Device QMS Scoping Checklist

Connect your device, quality processes and supporting evidence.

QMS / scope: _____ Reviewer / date: _____

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

01 Define the device scope

- ☐ Record intended use, configuration and lifecycle stage.
- ☐ Identify device families and relevant product interfaces.
- ☐ List target markets and responsible organizations.

02 Map the framework

- ☐ Confirm applicable quality and regulatory frameworks.
- ☐ Document QMS scope and justified applicability decisions.
- ☐ Assign owners for requirements and changes.

03 Connect lifecycle evidence

- ☐ Identify design, risk and performance evidence needs.
- ☐ Link verification, validation and release records.
- ☐ Define document control and traceability arrangements.

04 Control outsourced work

- ☐ Identify suppliers and outsourced quality activities.
- ☐ Define responsibilities and quality agreements as needed.
- ☐ Retain qualification and performance-review records.

05 Review QC arrangements

- ☐ Define acceptance criteria and review responsibilities.
- ☐ Identify inspection, test or other acceptance evidence.
- ☐ Define handling of nonconformance and escalation.

06 Maintain oversight

- ☐ Connect complaints, CAPA and controlled changes.
- ☐ Plan audits, monitoring and management review inputs.
- ☐ Assign priority actions, owners and review dates.

Priority gap / evidence reference:

Action / owner / due date: