Procedure for Control of Documents and Records

Document Control Information

The first page of every controlled document shall include the mandatory document control information to ensure identification, traceability, and accountability.

This document is a controlled document of the Quality Management System (QMS). It shall be used only in its current approved version.

Each controlled document governed by this procedure shall clearly identify:

- A unique Document Identification Code (ID) with an established prefix according to the organization's document coding system.
- Document title.
- Version or revision number.
- Effective date.
- Status (e.g., Draft, Approved, Obsolete).
- Author.
- Reviewer.
- Approver.

Revision Traceability

Each document shall include a Revision History section indicating:

- Version number
- Date of revision
- Description of changes introduced

The Author, Reviewer, and Approver shall be clearly identified to ensure accountability throughout the document lifecycle.

Only the current approved version shall be available for use. Obsolete versions shall be withdrawn from points of use and retained only when required for traceability or regulatory purposes.

1. Purpose

This procedure defines the principles and requirements for controlling documents and records within a Quality Management System (QMS). It ensures that documented information remains accurate, approved, traceable, accessible, protected, and retained in accordance with ISO 13485:2016 requirements.

It prevents unintended use of obsolete documents and ensures that records provide reliable objective evidence of conformity.

2. Scope

This procedure applies to all documents and records forming part of the QMS, whether internal or external, paper-based or electronic.

It includes policies, procedures, work instructions, forms, templates, specifications, and plans.

This procedure applies to all personnel involved in creating, reviewing, approving, using, maintaining, storing, or archiving controlled documentation.

3. References

The following references are **always applicable** to this procedure:

- ISO 13485:2016 – Clause 4.2.4 Control of Documents
- ISO 13485:2016 – Clause 4.2.5 Control of Records

Conditionally applicable reference: Regulatory and customer requirements are referenced **only when they exist and are applicable** to the organization, its products/services, or its markets.

4. Definitions

Document: Controlled information describing requirements, instructions, or specifications necessary for QMS operation.

Record: Evidence that an activity was performed or a result achieved. Records are fixed after issuance and corrections must remain traceable.

Controlled Document: A document subject to approval, version control, and distribution rules.

Obsolete Document: A withdrawn version retained only for traceability or regulatory purposes.

If the organization uses a computerized system to create, approve, distribute, store, or archive QMS documents and records, the following definition applies:

Electronic Document Management System (EDMS): A computerized system used to manage documents and records, ensuring version control, access control, traceability, and data integrity.

5. Responsibilities

Top Management ensures resources are available to maintain effective document and record control.

Quality Manager owns the document control system and ensures compliance with ISO requirements.

Process Owners ensure accuracy and relevance of documents within their scope.

Authors draft documents in accordance with approved rules and ensure clarity and applicability.

Reviewers perform independent review to confirm technical accuracy, coherence, and compliance.

Approvers authorize release of documents. The individual who creates a document shall **not** be the same person who approves it.

Personnel use only approved documents and complete records accurately.

IT Function (where applicable) maintains security, backups, access control, and availability of electronic systems used for documented information.

6. Document and Record Control Process Map

The lifecycle of controlled documentation follows these stages:

1. Creation or identification of need
2. Drafting
3. Review and approval
4. Release and distribution
5. Use and record generation
6. Revision and re-approval (when required)
7. Archiving
8. Retention and secure destruction

7. Control of Documents

7.1 Identification

Each controlled document shall include a unique identifier, title, and an effective status/version identifier as defined by the organization's document control rules. Documents must remain legible and identifiable throughout their lifecycle.

7.2 Creation and Approval

Documents are created based on operational, quality, or compliance needs.

Documents shall be reviewed and formally approved before release. The person who creates a document shall not approve their own document.

7.3 Distribution and Access

Only approved versions are available at points of use. Access rights prevent unauthorized modification.

7.4 Periodic Review

Documents are reviewed at planned intervals or triggered by audits, regulatory changes, or process modifications. Controlled documents are managed through formal version control. All revisions shall be traceable, indicating who performed the change, when it was made, and what modifications were introduced. This applies to all QMS documents, including this procedure.

7.5 Obsolete Documents

Obsolete versions are removed from active use and clearly identified if retained for traceability.

7.6 External Documents

Externally sourced documents required for compliance are identified and monitored. Updates are assessed and implemented when applicable.

8. Control of Records

8.1 Identification and Completeness

Records must be legible, dated, and linked to the relevant activity, process, or product as applicable.

8.2 Corrections

Corrections must not obscure original information and must remain traceable.

8.3 Storage and Protection

Records are protected against loss, deterioration, and unauthorized access.

8.4 Electronic Systems Impacting the QMS

Any electronic system used to generate, manage, store, or retrieve QMS records shall be validated when it impacts the QMS, in accordance with the organization's **software validation procedure**, using a risk-based approach.

9. Training

Personnel are trained in document control rules and record completion requirements, where applicable.

Training evidence is retained as quality records.

10. Monitoring and Improvement

The effectiveness of document and record control is evaluated through audits, feedback, and management review.

Improvements are implemented through controlled change processes.

11. Records

The following records are generated and/or maintained as part of this procedure, where applicable:

- Document Master List
- External Document List (if external documents are controlled)
- Document Change Log / Change Requests
- Document Review and Approval Evidence
- Distribution or Access Evidence (e.g., controlled distribution list or system access logs, if used)
- Training Evidence related to document control
- Record Retention Rules

All records referenced in this procedure shall be maintained in accordance with Document Control and Record Retention Procedure.

A Records List identifies the records generated by this procedure, including their storage location and defined retention period.

12. Retention

Unless otherwise specified, records generated under this procedure shall be retained for a minimum of ten (10) years after the last device has been placed on the market.

Retention periods shall comply with applicable regulatory requirements, including but not limited to Regulation (EU) 2017/745 (EU MDR), Article 10(8), where applicable.

Records shall be protected throughout their retention period to ensure integrity, confidentiality, and retrievability.