

COMPLIANCE WORKING RECORD

Medical device change control pack

FICTIONAL evidence sample. Requires tailoring.

Document control

Field	Value
Document type	Evidence workpaper
Document reference	CASE-FICTIONAL
Jurisdiction	United States
Version	2026-10-09.product-sector.1
Status	FICTIONAL sample. Requires tailoring.
Classification	Private
Prepared by	Fictional responsible reviewer
Prepared on	October 9, 2026
Sources reviewed	October 9, 2026
Generated	October 9, 2026

Document control and frozen case

Assemble exact before/after device change, source-linked risk assessments, new-version verification and qualified regulatory/implementation decisions.

Field	Value
Case reference	CASE-FICTIONAL
Organization	Fictional Example Company
Subject	Fictional product or sector case
Responsible reviewer	Fictional responsible reviewer
Preparation date	October 9, 2026

Field	Value
Scope	Fictional customer-approved scope. Replace all example records before real use.
Customer policy	POLICY-FICTIONAL
Customer policy version	fictional-v1
Declared approver	Fictional qualified reviewer
Declared approval date	October 2, 2026
Decision boundary	No substantive decision or external filing made.

Named method and supported scope

Join selected change items to exact risk and test IDs. Check current device version, declared outcomes, literal checks and qualified reviewers. Preserve missing submission and implementation determinations in the complete change-control draft.

No automatic 510(k), PMA, safety, risk acceptance or implementation decision. Current QMSR review replaces obsolete QS assumptions. Up to 100 rows per table, 20 originals and 25,000,000 combined original bytes. Complete oversized comparisons reject rather than truncate.

Original contents, annotations, approvals and legal applicability remain customer declarations. File hashes establish retained byte identity only.

No certificate issuance, environmental filing, recall notification, test execution, clinical decision, regulatory submission or independent certification occurs.

All accepted records remain complete. Recovery preserves original bytes and frozen results without creating fresh payment, source authentication, consent or approval authority.

Complete result counts

Measure	Value
Changes with unresolved risk or verification	0
Missing supported current decision kinds	0

Complete preparation draft

Draft only. Unresolved positions remain explicit. No communication is sent.

Medical-device change-control preparation draft. Not authorization to implement or market a device.

Device. DEVICE1

Change. CHANGE1. FICTIONAL bounded device change

Version transition. fictional-before to fictional-v1

Every exact design/manufacturing/labeling change.
[{"reference":"ITEM1","sourceIds":["S1"],"area":"Design","beforeText":"FICTIONAL prior component","afterText":"FICTIONAL revised component","riskIds":["RISK1"],"testIds":["TEST1"],"approvedBy":"Fictional qualified reviewer","approvedOn":"2026-10-02"}]

Every risk assessment.
[{"reference":"RISK1","sourceIds":["S1"],"changeItemReference":"ITEM1","hazard":"FICTIONAL selected hazard","beforeRisk":"FICTIONAL prior risk","afterRisk":"FICTIONAL current risk","control":"FICTIONAL qualified risk control","reviewer":"Fictional qualified reviewer","on":"2026-10-03","position":"Accepted"}]

Every verification result. [{"reference":"TEST1","sourceIds":["S1"],"changeItemReference":"ITEM1","deviceReference":"DEVICE1","deviceVersion":"fictional-v1","method":"FICTIONAL exact check","checkMode":"Literal equality","expected":"FICTIONAL preserved","actual":"FICTIONAL preserved","outcome":"Passed","testedOn":"2026-10-03","reviewer":"Fictional qualified reviewer"}]

Every current human decision. [{"reference":"DECISION1","sourceIds":["S1"],"kind":"Regulatory submission assessment","deviceVersion":"fictional-v1","position":"Approved","rationale":"FICTIONAL qualified determination. No automatic filing decision.","approvedBy":"Fictional qualified reviewer","approvedOn":"2026-10-04"}, {"reference":"DECISION2","sourceIds":["S1"],"kind":"Implementation","deviceVersion":"fictional-v1","position":"Approved","rationale":"FICTIONAL human review assertion only","approvedBy":"Fictional qualified reviewer","approvedOn":"2026-10-04"}]

Missing supported decision kinds.

1. Original evidence source (S1)

State. Customer verification linked

Customer-declared original identity and verification only. Content is not extracted or independently authenticated.

Field	Value
id	S1
fileId	F1
locator	Fictional section one

Field	Value
sourceDate	October 1, 2026
custodian	Fictional customer custodian
description	Fictional source declaration. Does not establish actual evidence.
verification	Customer verified
verifiedBy	Fictional reviewer
verifiedOn	October 2, 2026
Exact evidence source references	S1

2. Original byte manifest (F1)

State. Indexed

Complete export requires these exact original bytes.

Field	Value
id	F1
name	FICTIONAL-product-sector-evidence.txt
mimeType	text/plain
bytes	220
sha256	09af1d0212932d147d35388697e14909c29d77332a1caa645e4c7d0cfe8c4609
Exact evidence source references	S1

3. Frozen customer policy (POLICY-FICTIONAL)

State. Documented

Exact approved customer scope. No automatic legal applicability.

Field	Value
reference	POLICY-FICTIONAL

Field	Value
version	fictional-v1
approvedBy	Fictional qualified reviewer
approvedOn	October 2, 2026
sourceIds	["S1"]
Exact evidence source references	S1

4. Device change, risk and verification traceability (ITEM1)

State. Customer change evidence assembled

Design risk acceptability, submission obligations and implementation remain qualified human decisions under the current customer-selected requirements.

Field	Value
reference	ITEM1
sourceIds	["S1"]
area	Design
beforeText	FICTIONAL prior component
afterText	FICTIONAL revised component
riskIds	["RISK1"]
testIds	["TEST1"]
approvedBy	Fictional qualified reviewer
approvedOn	October 2, 2026
Device before version	fictional-before
Device after version	fictional-v1

Field	Value
Every selected risk	[{"reference":"RISK1","sourceIds":["S1"],"changeItemReference":"ITEM1","hazard":"FICTIONAL selected hazard","beforeRisk":"FICTIONAL prior risk","afterRisk":"FICTIONAL current risk","control":"FICTIONAL qualified risk control","reviewer":"Fictional qualified reviewer","on":"2026-10-03","position":"Accepted"}]
Every selected verification	[{"reference":"TEST1","sourceIds":["S1"],"changeItemReference":"ITEM1","deviceReference":"DEVICE1","deviceVersion":"fictional-v1","method":"FICTIONAL exact check","checkMode":"Literal equality","expected":"FICTIONAL preserved","actual":"FICTIONAL preserved","outcome":"Passed","testedOn":"2026-10-03","reviewer":"Fictional qualified reviewer"}]
Gaps	
Exact evidence source references	S1

5. Current device change human decision (DECISION1)

State. Customer decision recorded

This application makes no 510(k), PMA, safety or implementation decision.

Field	Value
reference	DECISION1
sourceIds	["S1"]
kind	Regulatory submission assessment
deviceVersion	fictional-v1
position	Approved
rationale	FICTIONAL qualified determination. No automatic filing decision.
approvedBy	Fictional qualified reviewer
approvedOn	October 4, 2026
Exact evidence source references	S1

6. Current device change human decision (DECISION2)

State. Customer decision recorded

This application makes no 510(k), PMA, safety or implementation decision.

Field	Value
reference	DECISION2
sourceIds	["S1"]
kind	Implementation
deviceVersion	fictional-v1
position	Approved
rationale	FICTIONAL human review assertion only
approvedBy	Fictional qualified reviewer
approvedOn	October 4, 2026
Exact evidence source references	S1

Complete accepted task inputs

The following exact accepted fields preserve every supplied task record, including orphan records and contradictions. They are customer annotations, not independently extracted or authenticated evidence.

Field	Value
deviceReference	DEVICE1
beforeVersion	fictional-before
afterVersion	fictional-v1
changeReference	CHANGE1
changeDescription	FICTIONAL bounded device change
changes 1. reference	ITEM1
changes 1. sourceIds	S1
changes 1. area	Design

Field	Value
changes 1. beforeText	FICTIONAL prior component
changes 1. afterText	FICTIONAL revised component
changes 1. riskIds	RISK1
changes 1. testIds	TEST1
changes 1. approvedBy	Fictional qualified reviewer
changes 1. approvedOn	October 2, 2026
risks 1. reference	RISK1
risks 1. sourceIds	S1
risks 1. changeItemReference	ITEM1
risks 1. hazard	FICTIONAL selected hazard
risks 1. beforeRisk	FICTIONAL prior risk
risks 1. afterRisk	FICTIONAL current risk
risks 1. control	FICTIONAL qualified risk control
risks 1. reviewer	Fictional qualified reviewer
risks 1. on	October 3, 2026
risks 1. position	Accepted
tests 1. reference	TEST1
tests 1. sourceIds	S1
tests 1. changeItemReference	ITEM1
tests 1. deviceReference	DEVICE1
tests 1. deviceVersion	fictional-v1
tests 1. method	FICTIONAL exact check
tests 1. checkMode	Literal equality
tests 1. expected	FICTIONAL preserved

Field	Value
tests 1. actual	FICTIONAL preserved
tests 1. outcome	Passed
tests 1. testedOn	October 3, 2026
tests 1. reviewer	Fictional qualified reviewer
decisions 1. reference	DECISION1
decisions 1. sourceIds	S1
decisions 1. kind	Regulatory submission assessment
decisions 1. deviceVersion	fictional-v1
decisions 1. position	Approved
decisions 1. rationale	FICTIONAL qualified determination. No automatic filing decision.
decisions 1. approvedBy	Fictional qualified reviewer
decisions 1. approvedOn	October 4, 2026
decisions 2. reference	DECISION2
decisions 2. sourceIds	S1
decisions 2. kind	Implementation
decisions 2. deviceVersion	fictional-v1
decisions 2. position	Approved
decisions 2. rationale	FICTIONAL human review assertion only
decisions 2. approvedBy	Fictional qualified reviewer
decisions 2. approvedOn	October 4, 2026

Recovery and original attachment boundary

The complete local ZIP includes every original file listed in the retained manifest. A structured JSON or cloud record alone preserves the descriptor and annotation, not the original file bytes. Attach matching bytes before producing a complete original-attachment pack.

Customer recovery restores neither source authentication, approval authority nor paid export access. Payment ownership is checked before each commercial export.

Official sources

Source	Provision	Date	Link
Food and Drug Administration: Quality Management System Regulation. Effective February 2, 2026	FDA confirms QMSR became effective February 2, 2026 and incorporates ISO 13485:2016 by reference. The former QSIT inspection process was replaced. Exact customer-authorized requirements and current controlled records remain necessary. This preparation method neither reproduces a full licensed ISO checklist nor certifies compliance or creates the former audit-record exemption.	October 9, 2026	https://www.fda.gov/medical-devices/post-market-requirements-devices/quality-management-system-regulation-qmsr
Food and Drug Administration: Deciding When to Submit a 510(k) for a Change to an Existing Device	FDA's October 2017 guidance supports qualified review of changes to existing devices and documented regulatory-submission determinations within its scope. This method assembles customer before/after, risk, testing and human decisions. It does not decide 510(k), PMA, labeling, safety or market authorization.	October 9, 2026	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device