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Product Realization

Readiness Checklist | ISO 13485:2016

Device / role: _____ Reviewer / date: _____

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

1. Product realization and risk planning | 7.1

- ☐ Define device scope, role, resources, objectives and justified applicability.
- ☐ Plan verification, validation, acceptance criteria and required records.
- ☐ Document risk management; connect risk measures to lifecycle activities.

2. Customer and regulatory requirements | 7.2

- ☐ Determine customer, intended-use and applicable regulatory requirements.
- ☐ Review before supply commitments; resolve differences and retain outcomes.
- ☐ Control changed requirements and define customer communication.

3. Design and development | 7.3, where applicable

- ☐ Link inputs, outputs, reviews, verification, validation and transfer evidence.
- ☐ Evaluate and approve changes; maintain design and development files.

4. Purchasing and outsourced processes | 7.4; 4.1.5

- ☐ Evaluate and monitor suppliers using risk and purchased-product impact.
- ☐ Define purchasing requirements and relevant supplier change notifications.
- ☐ Verify purchases, control outsourced processes and retain evidence.

5. Production and service provision | 7.5

- ☐ Use current instructions, suitable equipment, acceptance checks and records.
- ☐ Apply identification, required traceability, preservation and relevant service controls.
- ☐ Validate processes where subsequent checks cannot adequately verify output.
- ☐ Apply cleanliness and sterile-device controls where relevant.

6. Monitoring and measuring equipment | 7.6

- ☐ Define suitable measurements; calibrate or verify equipment where required.
- ☐ Control status and protection; assess affected results if equipment is unsuitable.
- ☐ Validate measurement software as required; retain equipment and software records.

Priority gap / evidence reference / owner / target date:

Initial readiness aid, not a complete audit. Confirm role, product and market applicability against the licensed standard and current regulations. ISO 14971:2019 is a supporting risk-management standard.