Evidence Product Checklist

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

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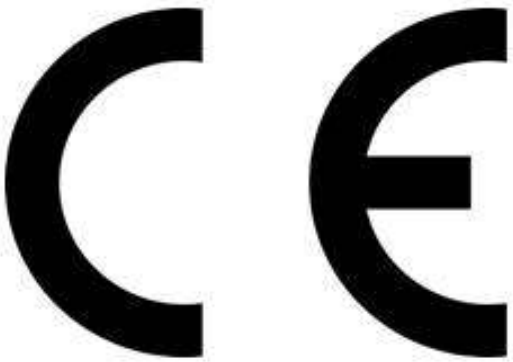
ISBN 978-0-9859732-4-7



*(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

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).

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.) *agrees* 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.) *disagrees* 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.) *disagrees* 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 *combined* 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 *combined* 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.) *is not planned* 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.) *is not planned* 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.) *is not planned* by the organization and *should be* 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 checklis*t* (document, etc.*) is not planned* by the organization and *should be* planned by it. This note would go in column with the heading (Comments).

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.

Section 2
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
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*

* Suggested item

Section 2
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
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					

* Suggested item

Section 2
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
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*

* Suggested item

Section 2
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
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*

* Suggested item

Section 2
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
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*

* Suggested item