QMS Implementation

Medical Device Readiness Checklist

Scope / sites: _____ Reviewer / date: _____

Mark Ready, Gap or N/A. Reference evidence and justify N/A decisions.

1. Scope and ownership

- ☐ Define device activities, sites, markets and outsourced responsibilities.
- ☐ Map process interactions and assign document and process owners.
- ☐ Agree implementation deliverables, resources and review points.

2. Documents and approvals

- ☐ Identify required manuals, procedures, instructions and forms.
- ☐ Confirm review, approval, revision status and effective-date arrangements.
- ☐ Assign responsibility for relevant external documents and updates.

3. Access and record control

- ☐ Make current approved instructions available where work is performed.
- ☐ Prevent unintended use of obsolete versions and uncontrolled copies.
- ☐ Define record integrity, retrieval, retention and disposition controls.

4. eQMS and migration

- ☐ Define intended use, user roles, permissions and approval workflows.
- ☐ Assess validation needs and agree assurance evidence for configured use.
- ☐ Check migrated content, revision history and access before release.

5. Training and rollout

- ☐ Assign relevant training to affected roles before controlled rollout.
- ☐ Assess competence or training effectiveness using suitable evidence.
- ☐ Check early records and observed practice for implementation problems.

6. Follow-up and sustained use

- ☐ Track gaps, owners, due dates and evidence of completed actions.
- ☐ Review whether process handoffs and document changes work in practice.
- ☐ Plan an objective internal audit when implementation evidence is available.

Priority gap / evidence reference / owner / target date:

Planning aid, not a certification assessment. Confirm applicable requirements for the device, organization and target markets. Software validation scope must reflect intended use and risk. Reviewed October 15, 2026.