Medical Device Complaint Reportability Assessment Checklist

Complaint Information

- Complaint has been logged with a unique reference number.
- Device identification details are available (model, lot/serial number, UDI if applicable).
- Date of event and date complaint was received are documented.
- Event description is complete and understandable.

Reportability Assessment

- Did the event involve a patient death?
- Did the event involve a serious injury?
- Did the device malfunction?
- Could the malfunction lead to serious injury or death if it occurred again?
- Is the event related to incorrect labelling, packaging, or instructions for use?

Investigation Status

- Initial investigation has been initiated.
- Relevant evidence has been collected.
- Root cause analysis has been started (if required).
- Additional information has been requested where needed.

Regulatory Assessment

- Applicable markets have been identified (FDA, EU MDR, Health Canada, TGA).
- Reporting timelines have been considered.
- Reportability assessment has been documented.
- Decision rationale has been recorded.

Downstream Actions

- CAPA assessment completed (if required).
- Risk Management File impact evaluated.
- Supplier quality review required?
- Engineering review required?
- Complaint trend reviewed.

Final Review

- Complaint closure documentation is complete.
- Supporting evidence is attached.
- Independent quality review completed (if applicable).