62304 Edition 1.0 2015-06 – IEC 62304:2006/AMD1:2015)

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Evidence Product Checklist For Standard IEC 62304:2015* Medical device software – Software life cycle processes

***IEC 62304 Edition 1.0 2015:06 – IEC 62304:2006/AMD1:2015**

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Evidence Product Checklist

For Standard IEC 62304:2015 Medical device software – Software life cycle processes (including Amendment 1)

Introduction to Amendment 1

IEC released amendment 1 for IEC 62304 in June of 2015. The purpose of this revision was:

1. Additional requirements to address software life cycle processes specific to legacy software.
2. Clarification of requirements and updates for Software Safety Classification to include a risk-based approach, focus on overall medical device risk analysis, and with a strong reference for using ISO 14971 processes.
3. Minor revisions to approximately 40% of the standard. .

This checklist addresses the amendment and the base standard.

Introduction to the checklist

The process of defining what is necessary for compliance with a standard for software life cycle processes such as “IEC 62304:2015” is often confusing and laborious because the directions contained in the guidelines are unclear or ambiguous. To aid in determining what is actually “recommended” by the document in the way of physical evidence of compliance, the experts at SEPT have produced this checklist. This checklist is constructed around a classification scheme of physical evidence comprised of procedures, plans, records, documents, audits, and reviews. There must be an accompanying record of some type when an audit or review has been accomplished. This record would define the findings of the review or audit and any corrective action to be taken. For the sake of brevity this checklist does not call out a separate record for each review or audit. All procedures should be reviewed but the checklist does not call out a review for each procedure, unless the standard calls out the procedure review. In this checklist “manuals, reports, scripts and specifications” are included in the document category.

The author has carefully reviewed the document “IEC 62304:2015 Medical device software – Software life cycle processes” and defined the physical evidence recommended based upon this classification scheme. SEPT has conducted a second review of the complete list to ensure that the documents’ producers did not leave out a physical piece of evidence that a “reasonable person” would expect to find. It could certainly be argued that if the document did not call it out then it is not recommended; however, if the document was used by an organization to improve its process, then it would make sense to recognize missing documents. Therefore, there are documents specified in this checklist that are implied by the standard, though not specifically called out in the document, and they are designated by an asterisk (*) throughout this checklist. These items are classified as suggested. If a document is called out more than one time, only the first reference is stipulated. If there are no new requirements or suggestions in a

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particular clause or sub-clause then the clause or sub-clause is omitted throughout sections 2-8.

There are occasional situations in which a procedure or document is not necessarily separate and could be contained within another document. For example, the "Data Base Requirements Document" could be a part of the Software Requirements Document". The author has called out these individual items separately to ensure that the organization does not overlook any facet of physical evidence. If the organization does not require a separate document, and an item can be a subset of another document or record, then this fact should be denoted in the detail section of the checklist for that item. This should be done in the form of a statement reflecting that the information for this document may be found in section XX of Document XYZ. If the organizational requirements do not call for this physical evidence for a particular project, this should also be denoted with a statement reflecting that this physical evidence is not recommended and why. The reasons for the evidence not being recommended should be clearly presented in this statement. Further details on this step are provided in the Detail Steps section of the introduction. The size of these documents could vary from paragraphs to volumes depending upon the size and complexity of the project or business requirements.

IEC 62304:2015 – Medical device software – Software life cycle processes checklist

This checklist was prepared by analyzing each clause of this document for the key words that signify a:

- Procedure
- Plan
- Records
- Document (Including Lists, Manuals, Reports, Scripts and Specifications)
- Audit
- Review

This checklist specifies evidence that is unique. After reviewing the completed document, the second review was conducted from a common sense "reasonable man" approach. If a document or other piece of evidence appeared to be recommended, but was not called out in the document, then it is added with an asterisk (*) after its notation in the checklist. The information was transferred into checklist tables, based on the type of product or evidence.

Using the Checklist

When a company is planning to use IEC 62304:2015 Medical device software – Software life cycle processes standard, the company should review the evidence checklist. If the company's present process does not address an IEC 62304:2015 product, then this question should be asked: Is the evidence product required for the type of business of the company? If in the view of the company the evidence is not required, the rationale should be documented and inserted in the checklist and quality manual. This rationale should pass "*the reasonable person rule.*" If the evidence is required, plans should be prepared to address the missing item(s).

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Detail Steps

An organization should compare the proposed output of their organization against the checklist. In doing this, they will find one of five conditions that exist for each item listed in the checklist. The following five conditions and the actions required by these conditions are listed in the table below. This table applies for section 2 through 8

Condition	Action Required
1. The title of the documented evidence specified by the checklist (document, plan, etc.) <i>agrees</i> with the title of the evidence being planned by the organization.	Record in checklist that the organization is compliant. This note (Yes) would go in column with the heading "Availability".
2. The title of the documented evidence specified by the checklist (document, etc.) <i>disagrees</i> with the title of the evidence planned by the organization but the content is the same.	Record in the checklist the evidence title the organization uses and record that the organization is compliant, would go in column with the heading "Availability". The note would say "The title of the documented evidence specified by the checklist (document, etc.) <i>disagrees</i> with the title of the evidence planned by the organization but the content is the same".
3. The title of the documented evidence specified by the checklist (document, etc.) is <i>combined</i> with another piece of evidence.	Record in the checklist the title of the evidence (document, etc.) in which this information is contained. This note (The title of the documented evidence specified by the checklist (document, etc.) is <i>combined</i> with another piece of evidence.) would go in column with the heading "Availability".
4. The title of the documented evidence specified by the checklist (document, etc.) <i>is not planned</i> by the organization because it is not required.	Record in the checklist that the evidence is not required and the rationale for this decision. This note (The title of the documented evidence specified by the checklist (document, etc.) <i>is not planned</i> by the organization because it is not required) would go in the column with the heading "(Not Required/Rationale)".
5. The title of the documented evidence called out by the checklist (document, etc.) <i>is not planned</i> by the organization and <i>should be</i> planned by it.	Record in the checklist when this evidence will be planned and reference a plan for accomplishing this task. (The title of the documented evidence called out by the checklist (document, etc.) <i>is not planned</i> by the organization and <i>should be</i> planned by it. This note would go in column with the heading (Comments).

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Components of the Checklist

This checklist is composed of 9 sections:

- Section 1. Introduction to amendment 1 and the checklist
- Section 2. Composites of all recommended and suggested “IEC 62304:2015 - Medical device software – Software life cycle processes” evidence products.
- Sections 3-8. Individual checklists for each evidence type.
- Section 9. “About the Author”

Product Support

All reasonable questions concerning this checklist or its use will be addressed free of charge for 60 days from time of purchase, up to a maximum of 4 hours consultation time.

Warranties and Liability

Software Engineering Process Technology (SEPT) makes no warranties implied or stated with respect to this checklist, and it is provided on an “*as is*” basis. SEPT will have no liability for any indirect, incidental, special or consequential damages or any loss of revenue or profits arising under, or with respect to the use of this document.

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IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
4 General requirements					
4.1 Quality management system Class A, B, C	ISO 13485 Requirements or Equivalent for Procedures	ISO 13485 Requirements or Equivalent for Plans	ISO 13485 Requirements or Equivalent for Records	ISO 13485 Requirements or Equivalent for Documents	ISO 13485 Requirements or Equivalent for Audits - ISO 13485 Requirements or Equivalent for Reviews
4.2 Risk Management Class A, B, C	ISO 14971 Requirements for Procedures	ISO 14971 Requirements for Plans	ISO 14971 Requirements for Records	ISO 14971 Requirements for Documents	ISO 14971 Requirements for Audits* - ISO 14971 Requirements for Reviews*

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IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
4.3 Software safety classification Class A, B, C	• Assignment of Software Safety Class Procedure • Risk Management File Document Procedure* • Software Safety Class Document Procedure*		• Software Safety Class Records*	• Risk Management File Document • Software Safety Class Document	• Risk Management File Document Review* • Software Safety Class Document Review* • Software Safety Class Records Review*
4.4 Legacy Software					
4.4.1 General					

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IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
4.4.2 Risk Management Activities Class A, B, C	- Assessing Any Feedback on the Use of Legacy Software Procedure* - Performing Risk Management Activity Associated With the Continued Use of Legacy Software Procedure*				
4.4.3 Gap analysis Class A, B, C	Gap Analysis of Legacy Software Versus Using Other Available Software Procedure*		Software System Test (Associated with Gap Analysis) Records		
4.4.4 Gap closure activities Class A, B, C	Closure of All Gap Activities Plan Procedure*	Closure of All Gap Activities Plan			Closure of All Gap Activities Plan Review*

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4.4.5 Rationale for use of Legacy Software Class A, B, C	Legacy Software Documentation Procedure*		Rational For the Continued Use of Legacy Software Record	Legacy Software Documentation	Legacy Software Documentation Review*
5 Software development process					
5.1 Software development planning					
5.1.1 Software development plan Class A, B, C	- Software Development Plan Procedure* - System Development Plan Procedure*	- Software Development Plan - System Development Plan*			- Software Development Plan Review* - System Development Plan Review*
5.1.2 Keep software development plan updated Class A, B, C			Software Development Plan Update Records		Software Plan Update Records Review*

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IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
5.1.3 Software development plan reference to system design and development Class A, B, C	- Design and Development Validation Procedure - Software and System Development Coordination Procedure - System Requirements Document Procedure*			System Requirements Document	System Requirements Document Review*
5.1.4 Software development standards, methods and tools planning Class C	Software Development Standards, Methods and Tools Plan Procedure*	Software Development Standards, Methods and Tools Plan			Software Development Standards, Methods and Tools Plan Review*
5.1.5 Software integration and integration testing planning Class B, C	- Software Integration (Including SOUP) Plan Procedure* - Software Integration Test Plan Procedure*	- Software Integration (Including SOUP) Plan - Software Integration Test Plan			- Software Integration (Including SOUP) Plan Review* - Software Integration Test Plan Review*

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IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
5.1.6 Software verification planning Class A, B, C	Software Verification Plan Procedure*	Software Verification Plan			Software Verification Plan Review*
5.1.7 Software risk management planning Class A, B, C	Software Risk Management Plan Procedure*	Software Risk Management Plan			Software Risk Management Plan Review*
5.1.8 Documentation planning Class A, B, C	Software Documentation Plan Procedure*	Software Documentation Plan			Software Documentation Plan Review*
5.1.9 Software configuration management planning Class A, B, C	Software Configuration Management Plan Procedure*	Software Configuration Management Plan			Software Configuration Management Plan Review*
5.1.10 Supporting items to be controlled Class B, C	Support Item Document Procedure*			Support Item Document	Support Item Document Review*
5.1.11 Software configuration item control before verification Class B, C			Configuration Items Under Configuration Management Prior to Verification Records		Configuration Items Under Configuration Management Prior to Verification Records Review*

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5.1.12 Identification and avoidance of common software defects Class B, C	Identification of Categories of Defects That May Be Introduced Due To Programming Technology That Is Relevant To the Software System Procedure		Software Defects Due To Programming Technology Used By the Software Developer But Did Cause Unacceptable Risk Records		
5.2 Software requirements analysis					
5.2.1 Define and document software requirements from system requirements Class A, B, C	Software Requirements Document Procedure*			Software Requirements Document	Software Requirements Document Review*

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5.2.2 Software requirements content Class A, B, C	• Data Base Requirements Document Procedure* • Regulatory Requirements Document Procedure* • Requirements Related to IT-Network Aspects Document Procedure* • Software Acceptance Requirements Document Procedure* • Software and System Security/Malware Requirements Document Procedure*			• Data Base Requirements Document • Regulatory Requirements Document • Requirements Related to IT-Network Aspects Document • Software Acceptance Requirements Document • Software and System Security/Malware Requirements Document • Software Installation Requirements Document • Software Maintenance Requirements Document	• Data Base Requirements Document Review* • Regulatory Requirements Document Review* • Requirements Related to IT-Network Aspects Document Review* • Software Acceptance Requirements Document Review* • Software and System Security/Malware Requirements Document Review*
5.2.2 Software requirements content	• Software Installation			• System Operations	• Software Installation

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Class A, B, C (Cont. 1)	Requirements Document Procedure* • Software Maintenance Requirements Document Procedure* • System Operations Requirements Document Procedure* • Usability Engineering Requirements Document Procedure* • User Documentation Document Procedure* • User Interface Requirements Implemented by Software Procedure*			Requirements Document • Usability Engineering Requirements Document • User Documentation Document • User Interface Requirements Implemented by Software Document • User Maintenance Requirements Document	Requirements Document Review* • Software Maintenance Requirements Document Review* • System Operations Requirements Document Review* • Usability Engineering Requirements Document Review* • User Documentation Document Review*

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5.2.2 Software requirements content Class A, B, C (Cont. 2)	User Maintenance Requirements Document Procedure*				- User Interface Requirements Implemented by Software Document Review* - User Maintenance Requirements Document Review*
5.2.3 Include risk control measures in software requirements Class B, C	Software Risk Controls Measures Document Procedure*			Software Risk Controls Measures Document	Software Risk Controls Measures Document Review*
5.2.4 Re-evaluate medical device risk analysis Class A, B, C			Re-Evaluate Medical Device Risk Analysis Records		Re-Evaluate Medical Device Risk Analysis Records Review*
5.2.5 Update requirements Class A, B, C			Requirement Update Records		Requirement Update Records Review*

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IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
5.2.6 Verify software requirements Class A, B, C	• Software Test Scripts Document Procedure* • Software Testing Criteria Document Procedure*		• Software Requirements Verification Records	• Software Test Scripts Document • Software Testing Criteria Document	• Software Requirements Verification Records Review* • Software Test Scripts Document Review* • Software Testing Criteria Document Review*
5.3 Software architectural design					
5.3.1 Transform software requirements into an architecture Class B, C	• Software Architecture Document Procedure*			• Software Architecture Document	• Software Architecture Document Review*
5.3.2 Develop an architecture for the interfaces of software items Class B, C	• Hardware, System and Software Interface Document Procedure*			• Hardware, System and Software Interface Document	• Hardware, System and Software Interface Document Review*

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IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
5.3.3 Specify functional and performance requirements of SOUP item Class B, C	Functional and Performance Requirements for SOUP Document Procedure*			Functional and Performance Requirements for SOUP Document	Functional and Performance Requirements for SOUP Document Review*
5.3.4 Specify system hardware and software required by SOUP item Class B, C			System and Software Necessary to Support a SOUP Item Manufacturer Records		System and Software Necessary to Support a SOUP Item Manufacturer Records Review*

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5.3.5 Identify segregation necessary for risk control Class C	Software Items That Were Segregated Because of Risk Control and Why It Was Effective Document Procedure*		Identify Segregation of Software Items Necessary for Risk Control Records	Software Items That Were Segregated Because of Risk Control and Why It Was Effective Document	- Identify Segregation of Software Items Necessary for Risk Control Records Review* - Software Items That Were Segregated Because of Risk Control and Why It Was Effective Document Review*
5.3.6 Verify software architecture Class B, C			- Software Architecture Risk Control Verifications Records - Software Architecture Verifications Records		- Software Architecture Risk Control Verifications Records Review* - Software Architecture Verifications Records Review*
5.4 Software detailed design					

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IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
5.4.1 Subdivide software into software units Class B, C			Transformation of Software Architecture Into Software Unit Records		Transformation of Software Architecture Into Software Unit Records Review*
5.4.2 Develop detailed design for each software unit Class C	Software Detail Design Document Procedure*			Software Detail Design Document	Software Detail Design Document Review*
5.4.3 Develop detailed design for interfaces Class C	Software Detail Design Interface Document Procedure*			Software Detail Design Interface Document	Software Detail Design Interface Document Review*
5.4.4 Verify detailed design Class C			Software Detail Design Verifications Records		Software Detail Design Verifications Records Review*
5.5 Software unit implementation					
5.5.1 Implement each software unit Class A, B, C			Software Unit Implementation Records*		Software Unit Implementation Records Review*

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IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
5.5.2 Establish software unit verification process Class B, C	• Software Testing Procedure • Software Unit Testing Procedure • Software Unit Verification Methods Document Procedure • Software Unit Verification Procedure • Software Unit Verification Strategy Document Procedure		• Software Unit Test Records • Software Unit Verification Records	• Software Unit Verification Methods Document • Software Unit Verification Strategy Document	• Software Testing Procedure Review • Software Unit Test Records Review* • Software Unit Testing Procedure Review • Software Unit Verification Methods Document Review* • Software Unit Verification Records Review* • Software Unit Verification Strategy Document Review *

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5.5.3 Software unit acceptance criteria Class B, C	- Coding Standards Document Procedure* - Software Unit Acceptance Criteria Document Procedure*			- Coding Standards Document* - Software Unit Acceptance Criteria Document	- Coding Standards Document Review* - Software Unit Acceptance Criteria Document Review* - Software Unit Coding Review*
5.5.4 Additional software unit acceptance criteria Class C	Additional Software Unit Acceptance Criteria for Class C Software Document Procedure*			Additional Software Unit Acceptance Criteria for Class C Software Document	Additional Software Unit Acceptance Criteria for Class C Software Document Review*
5.5.5 Software unit verification Class B, C			Software Unit Coding Review Records		Software Unit Coding Review Records Review*
5.6 Software integration and integration testing					

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5.6.1 Integrate software units Class B, C			Integration Software Unit Per Plan Records		Integration Software Unit Per Plan Records Review*
5.6.2 Verify software integration Class B, C			Verify Software Integration Records		Verify Software Integration Records Review*
5.6.3 Software integration testing Class B, C			Software Unit Integration Test Records		Software Unit Integration Test Records Review*
5.6.4 Software integration testing content Class B, C			Certification of Integration Testing Content Record		Certification of Integration Testing Content Record Review*
5.6.5 Evaluate software integration test procedures Class B, C	Integration Test Procedure				Integration Test Procedure Review

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IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
5.6.6 Conduct regression tests Class B, C	Regression Testing Plan Procedure*	Regression Testing Plan*	Regression Testing Records		- Regression Testing Plan Review* - Regression Testing Records Review*
5.6.7 Integration test record contents Class B, C	- Integration Test Script Document Procedure* - Software Anomalies List Procedure*		- Integration Testing Tester Records - Software Anomalies Records	- Integration Test Scripts Document - Software Anomalies List	- Integration Test Script Document Review* - Integration Testing Tester Records Review* - Software Anomalies List Review* - Software Anomalies Records Review*
5.6.8 Use software problem resolution process Class B, C	Problem Resolution Process Procedure				Problem Resolution Process Procedure Review*
5.7 Software system testing					

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IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
5.7.1 Establish tests for software requirements Class A, B, C	- Evaluate The Adequacy Of The Verification Strategies And Test Procedures Procedure - Software System Testing Criteria Document Procedure*		Evaluate The Adequacy Of The Verification Strategies And Test Procedures Record	Software System Testing Criteria Document	Software System Testing Criteria Document Review*
5.7.2 Use software problem resolution process Class A, B, C	Software Anomalies Processing Procedure*				
5.7.3 Retest after changes Class A, B, C	Retest After Changes During Software System Testing Procedure*				

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5.7.4 Evaluate software system testing Class A, B, C	• Software Test Pass/Fail Criteria Document Procedure* • System Test Procedure • Verification System Test Strategy and Test Procedure Document Procedure*		• Software System Testing Verification Records • Traceability Between Software Requirements and Test/ Verification Records	• Software Test Pass/Fail Criteria Document • Verification System Test Strategy and Test Procedure Document	• Software System Testing Verification Records Review • Software Test Pass/Fail Criteria Document Review* • System Test Procedure Review • Verification System Test Strategy and Test Procedure Document Review*
5.7.5 Software system test record contents Class A, B, C	• Software System Test Records Procedure		• Software System Test (By Case) Records		
5.8 Software release for utilization at a system level					

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5.8.1 Ensure software verification is complete Class A, B, C			- Software Verification Activity Completed Records - Software Verification Evaluation Records		- Software Verification Completed Records Review* - Software Verification Evaluation Records Review*
5.8.2 Document known residual anomalies Class A, B, C	Residual Anomalies Document Procedure*			Residual Anomalies Document	Residual Anomalies Document Review*
5.8.3 Evaluate known residual anomalies Class B, C			Evaluation of Known Residual Anomalies Records		Evaluation of Known Residual Anomalies Records Review*
5.8.4 Document released versions Class A, B, C	Medical Device Software Release Procedure		Medical Device Software Release Records		Medical Device Software Release Records Review*

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5.8.5 Document how released software was created Class B, C	Creation Steps Required to Release Software Procedure				
5.8.6 Ensure activities and tasks are complete Class B, C			Software Plans, Activities, Tasks and Associated Documentation is Completed Records		Software Plans, Activities, Tasks and Associated Documentation is Completed Records Review
5.8.7 Archive software Class A, B, C	Medical Device Software and Documentation Archive Procedure*		Medical Device Software and Documentation Archive Records		Medical Device Software and Documentation Archive Records Review*
5.8.8 Assure reliable delivery of released software Class A, B, C	Assure Reliable Delivery of Released Software Procedure				

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IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
6 Software maintenance process					
6.1 Establish software maintenance plan Class A, B, C	Software Maintenance Plan Procedure*	Software Maintenance Plan			Software Maintenance Plan Review*
6.2 Problem and modification analysis					
6.2.1 Document and evaluate feedback Class A, B, C	Problem Report Procedure*				
6.2.1.1 Monitor feedback Class A, B, C			Monitor Feedback on Released Medical Device Software Product Records		Monitor Feedback on Released Medical Device Software Product Records Review
6.2.1.2 Document and evaluate feedback Class A, B, C	Medical Device Software Problem Resolution Process Procedure		Medical Device Software Feedback Records		Medical Device Software Feedback Records Review

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6.2.1.3 Evaluate problem report's affects on safety Class A, B, C			• Problem Report Affecting Safety Records		• Problem Report Affecting Safety Records Review*
6.2.2 Use software problem resolution process Class A, B, C			• Change In Safety Class of Software System Record • Notification to All Affect Parties That a Change in Safety Class of Software System Has Been Made Record • Use of Software Problem Resolutions Process to Address Problem Reports Records*		• Use of Software Problem Resolution Process to Address Problem Reports Records Review*

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6.2.3 Analyse change requests Class A, B, C			Analyze Change Request for Effects on the Interfacing Organization, Released Medical Device Software and Interfacing Systems Records		Analyze Change Request for Effects on the Interfacing Organization, Released Medical Device Software and Interfacing Systems Records Review*
6.2.4 Change request approval Class A, B, C	Medical Device Software Change Request for Released Medical Device Software Procedure				

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6.2.5 Communicate to users and regulators Class A, B, C			Communication to Users and Regulators of All Software Problems of Released Medical Device Software Records		Communication to Users and Regulators of All Software Problems of Released Medical Device Software Record Review*
6.3 Modification implementation					
6.3.1 Use established process to implement modification Class A, B, C			Used Established Process to Implement Modification Certification Records		Used Established Process to Implement Modification Certification Records Review*
6.3.2 Re-release modified software system Class A, B, C			Re-release Modified Software System Records		Re-release Modified Software System Records Review*

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IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
7 Software risk management process					
7.1 Analysis of software contributing to hazardous situations					
7.1.1 Identify software items that could contribute to a hazardous situation Class B, C	Risk Management File Procedure		Software Items That Could Contribute To a Hazard Situation Records		Software Items That Could Contribute to a Hazard Situation Records Review*
7.1.2 Identify potential causes of contribution to a hazardous situation Class B, C			Software Items That Are Potential Contributor To a Hazard Situation Records		Software Items That Are Potential Contributor to a Hazard Situation Records Review*
7.1.3 Evaluate published SOUP anomaly lists Class B, C					SOUP Anomalies List Review

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* Suggested item

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IEC 62304:2015 Evidence Products Checklist By Clause

IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
7.1.4 Document potential causes Class B, C			• Risk Management File of Sequence of Events That Could Result in a Potential Hazard Situation Records • Risk Management File of Software Items That Are Potential Contributor To a Hazard Situation Records		• Risk Management File of Sequence of Events That Could Result In a Potential Hazard Situation Records Review* • Risk Management File of Software Items That Are Potential Contributor To a Hazard Situation Records Review*
7.2 Risk control measures					

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* Suggested item

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IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
7.2.1 Define risk control measures Class B, C	Risk Control Measures In Accordance With ISO 14971 Procedure		Risk Control Measures Taken Per ISO 14971 For Hazardous Situations for Each Case Records		Risk Control Measures Taken Per ISO 14971 For Hazardous Situations for Each Case Review*
7.2.2 Risk control measures implemented in software Class B, C	Risk Control Measure Document Procedure*		Relate Risk Control Measure to Safety Class and to a Software Item Record	Risk Control Measure Document	- Relate Risk Control Measure to Safety Class and to a Software Item Record Review* - Risk Control Measure Document Review*
7.3 Verification of risk control measures					

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* Suggested item

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IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
7.3.1 Verify risk control measures Class B, C	Verification of Risk Control Measures Procedure		Verification of Risk Control Measures Taken for Hazardous Situations Records		Verification of Risk Control Measures Taken for Hazardous Situations Records Review*
7.3.2 Not used					
7.3.3 Document traceability Class B, C	Software Hazards Traceability Document Procedure*			Software Hazards Traceability Document	Software Hazards Traceability Document Review*
7.4 Risk management of software changes					
7.4.1 Analyse changes to medical device software with respect to safety Class A, B, C			Analyse Changes To Medical Device Software With Respect To Safety Records		Analyse Changes To Medical Device Software With Respect To Safety Records Review*

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* Suggested item

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IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
7.4.2 Analyse impact of software changes on existing risk control measures Class B, C			Analyse Impact of Software Changes On Existing Risk Control Measures Records		Analyse Impact of Software Changes On Existing Risk Control Measures Records Review*
7.4.3 Perform risk management activities based on analyses Class B, C			Perform Risk Management Activities Based On Analysis Records		Perform Risk Management Activities Based On Analysis Records Review*
8 Software configuration management process					
8.1 Configuration identification					

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* Suggested item

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IEC 62304:2015 Evidence Products Checklist By Clause

IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
8.1.1 Establish means to identify configuration items Class A, B, C	- System Configuration Items Document Procedure* - Unique Identification of Configuration Items Scheme Document Procedure*			- System Configuration Items Document - Unique Identification of Configuration Items Scheme Document	- System Configuration Items Document Review* - Unique Identification of Configuration Items Scheme Document Review*
8.1.2 Identify SOUP Class A, B, C	SOUP Document Procedure*			SOUP Document	SOUP Document Review*
8.1.3 Identify system configuration documentation Class A, B, C			System Configuration Documentation Records		System Configuration Documentation Records Review*
8.2 Change control					
8.2.1 Approve change requests Class A, B, C	Change Control Procedure		Change Request Records		Change Request Records Review*

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* Suggested item

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IEC 62304:2015 Evidence Products Checklist By Clause

IEC 62304:2015 Clause Number, Name and Software Safety Classifications	Procedures	Plans	Records	Documents	Audits and Reviews
8.2.2 Implement changes Class A, B, C			Change Request Implementation Records		Change Request Implementation Records Review*
8.2.3 Verify changes Class A, B, C	Verification of Changes Procedure*		Change Request Verification Records		Change Request Verification Records Review*
8.2.4 Provide means for traceability of change Class A, B, C	Relationship and Dependencies Between Change Request, Relevant Problem Reports and Approved Change Request Records Procedure*		Relationship and Dependencies Between Change Request, Relevant Problem Reports and Approved Change Request Records		Relationship and Dependencies Between Change Request, Relevant Problem Reports and Approved Change Request Records Review*

10/20/2015

* Suggested item