**ISO 13485 Starter Quality Management System (QMS) Documentation**

**Product Name:** Chest X-Ray Abnormality Detection AI  
**Company:** Medimaze Solutions Pvt Ltd  
**Device Class:** Class B (Software as a Medical Device - SaMD)

### 1. Quality Manual (Starter Version)

#### 1.1. Quality Policy

Medimaze Solutions Pvt Ltd is committed to developing safe, effective, and reliable medical software to assist with chest X-ray interpretation. Our organization ensures compliance with ISO 13485 and applicable regulatory requirements through a robust Quality Management System and a culture of continuous improvement.

#### 1.2. Quality Objectives

* Ensure 100% traceability of software requirements and test cases.
* Complete internal audits every 6 months.
* Ensure 100% documented risk assessments for each release.
* Provide customer support resolution within 48 hours.

#### 1.3. QMS Scope

The QMS covers design, development, validation, deployment, support, and maintenance of the Chest X-ray Abnormality Detection AI. Excludes physical manufacturing and sterilization activities.

#### 1.4. Organizational Boundaries

* **Design & Development:** AI/ML and Software Teams (Pune Office)
* **Validation & Risk:** Data Science and QA Teams
* **Deployment:** Infrastructure and DevOps Team
* **Support:** Clinical Liaison and Customer Support Team

#### 1.5. Exclusions

Excluded: Sterilization, physical production, and implantable device procedures – not applicable to software-only product. Justified per ISO 13485:2016 Clause 1.2.

### 2. Medical Device File (Starter)

| Section | Details |
| --- | --- |
| **Device Name** | Chest X-ray Abnormality Detection AI |
| **Class** | Class B (as per MDR/FDA classification) |
| **Intended Use** | Aids radiologists in identifying abnormalities in PA chest X-rays |
| **Device Description** | Software tool using AI models (e.g., YOLO, nnUNet) to flag >10 chest pathologies |
| **Labeling** | Versioned software UI, digital user guide, PDF IFU available |
| **Technical Specs** | Python backend, Deep Learning models, FastAPI server, CPU-only inference |
| **Installation/Servicing** | Remote setup via web-based installer, cloud API support, no physical servicing required |
| **Instructions for Use (IFU)** | Embedded within app and as downloadable PDF |

### 3. Design and Development File (Structure)

* **Design Plan:** Phases – Requirement Collection, Architecture, Development, Testing, Release
* **Inputs & Outputs:** Clinical inputs, Regulatory inputs → AI features, UI design, validation criteria
* **Reviews:** Signed review checkpoints for each phase
* **V&V Documentation:** Model evaluation reports, test datasets, integration tests
* **Change Log:** Version control system history, summary of major changes

### 4. Risk Management File (ISO 14971 Starter Table)

| Hazard | Cause | Harm | Risk Control | Residual Risk |
| --- | --- | --- | --- | --- |
| False Negative | Missed abnormality by AI | Diagnostic delay | Validation, Human-in-loop review | Acceptable |
| False Positive | Over-sensitive AI detection | Unnecessary follow-up | Clinical threshold tuning | Acceptable |
| Labeling Error | Software bug or data mismatch | Misinterpretation | Automated tests, UI checks | Acceptable |

### 5. SOPs (Summarized Drafts)

#### 5.1. Document Control Procedure

* All documents are version-controlled via Git or cloud DMS
* Changes reviewed and approved by QA lead
* Obsolete documents are archived for 5 years

#### 5.2. Software Validation SOP

* Validation plan created before release
* Model performance (AUROC, Sensitivity, Specificity) evaluated
* Internal team testing + end-user beta feedback used for final validation

#### 5.3. Complaint Handling SOP

* All complaints logged in CRM/email system
* Assigned to support team within 24 hours
* Root cause analysis if required, documented in CAPA register

#### 5.4. Internal Audit SOP

* Bi-annual audits conducted by independent QA staff
* Non-conformities documented and tracked via CAPA

#### 5.5. CAPA SOP

* Corrective/Preventive Actions initiated from audit or incident
* Actions tracked to closure, reviewed in management meeting

#### 5.6. Supplier Evaluation SOP

* New vendors assessed for compliance with software quality needs
* Evaluation forms retained for each supplier
* Re-evaluation annually or on performance issues

### 6. Validation & Traceability

* **Traceability Matrix:** Maintained between requirements ↔ tests ↔ results
* **CSV Artifacts:** Test logs, model outputs, acceptance criteria
* **Deployment Logs:** Server info, build version, install time

### 7. Additional Records (To Maintain)

* Internal audit reports
* Management review meeting minutes
* Complaint register (email tickets, summaries)
* Developer and clinical training logs

*This document is a starter framework for ISO 13485 compliance. Further detailing, SOPs, records, and templates can be developed with actual process flows.*