Elexes

# Missed Medical Device Reporting Deadline Response Checklist

## 01 Reporting Assessment

- [ ] Has the correct awareness date been identified?
- [ ] Has the applicable reporting requirement and deadline been confirmed?
- [ ] Was the delayed report submitted and the reason for delay documented?
- [ ] Has the responsible reporting entity been confirmed?

## 02 Complaint & Impact Review

- [ ] Is the complaint record complete and the event outcome documented?
- [ ] Was the reportability assessment performed using applicable criteria?
- [ ] Have similar complaints or potentially affected reports been reviewed?
- [ ] Have other markets and reporting obligations been assessed?

## 03 Root Cause & Corrective Action

- [ ] What caused the reporting delay?
- [ ] Were procedure, training, resource, system or ownership gaps identified?
- [ ] Has the need for CAPA been assessed?
- [ ] Are corrective actions assigned with responsible owners and timelines?

## 04 Effectiveness & Closure

- [ ] Have procedures, workflows or escalation controls been updated where needed?
- [ ] Has effectiveness of corrective actions been verified?
- [ ] Is the remediation rationale documented and approved?