Iso 13485 Audit Checklist

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Quality Management System

- [ ] Scope of QMS defined for medical devices
- [ ] Quality manual maintained
- [ ] Quality policy appropriate
- [ ] Quality objectives measurable
- [ ] Management commitment demonstrated
- [ ] Customer focus maintained
- [ ] Regulatory requirements identified
- [ ] Risk-based approach implemented
- [ ] Documentation requirements met
- [ ] Software validation performed
- [ ] Process validation completed
- [ ] Effectiveness evaluated

Management Responsibility

- [ ] Management commitment evident
- [ ] Customer/regulatory focus clear
- [ ] Quality policy communicated
- [ ] Planning documented
- [ ] Responsibilities defined
- [ ] Management representative appointed
- [ ] Internal communication effective
- [ ] Management review conducted
- [ ] Review inputs comprehensive
- [ ] Review outputs actionable
- [ ] Improvement actions taken
- [ ] Resources provided

Resource Management

- [ ] Resources determined and provided
- [ ] Human resources competent
- [ ] Training needs identified
- [ ] Training effectiveness evaluated
- [ ] Infrastructure maintained
- [ ] Work environment controlled
- [ ] Contamination control implemented
- [ ] Sterile barrier systems validated

- [ ] Equipment maintained
- [ ] Utilities monitored
- [ ] Information systems validated
- [ ] Supporting services controlled

Product Realization

- [ ] Planning of realization processes
- [ ] Customer requirements determined
- [ ] Regulatory requirements identified
- [ ] Risk management per ISO 14971
- [ ] Design and development planned
- [ ] Design inputs documented
- [ ] Design outputs verified
- [ ] Design reviews conducted
- [ ] Design verification performed
- [ ] Design validation completed
- [ ] Design transfer controlled
- [ ] Design changes managed

Purchasing Controls

- [ ] Purchasing process established
- [ ] Supplier evaluation criteria defined
- [ ] Approved supplier list maintained
- [ ] Purchasing information clear
- [ ] Product specifications defined
- [ ] Verification of purchased product
- [ ] Supplier performance monitored
- [ ] Supplier agreements documented
- [ ] Critical suppliers identified
- [ ] Re-evaluation performed
- [ ] Records maintained
- [ ] Traceability ensured

Production & Service

- [ ] Production planned and controlled
- [ ] Product cleanliness controlled
- [ ] Installation activities validated
- [ ] Servicing activities documented
- [ ] Sterile medical devices validated
- [ ] Validation of processes
- [ ] Identification throughout realization
- [ ] Traceability maintained
- [ ] Customer property controlled
- [ ] Product preservation ensured
- [ ] Monitoring devices calibrated

- [ ] Records maintained

Monitoring & Measurement

- [ ] Customer satisfaction monitored
- [ ] Complaint handling procedure
- [ ] Regulatory reporting performed
- [ ] Internal audits conducted
- [ ] Process monitoring active
- [ ] Product monitoring performed
- [ ] Nonconforming product controlled
- [ ] Advisory notices issued when required
- [ ] Measurement equipment calibrated
- [ ] Statistical techniques applied
- [ ] Data analysis performed
- [ ] Trending conducted

Control of Nonconforming Product

- [ ] Procedure for nonconforming product
- [ ] Identification and segregation
- [ ] Evaluation and disposition
- [ ] Rework procedures validated
- [ ] Concessions documented
- [ ] Regulatory requirements met
- [ ] Investigation of nonconformities
- [ ] Records maintained
- [ ] Re-verification performed
- [ ] Customer notification if required
- [ ] Advisory notices issued
- [ ] Recall procedures ready

Data Analysis & Improvement

- [ ] Data collection planned
- [ ] Analysis techniques appropriate
- [ ] Feedback system established
- [ ] Complaint handling effective
- [ ] Regulatory reporting timely
- [ ] Corrective action system
- [ ] Preventive action process
- [ ] Root cause analysis performed
- [ ] Effectiveness verified
- [ ] Continuous improvement demonstrated
- [ ] Risk management updated
- [ ] Post-market surveillance active

Documentation Requirements

- [ ] Document control procedure
- [ ] Documents approved before use
- [ ] Documents reviewed and updated
- [ ] Changes identified
- [ ] Obsolete documents controlled
- [ ] Documents legible and identifiable
- [ ] External documents controlled
- [ ] Records control procedure
- [ ] Records readily identifiable
- [ ] Records retrievable
- [ ] Retention times defined
- [ ] Records protected

Medical Device Files

- [ ] Device master record complete
- [ ] Device history record maintained
- [ ] Design history file comprehensive
- [ ] Technical documentation complete
- [ ] Risk management file current
- [ ] Clinical evaluation report
- [ ] Regulatory submissions documented
- [ ] Post-market surveillance data
- [ ] Vigilance reporting records
- [ ] Software validation records
- [ ] Process validation records
- [ ] Sterilization validation

Regulatory Compliance

- [ ] Regulatory requirements identified
- [ ] Regulatory strategy defined
- [ ] Submissions timely and accurate
- [ ] Regulatory changes tracked
- [ ] Compliance verified
- [ ] Audit readiness maintained
- [ ] Regulatory training current
- [ ] Communication with authorities
- [ ] Vigilance system active
- [ ] Field safety actions ready
- [ ] Recall procedures tested
- [ ] Market surveillance conducted