# INTERNAL AUDIT REPORT

## 1. Audit Summary

| | |
|---|---|
| **Audit ID:** | IA-2026-XXX |
| **Audit Type:** | |
| **Audit Date(s):** | |
| **Department/Area:** | |
| **Lead Auditor:** | |
| **Audit Team:** | |
| **Auditee(s):** | |

## 2. Audit Scope

**Processes/Areas Audited:**

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**Audit Criteria:**
☐ ISO 13485:2016 ☐ FDA 21 CFR 820 ☐ Internal Procedures

## 3. Findings Summary

| Category | Count | Reg. Impact | CAPA Req. | Response Due |
|---|---|---|---|---|
| **Major Nonconformity** | | | Yes | 15 days |
| **Minor Nonconformity** | | | Yes | 30 days |
| **Observation** | | | Optional | 60 days |
| **OFI** | | | No | N/A |
| **TOTAL** | | | | |

## 4. Detailed Findings

| **Finding #1** | |
|---|---|
| **Finding ID:** | F-2026-XXX-01 |
| **Classification:** | ☐ Major NC ☐ Minor NC ☐ Observation ☐ OFI |
| **Regulatory Impact:** | ☐ Yes ☐ No |
| **Requirement:** | [ISO 13485 Clause X.X / FDA 820.XX] |
| **Description:** | |
| **Objective Evidence:** | |
| **CAPA Required:** | ☐ Yes ☐ No CAPA ID: _____ |

| **Finding #2** | |
|---|---|
| **Finding ID:** | F-2026-XXX-02 |
| **Classification:** | ☐ Major NC ☐ Minor NC ☐ Observation ☐ OFI |
| **Regulatory Impact:** | ☐ Yes ☐ No |
| **Requirement:** | [ISO 13485 Clause X.X / FDA 820.XX] |
| **Description:** | |
| **Objective Evidence:** | |
| **CAPA Required:** | ☐ Yes ☐ No CAPA ID: _____ |

**Regulatory Impact = Yes** if finding relates to: FDA 21 CFR 820 requirements, ISO 13485 mandatory clauses, EU MDR essential requirements, product safety/efficacy, or could trigger regulatory notification.

## 5. Positive Observations

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| 1.<br>2.<br>3. |

## 6. Audit Conclusion

**Overall Assessment:**

☐ Effective ☐ Effective with Minor Issues ☐ Needs Improvement ☐ Ineffective

**Summary:**

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## 7. Approval

| Role | Signature | Date |
|---|---|---|
| Lead Auditor: | | |
| QM Representative: | | |
| Auditee Acknowledgement: | | |

## 8. Report Distribution

☐ Auditee ☐ QM Representative ☐ Department Manager ☐ Management Review

*Compliant with ISO 13485:2016 Section 8.2.4*