Elexes

18 EVIDENCE CHECKS

Change Control Review Checklist

Connect the request, impact review, evidence and closure.

Change reference: _____ Reviewer / date: _____

Tick when evidence is verified. Record your priority gap and next action below.

01 Define the request

- ☐ Assign a reference, owner and reason for the change.
- ☐ Describe current and proposed states with affected scope.
- ☐ Identify related changes, records and target milestones.

02 Assess the impact

- ☐ Review affected devices, processes, suppliers and markets.
- ☐ Assess risks, regulatory impact and related dependencies.
- ☐ Document the assessment rationale and required actions.

03 Plan the evidence

- ☐ Define verification, validation or qualification needs.
- ☐ Specify acceptance criteria and required evidence as applicable.
- ☐ Assign action owners, due dates and review responsibilities.

04 Authorize the change

- ☐ Obtain required reviews and documented approvals.
- ☐ Resolve regulatory prerequisites before affected release.
- ☐ Confirm implementation conditions and effective dates.

05 Implement and update

- ☐ Control the transition and affected product or inventory.
- ☐ Update procedures, specifications and training as needed.
- ☐ Retain implementation and supporting evidence references.

06 Review and close

- ☐ Confirm actions and evidence meet closure requirements.
- ☐ Review follow-up results and unresolved issues.
- ☐ Record approval, closure rationale and linked records.

Priority gap / evidence reference:

Action / owner / due date: