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## 1️⃣ Saudi Arabia Regulatory Requirements (SFDA)

### A. SFDA Medical Device Registration (MDMA / MDEL)

Your system qualifies as a **medical electrical device** + **healthcare IT software**, so you must comply with:

**Required Actions**

- Register company as **Medical Device Establishment (MDEL)**
- Register product under **Medical Device Marketing Authorization (MDMA)**
- Submit:
    - Technical File
    - Risk Management File
    - Clinical Evaluation (if required)
    - Safety & Performance Evidence
    - Labeling & IFU
    - QMS evidence (ISO 13485)

**Required Documents**

- Device description
- Intended use
- Classification justification
- Essential principles checklist
- Risk management report
- Electrical safety test reports
- Software lifecycle documentation
- Cybersecurity documentation
- Biocompatibility evidence (for infant tag materials)
- Clinical evidence (if biometrics used for identity verification)

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## 2️⃣ Quality Management System (ISO 13485)

**Mandatory for SFDA approval**

**You must implement:**

- Document control
- Design & development procedures
- Supplier qualification
- Incoming inspection
- Production & process control
- Complaint handling
- CAPA (Corrective & Preventive Actions)
- Internal audits
- Management review

**Required Deliverables**

- Quality Manual
- SOPs (Standard Operating Procedures)
- DHR (Device History Record)
- DMR (Device Master Record)
- QMS audit report

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### 3️⃣ Electrical Safety & EMC (IEC 60601 Series)

Applies to:

- Infant ankle tag
- Mother wrist tag
- RTLS readers
- Gate terminals
- Alarm controllers
- Footprint scanner

**Required Standards**

- **IEC 60601-1** — Electrical safety

- **IEC 60601-1-2** — EMC (Electromagnetic Compatibility)
- **IEC 60601-1-6** — Usability engineering
- **IEC 60601-1-11** — Home/clinical environment (if applicable)

**Tests Required**

- Leakage current
- Dielectric strength
- Grounding
- Temperature rise
- EMC emissions & immunity
- ESD protection
- Radiated RF immunity

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### 🛂 Software Lifecycle Compliance (IEC 62304)

Applies to:

- Backend platform
- Gate terminal software
- Footprint scanner software
- RTLS processing
- Mobile apps (if any)

**Required Deliverables**

- Software Development Plan
- Software Architecture Document
- Software Requirements Specification (SRS)
- Software Risk Analysis
- Unit test reports
- Integration test reports
- Verification & validation report
- Release notes

- Maintenance plan

**Software Safety Classification**

- Likely **Class B** (moderate risk)
- If alarms directly affect infant safety → borderline **Class C**

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## 5️⃣ Risk Management (ISO 14971)

**Required Activities**

- Hazard identification
- Risk estimation
- Risk control measures
- Residual risk evaluation
- Benefit-risk analysis
- Risk management report

**Common Hazards**

- Infant tag failure
- Tamper detection failure
- RTLS mis-localization
- Gate authorization failure
- Alarm not triggering
- Biometric mismatch
- Data breach
- Power failure

**Required Deliverables**

- Hazard Analysis
- FMEA / FTA
- Risk Control Matrix
- Verification of risk controls
- Residual risk report

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## 6️⃣ Cybersecurity Requirements

**Standards to follow**

- **FDA Cybersecurity Guidance (international reference)**
- **IEC 81001-5-1** (health software security)
- **NIST Cybersecurity Framework**
- **Saudi PDPL (Personal Data Protection Law)**

**Required Controls**

- Encryption (AES-256, TLS 1.3)
- Secure boot
- Firmware signing
- Device authentication (certificates)
- Role-based access control
- Audit logging
- Intrusion detection
- Secure OTA updates
- Vulnerability management

**Required Deliverables**

- Cybersecurity Risk Assessment
- Threat Model (STRIDE)
- Penetration Test Report
- Secure Development Lifecycle (SDL) documentation
- Patch management plan

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## 7️⃣ Biocompatibility (ISO 10993)

Applies to:

- Infant ankle tag strap
- Mother wristband

- Any material contacting skin

**Tests Required**

- Cytotoxicity
- Sensitization
- Irritation
- Chemical characterization

**Materials**

- Medical-grade silicone
- Medical-grade TPU
- Hypoallergenic adhesives

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## 8️⃣ Radio & Wireless Compliance

**Standards**

- **CITC/Saudi Communications Authority** requirements
- **ETSI EN 300 328** (BLE)
- **ETSI EN 302 208** (UHF RFID)
- **EN 301 489** (EMC for radio equipment)

**Tests**

- RF output power
- Frequency stability
- Spurious emissions
- Receiver sensitivity
- Antenna performance

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## 9️⃣ Data Protection & Privacy (Saudi PDPL)

**Requirements**

- Consent for biometric data
- Data minimization

- Purpose limitation
- Secure storage
- Access control
- Data retention policy
- Data breach notification
- Privacy impact assessment

**Deliverables**

- PDPL Compliance Report
- Data Flow Diagram
- Privacy Policy
- Data Processing Agreement
- DPIA (Data Protection Impact Assessment)

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### 🔟 Usability Engineering (IEC 62366-1)

**Required Activities**

- User research (nurses, security staff)
- Use error analysis
- UI/UX validation
- Human factors engineering

**Deliverables**

- Usability Engineering File
- Use Scenarios
- User Interface Specification
- Validation Report

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### 1️⃣1️⃣ Manufacturing & Factory Compliance

**Factory Requirements**

- ISO 13485 certified

- ESD-safe production lines
- Traceability system
- Incoming inspection
- Final QC testing

**Required Deliverables**

- Supplier Qualification Report
- Factory Audit Report
- Production Test Procedures
- Device Master Record (DMR)
- Device History Record (DHR)

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### 1️⃣2️⃣ Labeling & IFU Compliance

**Requirements**

- Arabic + English
- SFDA-approved format
- Include:
    - Device name
    - Intended use
    - Warnings
    - Contraindications
    - Manufacturer info
    - UDI (Unique Device Identifier)
    - Serial number
    - Firmware version

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### 1️⃣3️⃣ Clinical Evaluation (If Required)

**Required When:**

- Using biometrics for identity verification

- Using RTLS for safety-critical decisions

**Deliverables**

- Clinical Evaluation Report (CER)
- Literature review
- Performance data
- Pilot study results

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### 1️⃣4️⃣ Environmental & Safety Compliance

**Standards**

- RoHS (Restriction of Hazardous Substances)
- REACH (chemical safety)
- WEEE (electronic waste)

**Deliverables**

- RoHS Declaration
- REACH Declaration
- MSDS for materials

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### 1️⃣5️⃣ Final SFDA Submission Package Checklist

**Complete Package Includes:**

- Device description
- Intended use
- Essential principles checklist
- Risk management file (ISO 14971)
- Software documentation (IEC 62304)
- Electrical safety reports (IEC 60601-1)
- EMC reports (IEC 60601-1-2)
- Biocompatibility reports (ISO 10993)
- Cybersecurity documentation

- Usability engineering file (IEC 62366-1)
- Clinical evaluation (if required)
- Labeling & IFU
- QMS evidence (ISO 13485)
- Manufacturing process documentation
- Test reports
- Declaration of conformity
- PDPL compliance documentation

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