Outsourced Quality Support

Scope & Responsibility Checklist

Scope / sites: _____ Reviewer / date: _____

Mark Agreed, Open or N/A. Record decisions and explain scope limitations.

1. Scope and capacity

- ☐ Define device activities, markets and priority quality workstreams.
- ☐ Agree recurring tasks, outputs, capacity and scope exclusions.
- ☐ Separate routine support from major implementation or remediation.

2. Responsibilities and authority

- ☐ Assign who prepares, reviews, approves and escalates each activity.
- ☐ Retain manufacturer oversight and authorized decision ownership.
- ☐ Confirm any formal role or delegated authority through separate review.

3. Access and controlled working methods

- ☐ Agree approved systems, document locations and permissions.
- ☐ Confirm confidentiality, onboarding and relevant procedures.
- ☐ Define source information and timely inputs required from the client.

4. Records and action follow-through

- ☐ Set completion criteria and review routes for agreed outputs.
- ☐ Track open items, dependencies, owners and required evidence.
- ☐ Distinguish administrative closure from implementation effectiveness.

5. Communication and escalation

- ☐ Agree check-ins, status reporting and decision escalation routes.
- ☐ Define urgent request handling and any response expectations.
- ☐ Preserve objectivity when planning formal internal audit assignments.

6. Change control and handover

- ☐ Review workload changes and agree reprioritization or added scope.
- ☐ Record outstanding work, decisions and controlled document locations.
- ☐ Plan knowledge transfer and access changes when support ends.

Priority gap / evidence reference / owner / target date: