Elexes

QUALITY EVIDENCE / 18 CHECKS

Combination Product QMS Readiness Checklist

Connect product scope, controlled records and lifecycle evidence.

Device / scope: _____ Reviewer / date: _____

Tick when verified. Reference the evidence and assign the highest-priority action.

01 Define product configuration

- ☐ Identify constituent parts and product configuration.
- ☐ List relevant sites and outsourced activities.
- ☐ Define intended use and target markets.

02 Map applicable requirements

- ☐ Identify quality requirements by constituent part.
- ☐ Document the operating-system approach and rationale.
- ☐ Assign owners for applicability gaps.

03 Define quality interfaces

- ☐ Map processes shared across constituent parts.
- ☐ Clarify review and release responsibilities.
- ☐ Link relevant procedures and records.

04 Control suppliers

- ☐ Identify critical suppliers and contract activities.
- ☐ Review quality agreements and notification duties.
- ☐ Retain qualification and oversight evidence.

05 Assess changes

- ☐ Review impacts across constituent parts and sites.
- ☐ Identify affected evidence and approvals.
- ☐ Document implementation conditions.

06 Track quality evidence

- ☐ Index required acceptance and release records.
- ☐ Connect complaints, investigations and CAPA.
- ☐ Track actions, owners and follow-up.

Priority gap / evidence reference:

Action / owner / due date: