Elexes

Design and Risk Evidence Checklist

18 checks to connect your device decisions and supporting records.

Device / version: _____ Reviewer / date: _____

Tick verified items. Record the priority gap and next action below.

01 Product and scope

- ☐ Confirm intended use, users and use environment.
- ☐ Identify device versions and applicable markets.
- ☐ Assign risk management roles and reviewers.

02 Planning and criteria

- ☐ Maintain an approved risk management plan.
- ☐ Define risk acceptability criteria before evaluation.
- ☐ Plan reviews, verification and feedback activities.

03 Hazards and analysis

- ☐ Identify hazards, hazardous situations and harms.
- ☐ Document event sequences and foreseeable misuse.
- ☐ Estimate and evaluate risks using defined criteria.

04 Controls and traceability

- ☐ Assess control options in the required priority order.
- ☐ Link controls to requirements and implementation.
- ☐ Retain evidence of control effectiveness.

05 Review and release

- ☐ Evaluate individual and overall residual risk.
- ☐ Document benefit-risk analysis where required.
- ☐ Complete the risk management review and report.

06 Lifecycle maintenance

- ☐ Review production and post-production information.
- ☐ Assess design and software changes for risk impact.
- ☐ Track actions and update affected evidence.

Priority gap / evidence reference:

Owner / next action / target date: