Elexes

18 EVIDENCE CHECKS

SaMD QMS Readiness Checklist

Connect software scope, lifecycle records and release evidence.

Software / version: _____ Reviewer / date: _____

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

01 Define scope and roles

- ☐ Record intended use, functions and target markets.
- ☐ Define QMS scope and lifecycle responsibilities.
- ☐ Identify suppliers and outsourced development work.

02 Plan the lifecycle

- ☐ Define development and maintenance activities.
- ☐ Document reviews, outputs and required approvals.
- ☐ Assess applicable lifecycle and quality requirements.

03 Build traceability

- ☐ Baseline requirements and configuration references.
- ☐ Connect risk controls to implementation and tests.
- ☐ Retain traceability across affected lifecycle records.

04 Review test evidence

- ☐ Define verification and validation acceptance criteria.
- ☐ Retain results, anomaly decisions and review records.
- ☐ Document the evidence supporting intended use.

05 Control each release

- ☐ Identify the version and approved configuration.
- ☐ Review changes and affected evidence before release.
- ☐ Record authorized release decisions and conditions.

06 Maintain quality

- ☐ Track problems, complaints and relevant vulnerabilities.
- ☐ Review change impacts and evidence update needs.
- ☐ Assign follow-up actions and verify completion.

Priority gap / evidence reference:

Action / owner / due date: