Checklist of Mandatory Documents and Records

General Requirements

- [ ] Device description and specification
- [ ] Labels and instructions for use
- [ ] Design information
- [ ] EU declaration of conformity
- [ ] List of all UDI-DI
- [ ] Summary of safety and clinical performance

Quality Management

- [ ] Quality policy
- [ ] Quality manual
- [ ] Quality agreement with outsource partner
- [ ] Procedures for document control
- [ ] Procedures for management review

Risk Management

- [ ] Risk management plan
- [ ] Risk management file
- [ ] Risk management report

Clinical Evaluation

- [ ] Clinical evaluation plan
- [ ] Clinical evaluation report

Clinical Investigation

- [ ] Informed consent
- [ ] Investigator brochure
- [ ] Clinical investigation plan
- [ ] Safety and performance statement
- [ ] Proof of insurance
- [ ] Clinical investigation report
- [ ] Adverse event report
- [ ] Field safety corrective actions

Post-Market Surveillance

- [ ] Post-market surveillance plan
- [ ] Post-market surveillance report
- [ ] Periodic safety update report
- [ ] Post-market clinical follow-up plan
- [ ] Safety and performance statement
- [ ] Proof of insurance
- [ ] Clinical investigation report

eKare Inc.
3040 Williams Drive
Ste 610
Fairfax, VA 22031

1-844-443-5273
info@ekareinc.com
www.ekare.ai