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Quality Management System Requirements to Be Reflected with the Application of ISO/IEC 42001 to Digital Medical Device Manufacturing and Quality Management Standards (KGMP)

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Key Requirements under ISO/IEC 42001	Quality Manual and Procedures under ISO 13485:2016	Elements to Be Reflected in the Existing Quality Management System
1.2 Management Responsibility	Quality Manual	**1. AI Quality Management Policy** - Top management shall establish an AI Quality Management Policy and measurable AI quality objectives, and maintain and manage them including the following items:

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		• Ensure ethical, legal, and technical controls throughout the full lifecycle of AI system development and operation • Establish plans for AI training and validation activities and conduct regular performance reviews • Document and conduct training on the AI quality policy, quality objectives, ethical principles, and internal roles and responsibilities • Maintain quality records for AI-related data, models, source code, and deliverables, and ensure auditability **2. AI Quality Management Procedures** - The company shall operate procedures for the establishment and implementation of AI quality objectives, including the following: • Establishment of AI quality policy and specific objectives approved by top management *(e.g., detection accuracy ≥ 85%, error rate ≤ 2%, etc.)* • Procedures to set and manage objectives that comply with legal requirements and ethical principles (e.g., explainability, non-biasness, etc.) • Inclusion of AI quality objective performance, risk management results, and training status in management review items

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		3. Resource Management - The company shall secure and maintain the following resources to effectively implement AI control measures: • Securing qualified personnel capable of AI development and operation *(e.g., AI developers, data scientists, AI ethics experts)* • High-performance infrastructure resources such as GPU servers and large-scale data storage • Provision of training opportunities on relevant regulations and technical standards • Maintenance of competency evaluations and training completion criteria by role • Evaluation and implementation of system/computing resources required under ISO/IEC 42001, including location, computational performance, and network impact **4. AI Governance System** - The company shall establish and internalize the following governance system throughout the lifecycle of AI-based systems, including design, development, validation, operation, and disposal:

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		• Establish a dedicated AI governance team and assign a responsible person • Operate a decision-making structure and role-sharing system based on ethical principles • Systematically ensure compliance with relevant laws and standards (e.g., Medical Device Act, Personal Information Protection Act, ISO 13485, IEC 62304, ISO/IEC 42001) • Operate systematic procedures for top management's approval, responsibility, and review **5. AI Reliability Assurance Plan** - The company shall implement the following activities to ensure the reliability of output results from AI/ML-based digital medical devices and manage them as part of the quality management system: • Establish simulation and testing environments to validate output values • Operate expert panels to ensure clinical relevance and interpretability • Operate feedback collection and validation procedures using user evaluation groups • Reflect evaluation results as quality indicators in management reviews and use them for continuous improvement

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	Management Review (SOP)	**1. Inputs for Management Review** • Status of achievement of AI quality objectives • Compliance with AI ethics and explainability principles • Review of quality issues such as data bias (e.g., less than 5%) and model performance • Training completion status of stakeholders (e.g., departments, external partners) • Status of quality record maintenance and performance of risk controls
	Document and Record Management (SOP)	**1. Records Related to AI Quality** • Data collection, AI model training/data logs • Records of warnings/errors • Performance evaluation records, external assessment reports • Documents of review and approval by top management

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1.3. Resource Management	Resource Management (SOP)	**1. Human Resource Management Items** • Define competency requirements for personnel in charge of AI-related tasks (e.g., model developers, validators), including academic background, work experience, and training history • Designate responsible personnel and document roles (e.g., AI Technical Officer, Data Steward) • Establish and manage onboarding and periodic training plans and maintain training completion records • Specify competency evaluation criteria for task execution (e.g., understanding of algorithms, ability to analyze data bias) **2. Infrastructure Resource Management Items** • Specify AI development infrastructure: including GPU servers, parallel computing environments, and data storage • In accordance with ISO/IEC 42001: specify the location of system and computing resources, status of processing resources (including network and storage), and the HW/SW impact for AI workload execution

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2. Risk Management	Risk Management (SOP)	**1. Additional AI Risk Factors** • Data bias (BIAS) • Lack of explainability • Open source vulnerabilities • Unintended changes caused by automatic updates **2. AI/ML Considerations in Risk Management Procedures** • Risk Identification - Include additional risk items potentially caused by AI/ML systems and algorithms (e.g., misdiagnosis risk, data distortion, prediction uncertainty) • Risk Analysis - Define risk scenarios for each function (e.g., data input processing, learning algorithm, output interpretation) - Assess likelihood and severity of risks by function

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		• Risk Evaluation and Acceptance Criteria - In addition to general medical device criteria, include AI ethics and explainability (predictability) considerations - Set reassessment intervals based on whether the AI function involves autonomous learning/updates • Risk Control - Define model validation and retraining cycles - Specify performance metrics: sensitivity, specificity, explainability (predictability) - Include security, licensing, and version control measures when using open-source software • Residual Risk and Documentation - Evaluate medical benefit versus residual risk

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3. Governance System	AI Governance Operating Procedure (New SOP Required)	**1. Purpose** • To operate AI-based medical devices under consistent corporate accountability and ethical standards **2. Scope of Application** • Applicable to the development, validation, distribution, and post-market management of all digital medical devices including AI/ML-based software **3. Operational Items** • Establish governance structure (organizational chart, designation of responsible persons) • Define and approve ethical principles • Clarify roles throughout the system lifecycle • Engage external experts and hold regular meetings • Maintain and comply with applicable laws and standards

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	AI Ethics and Legal Compliance Monitoring Procedure (New SOP Required)	**1. Purpose** • To periodically verify the effective implementation and maintenance of the AI governance system **2. Scope of Application** • Perform inspections on monitoring items at least once a year (with participation of external experts) **3. Monitoring Items** • Compliance with AI ethical principles • Occurrence and control history of data bias and security issues • Participation status of external advisory members • Model performance monitoring and retraining records • Reflection in internal audits and management reviews

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	Procedure for Operation and Participation of External Experts in Decision-Making (New SOP Required)	**1. Requirements for External Advisory Panel Composition** • Include professionals such as medical ethics experts, lawyers, and data scientists **2. Meeting Operations** • Hold meetings at least once per quarter, with ad-hoc reviews upon changes or updates to AI systems • Maintain records of all related proceedings
4. Reliability Assurance Plan	Design/Development and Validation Planning (SOP)	**1. Specification of Test Environment** • Clearly define the simulator or test environment • Specify the usage method of data generation and validation tools

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		2. Advisory Body for Expected Output • Participation of internal staff and external experts is required • Define meeting frequency, participant qualifications, discussion topics, and record management **3. Reliability Assurance Plan** • Conduct reliability analysis and maintain records based on simulation results, advisory body discussions, and user evaluations
5. AI/ML Training Data Resource Management	Resource Management (SOP)	**1. AI/ML Training Data Resource Management** - To ensure the quality and reliability of AI/ML functions, the following data resources shall be secured and managed.

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		• Data Quality - Maintain metadata including source, format, collection method, and collector information - Identify outliers and conduct regular sample inspections • Data Protection - Perform pseudonymization/anonymization, encrypt storage, and control access rights - Maintain and inspect logs (access/modification/deletion history) • Bias Mitigation - Verify representativeness across demographic groups (e.g., sex, age, disease groups) - Operate corrective action process in case of bias detection • Auditability of Data - Implement a traceable system covering the full lifecycle from collection to disposal - Maintain records of all modifications, evaluations, and outcomes

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6. AI/ML Function – Artificial Intelligence Model Development	Design/Development and Verification Planning (SOP)	**1. Items to Be Reflected in AI Model Design Planning** • Confirm whether AI/ML models are to be applied • Define the plan and review method for open-source usage (e.g., SBOM, CVE inspection) • Define data utilization plans (internal/external data, de-identification of patient information) ✓ SBOM (Software Bill of Materials): A document listing all open-source, commercial libraries, components, and modules included in a product (includes name, version, license, source, and dependency information) ✓ CVE (Common Vulnerabilities and Exposures): A database assigning unique identifiers to officially registered cybersecurity vulnerabilities (includes name, description, affected software, mitigation method, and severity such as CVSS scores)

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		2. Items to Be Reflected in AI Model Design Inputs • In addition to functional requirements, specify performance metrics (e.g., ROC-AUC), bias mitigation requirements, and explainability requirements • Include ethical considerations (e.g., interpretability of results, reflection of clinical feedback) **3. Items to Be Reflected in AI Model Design Outputs** • AI model architecture, training/validation methods, supporting documentation, and model limitations • Documentation of open-source component list and license review **4. Items to Be Reflected When AI Model Design Is Modified** • Specify re-verification requirements when library versions are changed • Apply design change procedures when training data is modified

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		5. Items to Be Reflected in AI Model Verification • Confirm whether performance metrics meet threshold criteria • Analyze bias (e.g., classification accuracy by gender, age, disease group) • Review open-source security issues (CVE status, patch application) • Assess explainability by evaluating the ability to interpret prediction rationale using supporting documentation **6. Items to Be Reflected in AI Model Validation** • Conduct tests under actual user conditions • Verify prediction results using clinical environments or simulators • Investigate user panel comprehension, interpretability, and potential for risk misunderstanding • Document additional improvements based on user feedback

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7. AI/ML Function – System Development	Design/Development and Verification Planning (SOP)	**1. Items to Be Reflected in System Design Inputs (for products applying AI models)** • Real-time alert function to notify users/operators in case of system malfunction • Ensure user interface (UI) safety (avoid biased wording, excessive messages, etc.) • Define system response requirements in cases of input errors, abnormal inputs, or delayed responses • Basic cybersecurity requirements (e.g., encryption, access control, authentication) • Include automatic detection and notification of AI performance degradation **2. Items to Be Reflected in System Design Outputs** • Alert function: specify conditions (e.g., input errors, prediction cases) and alert methods (e.g., SMS, email, UI messages) • Logic for detecting performance degradation (e.g., warnings upon reduced input data quality) • Incorporation of security design • UI/UX elements that support user feedback and safety evaluation • Inclusion of warning messages and misuse prevention phrases in the IFU (Instructions for Use) and UI

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		3. Items to Be Reflected in System Design Verification • Scenario-based testing: - Whether appropriate alerts are provided upon erroneous data input - Whether the system continues to operate without stopping under delayed response conditions • UI/UX review: - Identify any misleading expressions or elements that may cause user misjudgment - Prevent excessive warnings for sensitive users • Security testing: - Verification of login authentication and encryption implementation - Vulnerability testing • Code interface review: - Validation of external user inputs - Inclusion of logic to handle malicious inputs

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		4. Items to Be Included in System Design Validation • Simulate malfunction conditions for test participants and confirm alert receipt • Verify whether the system provides accurate and safe guidance messages during errors • Include usability evaluation items such as "alert reliability," "risk of user confusion," and "UI intuitiveness"
8. AI/ML Function Operation and Monitoring	Post-Market Surveillance (SOP)	**1. Log Analysis During Operation** • Store input data, prediction results, and explanation information that form the basis of AI output • Trace logs for decision errors, abnormal inputs, and exceptions **2. Collection of User Feedback** • Collect cases of functional misuse, misinterpretation, and system errors • Analyze AI performance and document improvements based on user feedback

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		3. Traceability Function • Maintain the ability to reconstruct decision-making context based on user input, model version, and result logs (e.g., date, patient ID, model version, input characteristics, user selection, etc.)
	Software Change Control Procedure (SOP) or Software Configuration Management (SCM) (SOP)	**1. Change Record Management** • When upgrading or modifying the AI model, log-based analysis must be performed on performance changes and impact on decision criteria compared to previous versions • Ensure that operational logs are well-maintained to allow traceability of design changes