

CardioGrace – Mobile App Technical & Regulatory Requirements

Product Goal

Build a FibriCheck-like smartphone camera PPG application for cardiac screening and triage with a doctor escalation layer. This is not a diagnostic app. The product must be regulator-friendly with explicit disclaimers, audit trails, versioning, cybersecurity controls, and QMS-ready documentation.

Patient App – Measurement Flow

- Finger-on-camera with flash (30–60 seconds)
- Real-time guidance for pressure, motion, and exposure
- Signal Quality Index (SQI) gating and re-scan prompts
- Context capture: posture, symptoms, timestamp

Outputs & Reports

- Heart rate and rhythm regularity flag
- Confidence scoring
- Physician-facing waveform, tachogram, plots, metadata
- Shareable and exportable PDF reports

Doctor Escalation Layer

- Green / Amber / Red triage classification (decision support only)
- Safety rails + personalized baseline anomaly detection
- Full audit-trail rationale per escalation
- One-tap clinician actions (call, message, ER recommendation)

Baseline Banking

- 7–14 days of short daily scans
- Post-baseline scans only when symptomatic or prompted
- Limited repeat scans to reduce misuse

Doctor Dashboard

- Patient lists, triage status, trends
- Waveform review and clinician override
- Governance logs and exportable notes

Technical Architecture

- Clean / MVVM modular architecture
- Camera capture, preprocessing, SQI
- Feature computation and triage logic
- Secure backend APIs and clinician dashboard
- CI/CD with versioned releases

Regulatory & QMS Readiness

- ISO 13485 – QMS structure
- ISO 14971 – risk management hooks
- IEC 62304 – software lifecycle compliance
- IEC 62366 – usability engineering

Cybersecurity & Privacy

- Encryption at rest and in transit
- OAuth2 / JWT with role-based access
- Immutable audit logs
- Secure secrets management

- DPDP, GDPR, HIPAA-aligned posture

Pilot Validation Support

- Rhythm flags validated only where ECG exists clinically
- Instability correlated with vitals and clinician scoring
- No ischemia or MI diagnosis claims

Expected Deliverables

- Technical architecture & milestones
- Module-wise effort estimates
- Security checklist mapped to implementation
- Regulatory-ready build documentation