Elexes

Medical Device Complaint Investigation Adequacy Checklist

Complaint & Device Information

- The complaint and reported failure are clearly documented.
- Device identification and relevant lot/serial information are captured.
- Patient/user outcome and use context have been assessed.
- Event and awareness dates are documented.

Investigation & Evidence

- The investigation addresses the actual reported issue.
- Appropriate technical evaluation or testing was performed where applicable.
- Manufacturing, service or supplier information was reviewed where relevant.
- Similar complaints or recurring issues were considered.
- Investigation limitations are documented.

Root Cause & Conclusion

- Potential causes were appropriately evaluated.
- The conclusion is supported by the available evidence.
- The level of certainty matches the evidence.
- “No fault found” or “user error” conclusions are adequately supported.

Regulatory & Quality Actions

- Reportability has been assessed.
- Risk-management implications have been evaluated.
- CAPA or other corrective actions have been considered.
- Supplier, labeling, design, manufacturing or training actions have been considered where applicable.

Closure

- The conclusion addresses the original complaint.
- Required actions are documented and tracked.
- The closure rationale is documented and approved.