Elexes

QUALITY EVIDENCE / 18 CHECKS

Implantable Device 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 implant scope

- ☐ Record intended use and device configuration.
- ☐ Identify materials and relevant use conditions.
- ☐ Confirm markets, activities and quality owners.

02 Connect design evidence

- ☐ Link requirements, risks and control measures.
- ☐ Index applicable verification and validation records.
- ☐ Record technical gaps and review decisions.

03 Review suppliers and processes

- ☐ Identify critical suppliers and outsourced activities.
- ☐ Retain qualification and process evidence.
- ☐ Define acceptance and escalation responsibilities.

04 Review packaging and sterility

- ☐ Identify applicable packaging and sterility claims.
- ☐ Index validation and supporting stability records.
- ☐ Review changes affecting protective barriers.

05 Maintain traceability

- ☐ Link identifiers to relevant production records.
- ☐ Define material and component references.
- ☐ Check selected records for traceability gaps.

06 Control lifecycle actions

- ☐ Connect feedback, complaints and CAPA.
- ☐ Assess changes and affected evidence.
- ☐ Assign actions, owners and review dates.

Priority gap / evidence reference:

Action / owner / due date: