



EVIDENCE PRODUCT CHECKLIST

For Standard ISO 13485:2016

*Medical devices - Quality management systems-
Requirements for regulatory purposes*

A checklist prepared by analyzing each clause of ISO 13485:2016



SEPT Product 89
ISBN 978-0-9859732-6-1
Author: Andy Coster, CCP

Produced by Software Engineering Process Technology (SEPT)
1705 16th Lane NE ; Suite P203 ; Issaquah WA 98029
Tel. 425-391-2344

3/3/2016

E-mail: Stanmagee@smartwire.net
Web Site: www.12207.com



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Software Engineering Process Technology
(SEPT)
2725 NW Pine Cone Drive
Issaquah, WA. 98027
Tel. 425-391-2344
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Web Site: www.12207.com

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Evidence Product Checklist for Standard ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

Overview of the base standard

ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the total product life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). This International Standard can also be used by suppliers or external parties that provide product including quality management system-related services to such organizations.

The updates included in the ISO 13485:2016 standard provide for a focus in utilizing risk management processes as not only part of the design and development, but also to be used throughout the quality system implementation as rationale for quality system decisions and in determining level of effort for quality system activities and deliverables.

Introduction to the SEPT checklist for implementing this standard

For 20 years (SEPT) Software Engineering Process Technology has been producing checklists for standards that address software issues. This is another checklist for a software related standard for the Medical devices industry that will aid an organization to comply with regulatory requirements.

The task of getting a new or modified medical device to market in a timely matter is a daunting task. Especially if the organization wants to apply a CE mark to its product. The last thing an organization wants in its product development cycle is to call in a Notified Body for certification and to find out that the organization is lacking the correct records or documents for the auditor to examine. SEPT experts found a 90% increase in artefacts required in the new 2016 standard compared to the previous 2003 version. This SEPT checklist list if used properly will give an organization the confidence that it has all the documentation required by this ISO 13485 standard. The checklist is a tool to ease the pain in becoming certified to ISO 13485 by clearly defining the artefacts required, whether your organization is upgrading to the new version or addressing certification to ISO 13485 for the first time.

The first step that an organization has in meeting the requirements of a quality management process standard such as Standard ISO 13485:2016 is to determine what is required. Often these quality systems and technical standards are confusing and laborious because the directions contained in the standards are unclear to a lay person. In order to reduce this fog surrounding these types of standards SEPT has been producing checklists for standards since 1994. The checklists lift this fog around a standard and state what is required and suggested by the standard in a clear and concise manner. To aid in determining what is actually “required” by the document in the way of physical evidence of compliance, the experts at SEPT have produced this checklist. The SEPT checklists are constructed around a classification scheme of physical evidence comprised of policies, 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

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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. When the subject standard references another standard for physical evidence, the checklist does not call out the requirements of the referenced standard.

The author has carefully reviewed the Standard “ISO 13485:2016 Medical devices - Quality management systems- Requirements for regulatory purposes” and defined the physical evidence required based upon this classification scheme. SEPT engineering department 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 required; however, if the standard 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. If a document is called out more than one time, only the first reference is stipulated.

There are occasional situations in which a procedure or document is not necessarily separate and could be contained within another document. For example, the "Design and Development Verification Plan" could be a part of the "Design and Development Plan". 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 required and why. The reasons for the evidence not being required 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.

General Principles of the Checklist for ISO Standard 13485:2016

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

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

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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 required, 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.

In total there are 271 required artefacts and 240 suggested artefacts included in the SEPT checklist. SEPT experts found a 92% increase in required artefacts within the new 2016 standard compared to the previous 2003 version.

Using the Checklist

When a company is planning to use ISO 13485:2016 standard, the company should review the evidence checklist. If the company’s present process does not address an ISO 13485:2016 standard product, then this question should be asked: Is the evidence product required for the type of business of the organization? If in the view of the organization 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.

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.
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, and the evidence is the same although the title is different.
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.
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.
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 the task.

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Components of the Checklist

This checklist is composed of 9 sections:

- Section 1. Introduction
- Section 2. Composites of all required and suggested “ISO 13485:2016 artifacts.
- 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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Section 2

ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
4 Quality management system						
4.1 General requirements						
4.1.1	General requirements (a)	- Organizational Roles Document Procedure* - QMS Document Procedure*			- Organizational Roles Document - QMS Document	- Organizational Roles Document Review* - QMS Document Review*
4.1.2	General requirements (b)	- QMS Processes Used Document Procedure* - QMS Risk Based Approach Procedure*			QMS Processes Used Document*	QMS Processes Used Document Review*
4.1.3	General requirements (c)	- QMS Implementation Action Plan Procedure* - QMS Process Monitoring, Measurement and Analysis Plan Procedure*	- QMS Implementation Action Plan* - QMS Process Monitoring, Measurement and Analysis Plan*	- Applicable Regulatory Requirements Records - ISO 13485 Conformance Records		- QMS Effectiveness Review - QMS Implementation Action Plan Review* - QMS Process Monitoring, Measurement and Analysis Plan Review* - QMS Resource and Information Availability Review

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* Suggested item QMS = Quality Management System

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
4.1.4	General requirements (d)	QMS Change Procedure*				

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* Suggested item QMS = Quality Management System

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
4.1.5	General requirements (e)	- Outsourcing of Processes Affecting Product Conformity Control Plan Procedure* - Outsourcing of Processes Affecting Product Conformity Quality Agreement Document Procedure*	Outsourcing of Processes Affecting Product Conformity Control Plan*		Outsourcing of Processes Affecting Product Conformity Quality Agreement Document	- Outsourcing of Processes Affecting Product Conformity Control Plan Review* - Outsourcing of Processes Affecting Product Conformity Quality Agreement Document Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
4.1.6	General requirements (f)	QMS Computer Software Validation Procedure		QMS Computer Software Validation Records		

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
4.2	Documentation requirements					
4.2.1	General	• Applicable Regulatory Requirements Document Procedure* • List of Documented Procedures Required by ISO 13485 (Document) Procedure* • QMS Control Processes Documents Procedure* • QMS Documentation Plan Procedure* • QMS Operation Processes Documents* • QMS Planning Processes Documents Procedure* • Quality Manual Document Procedure*	• QMS Documentation Plan*	• QMS (All required by ISO 13485) Records	• Applicable Regulatory Requirements Document • List of Documented Procedures Required by ISO 13485 (Document) • QMS Control Processes Documents • QMS Operation Processes Documents • QMS Planning Processes Documents • Quality Manual Document • Quality Objectives Document	• Applicable Regulatory Requirements Document Review* • List of Documented Procedures Required by ISO 13485 (Document) Review* • QMS Control Processes Documents Review* • QMS Documentation Plan Review* • QMS Operation Processes Documents Review* • QMS Planning Processes Documents Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
4.2.1	General (Cont. 1)	- Quality Objectives Document Procedure* Quality Policy				- Quality Manual Document Review - Quality Objectives Document Review*
4.2.2	Quality manual	- QMS Process Interaction Description Document Procedure* - QMS Scope Document Procedure*			- QMS Process Interaction Description Document - QMS Scope Document	- QMS Process Interaction Description Document Review* - QMS Scope Document Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
4.2.3	Medical device file	• Medical Device Description Document Procedure* • Medical Device Installation Requirements Document Procedure* • Medical Device Manufacturing, Packaging, Storage, Handling and Distribution Procedure • Medical Device Measuring and Monitoring Procedure • Medical Device Product Specification Document Procedure* • Medical Device Servicing Procedure		• Medical Device File(s) (Record)	• Medical Device Description Document • Medical Device Installation Requirements Document • Medical Device Product Specification Document	• Medical Device Description Document Review* • Medical Device Installation Requirements Document Review* • Medical Device Product Specification Document Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
4.2.4	Control of documents	- QMS Document Control Procedure QMS Document Retention Policy				QMS Document Control Procedure Review
4.2.5	Control of records	- Confidential Health Information Protection Procedure - Medical Device Record Retention Procedure* - Record Management Plan Procedure* - Record Management Procedure	Record Management Plan*	QMS Conformity and Effectiveness Records		- Record Management Plan Review* - Record Management Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
5 Management responsibility						
5.1 Management commitment		QMS Top Management Responsibility and Authority Document Procedure*		- Top Management Communicating the Importance of Meeting Customer and Regulatory Requirements Records - Top Management Conducting Management Reviews of the QMS Records - Top Management Ensuring Quality Objectives Are Established Records - Top Management Ensuring the Availability of Resources Records	QMS Top Management Responsibility and Authority Document	QMS Top Management Responsibility and Authority Document Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
5.1	Management commitment (Cont. 1)			Top Management Establishing Quality Policy Records		
5.2	Customer focus	Customer Focus (Requirements and Regulatory Requirements) Plan Procedure*	Customer Focus (Requirements and Regulatory Requirements) Plan*			Customer Focus (Requirements and Regulatory Requirements) Plan Review*
5.3	Quality policy	Quality Policy Procedure*				
5.4	Planning					
5.4.1	Quality objectives	Quality Objectives Procedure*				
5.4.2	Quality management system planning	QMS Plan Procedure*	QMS Plan*			QMS Plan Review*
5.5	Responsibility, authority and communication					
5.5.1	Responsibility and authority	Responsibilities and Authorities Document Procedure*			Responsibilities and Authorities Document	Responsibilities and Authorities Document Review*
5.5.2	Management representative	QMS Management Representative Responsibility and Authority Procedure*		QMS Management Representative Appointment Record*		

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
5.5.3	Internal communication	QMS Effectiveness Internal Communication Plan Procedure*	QMS Effectiveness Internal Communication Plan*			QMS Effectiveness Internal Communication Plan Review*
5.6 Management review						
5.6.1	General	QMS Management Review Procedure				QMS Management Review

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
5.6.2	Review input			• Applicable New or Revised Regulatory Requirements Records • Changes That Could Affect the QMS Records • QMS Audit Records • QMS Complaints Handling Records • QMS Corrective Action Records • QMS Feedback Records • QMS Follow -up Action from Past Management Review Records • QMS Management Review Records • QMS Monitoring and Product Measurement Records • QMS Preventive Action Records		

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
5.6.2	Review input (Cont. 1)			- QMS Process Monitoring and Measurement Records - Recommendation for Improvement to the QMS Records - Regulatory Authorities Report Records		
5.6.3	Review output	- QMS Effectiveness Improvement Plan Procedure* - QMS Management Review Document Procedure*	QMS Effectiveness Improvement Plan*	- Product Improvement Related to Customer Requirements per Management Review Records - QMS Regulatory Requirement Changes Record - QMS Resource Changes Due to Management Review Records	QMS Management Review Document	- QMS Effectiveness Improvement Plan Review* - QMS Management Review Document Review
6 Resource management						
6.1	Provision of resources	QMS Resource Management Plan Procedure*	QMS Resource Management Plan*			QMS Resource Management Plan Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
6.2	Human resources	- Quality Competence, Awareness and Training Procedure - Human Resource to Ensure Product Quality Plan Procedure* - Product Quality Identification of Training Needs Procedure - Product Quality Training Plan Procedure*	- Human Resource to Ensure Product Quality Plan* - Product Quality Training Plan*	Education, Training, Skills and Experience of Personnel Affecting Product Quality Records		- Human Resource to Ensure Product Quality Plan Review* - Product Quality Competence, Awareness and Training Review - Product Quality Training Plan Review*
6.3	Infrastructure	- Infrastructure Requirements in Support of Product Quality Document Procedure* - Requirements for Infrastructure Maintenance in Support of Product Quality Document Procedure*		Infrastructure Maintenance Records	- Infrastructure Requirements in Support of Product Quality Document - Requirements for Infrastructure Maintenance in Support of Product Quality Document *	- Requirements for Infrastructure Maintenance in Support of Product Quality Document Review* - Requirements for Infrastructure Maintenance in Support of Product Quality Document Review*
6.4	Work environment					

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
6.4.1	Work environment	- Health, Cleanliness and Clothing Requirements of Personnel That Could Affect Medical Device Safety or Performance Document Procedure* - Personnel Working Under Adverse Environmental Conditions Procedure - Work Environment Monitoring and Control for a Quality Product Procedure - Work Environment Needed to Produce a Quality Product Plan Procedure*	Work Environment Needed to Produce a Quality Product Plan*		Health, Cleanliness and Clothing Requirements of Personnel That Could Affect Medical Device Safety or Performance Document	- Health, Cleanliness and Clothing Requirements of Personnel That Could Affect Medical Device Safety or Performance Document Review* - Work Environment Needed to Achieve a Quality Product Plan Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
6.4.2	Contamination control	- Contamination Prevention of Work Environment, Personnel or Product Control Plan Procedure* - Contamination Prevention of Work Environment, Personnel or Product Control Procedure - Sterile Medical Device Requirements for Cleanliness During Assembly or Packaging Document Procedure*	Contamination Prevention of Work Environment, Personnel or Product Control Plan		Sterile Medical Device Requirements for Cleanliness During Assembly or Packaging Document	- Contamination Prevention of Work Environment, Personnel or Product Control Plan Review* - Sterile Medical Device Requirements for Cleanliness During Assembly or Packaging Document Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7 Product realization						
7.1 Planning of product realization		- Processes Needed for Product Realization Plan Procedure* - Risk Management Processes in Product Realization Procedure	Processes Needed for Product Realization Plan	- Organization Determination of Criteria for Product Acceptance Record - Organization Determination of Product Quality Objectives and Requirements Record - Organization Determination of Product Verification, Validation, Monitoring, Measurement, Inspection. Test, Handling, Storage, Distribution, And Traceability Record		Processes Needed for Product Realization Plan Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.1	Planning of product realization (Cont.1)			• Organization Determination of Resources Required for Product, Infrastructure, and Work Environment Record • Product Realization Process Meets Product Requirements Records • Risk Management Activities Concerning Product Realization Records		
7.2	Customer-related processes					

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.2.1	Determination of requirements related to the product	• Additional Organizational Requirements Document Procedure* • Regulatory Requirements Related to the Product Document Procedure* • Requirements Not Stated by Customer, but Still Required Document Procedure* • Requirements Required by the Organization for the Product Document Procedure*			• Additional Organizational Requirements Document* • Regulatory Requirements Related to the Product Document* • Requirements Not Stated by Customer but Still Required Document* • Requirements Required by the Organization for the Product Document* • Requirements Specified by Customer for Delivery and Post-Delivery Document*	• Additional Organizational Requirements Document Review* • Regulatory Requirements Related to the Product Document Review* • Requirements Not Stated by Customer but Still Required Document Review* • Requirements Required by the Organization for the Product Document Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.2.1	Determination of requirements related to the product (Cont.1)	- Requirements Specified by Customer for Delivery and Post-Delivery Document Procedure* - Training Requirements Related to the Product Document Procedure*			Training Requirements Related to the Product Document*	- Requirements Specified by Customer for Delivery and Post-Delivery Document Review* - Training Requirements Related to the Product Document Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.2.2	Review of requirements related to the product	- Product Requirement Changes Document Procedure* - Product Requirements Document Procedure*		Product Requirements Review and Actions Records	- Product Requirement Changes Document - Product Requirements Document	- Ability to Meet Product Requirements Review - Contract or Order Requirements Different from Previously Expressed or Resolved Review - Customer Requirements Confirmation Before Acceptance Review - Product Regulatory Requirements Are Satisfied Review - Product Requirement Changes Document Review - Product Requirements Are Defined and Documented Review

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.2.2	Review of requirements related to the product (Cont. 1)					• Product Requirements Document Review* • Product User Training Is Available or Planned Review

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.2.3	Communication	• Customer Advisory Notice Document Procedure* • Customer Communication Plan Procedure* • Customer Communication Procedure* • Customer Enquiries, Contracts or Order Handling Including Amendments Document Procedure* • Customer Feedback and Complaints Document Procedure* • Organization Communication with Regulatory Authorities Procedure • Product Information Document Procedure*	• Customer Communication Plan		• Customer Advisory Notice Document • Customer Enquiries, Contracts or Order Handling Including Amendments Document • Customer Feedback and Complaints Document • Product Information Document	• Customer Advisory Notice Document Review* • Customer Communication Plan Review* • Customer Enquiries, Contracts or Order Handling Including Amendments Document Review* • Customer Feedback and Complaints Document Review* • Product Information Document Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.3	Design and development					
7.3.1	General	Product Design and Development Procedure(s)				

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.3.2	Design and development planning	- Product Design and Development Plan Procedure* - Product Design and Development Resource and Competence Requirements Plan Procedure* - Product Design and Development Responsibilities and Authorities Plan Procedure* - Product Design and Development Review Plan Procedure* - Product Design and Development Stages Document Procedure*	- Product Design and Development Responsibilities and Authorities Plan - Product Design and Development Plan - Product Design and Development Resource and Competence Requirements Plan - Product Design and Development Review Plan		Product Design and Development Stages Document	- Product Design and Development Responsibilities and Authorities Plan Review* - Product Design and Development Plan Review* - Product Design and Development Resource and Competence Requirements Plan Review* - Product Design and Development Review Plan Review* - Product Design and Development Stages Document Review

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.3.2	Design and development planning (Cont. 1)	- Product Design and Development Traceability Methods of Outputs to Inputs Plan Procedure* - Product Design and Development Verification, Validation and Design Transfer Stage Plan Procedure*	- Product Design and Development Traceability Methods of Outputs to Inputs Plan - Product Design and Development Verification, Validation and Design Transfer Stage Plan			- Product Design and Development Traceability Methods of Outputs to Inputs Plan Review* - Product Design and Development Verification, Validation and Design Transfer Stage Plan Review

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.3.3	Design and development inputs	- Product Design and Development Input Applicable Regulatory Requirements and Standards Document Procedure* - Product Design and Development Inputs, Functional, Performance, Usability and Safety Requirements Document Procedure* - Product Information from Past Design, if Appropriate, Design and Development Inputs Document Procedure*		Product Design and Development Input Records	- Product Design and Development Input Applicable Regulatory Requirements and Standards Document* - Product Design and Development Inputs, Functional, Performance, Usability and Safety Requirements Document - Product Information from Past Design, if Appropriate, Design and Development Inputs Document - Risk Management Outputs Applicable to Product Design and Development Inputs Document	- Product Design and Development Input Adequacy Review - Product Design and Development Input Applicable Regulatory Requirements and Standards Document Review* - Product Design and Development Inputs, Functional, Performance, Usability and Safety Requirements Document Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.3.3	Design and development inputs (Cont. 1)	Risk Management Outputs Applicable to Product Design and Development Inputs Document Produce*				- Product Information from Past Design, if Appropriate, Design and Development Inputs Document Review* - Product Requirements Ambiguity Review - Product Requirements Quality Review* - Risk Management Outputs Applicable to Product Design and Development Inputs Document Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.3.4	Design and development outputs	Product Design and Development (Output) Document Procedure*		- Product Design and Development Output Records - Product Design and Development Outputs Can Be Verified Against the Design and Development Inputs Prior to Release Records - Product Design and Development Outputs Meets the Input Requirements Record - Product Design and Development Outputs Provide Appropriate Information for Purchasing, Production and Service Provision Records	Product Design and Development (Output) Document	Product Design and Development (Output) Document Review

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ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.3.4	Design and development outputs (Cont. 1)			- Product Design and Development Outputs Provides Product Acceptance Criteria Records - Product Design and Development Outputs Specify the Characteristic of the Product That Are Essential for Its Safe and Proper Use Records		
7.3.5	Design and development review	Product Design and Development Review Procedure		- Product Design and Development Review Records - Review, Date, Design Identification, Participants, Results, And Action Items Record		Product Design and Development Review

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.3.6	Design and development verification	Product Design and Development Verification Plan Procedure*	Product Design and Development Verification Plan	- Medical Device Interface Connection Verification that Design Outputs Meet Design Inputs Record - Product Design and Development Verification Conclusion and Actions Records - Product Design and Development Verification Results Records		- Product Design and Development Verification Plan Review* - Product Design and Development Medical Device Interface Verification Review

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.3.7	Design and development validation	- Product Design and Development Validation Plan Procedure* - Product Design and Development Validation Procedure*	Product Design and Development Validation Plan	- Medical Device Interface Connection Validation that Specified Application or Intended Use Requirements Are Met Record - Product Design and Development Validation Conclusions and Actions Records - Product Design and Development Validation of a Representative Product and Rationale for the Choice Record - Product Design and Development Validation Results Records		- Product Design and Development Validation for Items Used for Clinical and Performance Evaluation Review - Product Design and Development Validation Plan Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.3.8	Design and development transfer	Product Design and Development Output Transfer to Manufacturing Procedure		Product Design and Development Output Transfer to Manufacturing Results and Conclusion Records		
7.3.9	Control of design and development changes	- Product Design and Development Change Management Plan Procedure* - Product Design and Development Changes Control Procedure	Product Design and Development Change Management Plan*	- Product Design and Development Change Review Records - Product Design and Development Changes Records		- Product Design and Development Change Management Plan Review* - Product Design and Development Change Review
7.3.10	Design and development files	Product Design and Development Medical Device (File) Document Procedure*			Product Design and Development Medical Device (File) Document	Product Design and Development Medical Device (File) Document Review*
7.4 Purchasing						

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.4.1	Purchasing process	• Purchased Products Conform to Purchasing Information Procedure • Criteria for the Evaluation and Selection of Supplier Document Procedure* • Suppliers Monitoring and Re-evaluation Plan Procedure*	• Suppliers Monitoring and Re-evaluation Plan	• Evaluation, Selection, Monitoring and Re-evaluation of Supplier Capability or Performance Records • Supplier Action Records	• Criteria for the Evaluation and Selection of Supplier Document	• Criteria for the Evaluation and Selection of Supplier Document Review* • Supplier Non-Fulfillment Review • Supplier Performance Review • Suppliers Monitoring and Re-evaluation Plan Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.4.2	Purchasing information	- Product Purchasing Information Document Procedure* - Supplier Agreement for Notification of Product Changes that Affect Specified Purchase Requirements Document Procedure*		Product Purchasing Information Records	- Product Purchasing Information Document - Supplier Agreement for Notification of Product Changes that Affect Specified Purchase Requirements Document	- Product Purchasing Information Document Review - Purchasing Requirements Review Prior to Their Transmittal to The Supplier Review - Supplier Agreement for Notification of Product Changes that Affect Specified Purchase Requirements Document Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.4.3	Verification of purchased product	- Purchased Product Information Verification and Product Release Activities at Suppliers Premises Document Procedure* - Purchased Product Inspection Plan Procedure*	Purchased Product Inspection Plan*	Purchased Product Verification at Suppliers Premises Records	Purchased Product Information Verification and Product Release Activities at Suppliers Premises Document	- Organization Assessment of Purchased Product Changes Affecting Product Realization Process Review - Purchased Product Information Verification and Product Release Activities at Suppliers Premises Document Review* - Purchased Product Inspection Plan Review* - Risk Assessment for Purchased Items Versus Amount of Verification Required Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.5	Production and service provision					
7.5.1	Control of production and service provision	- Monitoring and Measurement of Process Parameters and Product Characteristics Procedure(s) - Operation for Control of Production and Services Procedure(s) - Operation for Labeling and Packaging of Product Procedure - Operation for Product Release, Delivery and Post-delivery Activity Procedure	- Production Plan - Service Provision Plan	- Medical Device Production Traceability by Batch or Unit Records - Number of Medical Devices Produced and the Number Approved for Distribution Records		- Medical Device Production Traceability by Batch or Unit Records Review - Number of Medical Devices Produced and The Number Approved for Distribution Records Review - Production Infrastructure Qualification Review - Production Monitoring and Measuring Equipment Review - Production Plan Review* - Service Provision Plan Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.5.1	Control of production and service provision (Cont. 1)	- Product and Service Provision Monitoring and Measurement Equipment Use and Availability Procedure - Product and Service Provision Qualification of Infrastructure Procedure - Production Plan Procedure* - Service Provision Plan Procedure* - Service Provision Procedure				

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.5.2	Cleanliness of product	- Product Cleanliness or Contamination Control Plan Procedure* - Product Cleanliness or Contamination Control Requirements Document Procedure*	Product Cleanliness or Contamination Control Plan		Product Cleanliness or Contamination Control Requirements Document	- Product Cleanliness or Contamination Control Plan Review* - Product Cleanliness or Contamination Control Requirements Document Review*
7.5.3	Installation activities	- External Party Requirements for Medical Device Installation and Verification Document Procedure* - Medical Device Installation, Verification and Acceptance Criteria Requirements Document Procedure*		Medical Device Installation and Verification (by all Parties) Records	- External Party Requirements for Medical Device Installation and Verification Document - Medical Device Installation, Verification and Acceptance Criteria Requirements Document	- External Party Requirements for Medical Device Installation and Verification Document Review* - Medical Device Installation, Verification and Acceptance Criteria Requirements Document Review

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.5.4	Servicing activities	- Medical Device Reference Materials and Measurements for Servicing and Verification Requirements Document Procedure* - Service Provision Reference Material and Measurement Requirements Procedure		Medical Device Servicing Activity Records	Medical Device Reference Materials and Measurements for Servicing and Verification Requirements Document	- Medical Device Reference Materials and Measurements for Servicing and Verification Requirements Document Review* - Servicing Activity Records Complaint Determination Review - Servicing Activity Records Improvement Determination Review
7.5.5	Particular requirements for sterile medical devices			- Sterilization Process Parameters by Batch Records - Sterilization Process Traceability to Each Batch of Medical Devices Records		

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.5.6	Validation of processes for production and service provision	• Production and Service Provision Process Validation Plan Procedure* • Production and Service Provision Process Validation Procedure • Software Used in Production and Service Provision Validation Procedure	• Production and Service Provision Process Validation Plan*	• Production and Service Provision Process Validation Records • Software Used in Production and Service Provision Validation, Conclusions, and Action Records		• Production and Service Provision Process Validation Plan Review* • Software Validation Risk Assessment Review
7.5.7	Particular requirements for validation of processes for sterilization and sterile barrier systems	• Sterilization and Sterile Barrier Systems Process Validation Procedure		• Sterilization and Sterile Barrier Systems Process Validation Results, Conclusions and Actions Records		• Sterilization and Sterile Barrier Systems Process Validation Prior to Implementation Review

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.5.8	Identification	- Medical Device Unique Identification Requirements Procedure - Nonconforming Product (Returns) Identification Procedure - Product Identification Procedure - Product Identification to Meet Regulatory Requirements Plan Procedure*	Product Identification to Meet Regulatory Requirements Plan	Product Identification and Product Status Records		Product Identification to Meet Regulatory Requirements Plan Review*
7.5.9	Traceability					
7.5.9.1	General	Product Traceability Procedure		Product Traceability Records		

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.5.9.2	Particular requirements for implantable medical devices			• Implantable Medical Device Component, Materials and Work Environment Conditions Used for Satisfying Safety and Performance Records • Implantable Medical Device Shipping Package Consignee Records • Implantable Medical Device Supplier and Distribution Traceability Records		
7.5.10	Customer property	• Customer Property Management Plan Procedure*	• Customer Property Management Plan*	• Customer Property Lost or Unsuitable for Use Report Records • Customer Property Records		• Customer Property Management Plan Review*

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ISO 13485:2016 Evidence Products Checklist by Clause

ISO 13485:2016 Clause Number and Name		Policies and Procedures	Plans	Records	Documents	Audits and Reviews
7.5.11	Preservation of product	• Preservation of Product Conformance to Requirements During Processing, Storage, Handling and Distribution Procedure • Product Packaging and Shipping Container Design and Construction Document Procedure* • Product Preservation During Internal Processing and Delivery Plan Procedure* • Product Special Preservation Definition Document Procedure*	• Product Preservation During Internal Processing and Delivery Plan*	• Product Special Preservation Conditions Records	• Product Packaging and Shipping Container Design and Construction Document • Product Special Preservation Definition Document	• Product Packaging and Shipping Container Design and Construction Document Review* • Product Preservation During Internal Processing and Delivery Plan Review* • Product Special Preservation Definition Document Review*

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