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QMS Remediation

Medical Device Readiness Checklist

Scope / sites: _____ Reviewer / date: _____

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

1. Findings, correspondence and priorities

- ☐ Collect findings, inspection dates, correspondence and previous commitments.
- ☐ Separate Form FDA 483 observations, warning letters and audit findings.
- ☐ Identify responsible owners, response windows and immediate priorities.

2. Immediate controls and impact

- ☐ Assess containment needs and potential product or process impact.
- ☐ Identify related records, products, variants, suppliers or sites to review.
- ☐ Escalate possible reporting obligations to responsible personnel.

3. Investigation and corrective action

- ☐ Test potential causes against available evidence.
- ☐ Distinguish immediate corrections from actions addressing the cause.
- ☐ Assign owners, target dates, dependencies and completion evidence.

4. Implementation and records

- ☐ Approve and implement relevant process and document changes.
- ☐ Retain accurate training, review, verification or validation evidence.
- ☐ Identify historical evidence gaps without inventing or backdating records.

5. Response and progress reporting

- ☐ Address observations individually with traceable evidence references.
- ☐ Distinguish completed actions from planned work and interim controls.
- ☐ Approve commitments and confirm submission instructions and timing.

6. Effectiveness and follow-up

- ☐ Define effectiveness criteria and a justified review period.
- ☐ Review recurrence, subsequent records or suitable performance measures.
- ☐ Distinguish internal closure from regulator or certification body acceptance.

Priority gap / evidence reference / owner / target date:

Planning aid, not a regulatory closure decision. Confirm applicable requirements, response timing and submission instructions. A Form FDA 483 is not a warning letter or final agency determination. Reviewed October 15, 2026.