

AI Quality Management System Protecting Health, Safety and Fundamental Rights

in accordance with EN 18286

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Protecting What Matters Most in the Age of Artificial Intelligence

In an era where AI systems increasingly influence decisions that affect people's lives, health, safety, and fundamental rights, organizations need more than good intentions. They need a systematic, auditable, and defensible approach to AI governance.

This AI Quality Management System has been purpose-built to fulfil the EU AI Act's stringent requirements. It provides a comprehensive, integrated framework that helps organizations develop, deploy, and monitor AI systems responsibly while demonstrably protecting health, safety, and the fundamental rights of individuals.

Why This System Matters

The deployment of AI carries significant responsibilities. Poorly governed AI can lead to:

- Physical or psychological harm to individuals
- Safety risks in critical applications (healthcare, transportation, justice)
- Discrimination, privacy violations, or other infringements of fundamental rights
- Loss of public trust and regulatory non-compliance

Regulatory expectations are rising rapidly. Frameworks such as the EN 18286 Quality Management System standard and the EU Artificial Intelligence Act place clear obligations on providers and deployers of high-risk AI systems, particularly around post-market monitoring, risk management, transparency, and accountability.

This AI Quality Management System translates these obligations into practical, repeatable processes that organizations can rely on.

Core Design Philosophy

The system is founded on five quality management processes that apply consistently across every activity:

- **Traceability** – Every record, decision, and piece of evidence is fully linked to the AI systems, people, and events that produced it.
- **Review and Approval** – Structured workflows ensure appropriate oversight and sign-off before critical actions are taken.
- **Evidence Generation and Record Keeping** – High-quality, immutable evidence is generated and preserved automatically as part of normal operations.
- **Nonconformity and Corrective Action** – Issues are identified early, documented, and resolved through controlled processes.
- **Change Management** – All modifications – whether to AI systems, configurations, or governing documents – are controlled, justified, and recorded.

These processes are reinforced by a Universal Control Framework that appears on every controlled document, form, and record. This ensures that users are constantly reminded of their obligations and have immediate access to the information and actions needed to maintain compliance.

KEY CAPABILITIES

Comprehensive AI System Oversight

Maintain a complete, up-to-date inventory of all AI systems with rich contextual information. Every quality management system activity, risk assessment, audit, and monitoring record is anchored to specific AI systems, creating clear lines of accountability.

Structured Governance and Management

Apply consistent frameworks for both high-level governance principles and day-to-day management practices. The system supports detailed documentation of strategies, risk controls, ethical considerations, and operational responsibilities while maintaining clear separation between governance and management concerns.

Rigorous Audit and Assurance

Conduct structured audits using predefined programmes that can be tailored to different risk profiles and domains.

When an audit is activated, the system captures a complete snapshot of the programme at that moment. This ensures that findings are always evaluated against the criteria that were in force at the time of the audit – providing strong defensibility.

The online audit environment allows teams to record findings, apply consistent scoring, document conclusions, and advance the work through a clear status workflow. Once approved, audits can be formally signed, locking the record and generating cryptographic evidence of completion.

Continuous Monitoring and Post-Market Surveillance

Go beyond one-time assessments. The system supports ongoing collection and analysis of operational data, detection of performance issues or unexpected behaviours, and structured management of incidents and feedback.

This capability is essential for fulfilling post-market monitoring obligations and for maintaining an accurate picture of real-world AI system performance and impact.

Integrated Risk and Change Control

Risk management is not a separate silo. Risks are identified, evaluated, and treated within the same environment used for quality management, auditing, and monitoring.

All significant changes — whether to AI systems themselves or to the policies and controls that govern them — flow through a centralized quality management process. Administrative and configuration changes are themselves treated as controlled QMS events, creating a complete audit trail of how the governance system itself evolves.

Evidence, Documentation and Integrity

The system excels at generating and preserving high-quality evidence.

- Complete snapshots of governing structures are retained with each audit or assessment.
- Cryptographic techniques protect the integrity of evidence packages.
- Attachments and supporting materials are managed alongside structured records.
- Evidence can be exported in formats suitable for regulatory submission, internal review, or long-term archival.

A dedicated records and evidence capability helps ensure that all mandatory and supporting documentation is created, maintained, and made available when needed.

Secure External Engagement

Not all relevant input comes from inside the organization. The system includes a controlled external portal that allows deployers, users, and other stakeholders to submit feedback, observations, or evidence in a secure, auditable manner.

This capability supports genuine post-market monitoring while protecting the integrity of the overall QMS through rate limiting, validation, and proper linkage to internal records.

Advanced Analysis and Integrity Assurance

The platform incorporates sophisticated analysis capabilities that can process operational logs, detect various forms of drift, model system behaviour over time, and map observed events to required controls.

Support for content provenance through watermarking technologies adds another layer of assurance, particularly valuable for generative AI applications.

BENEFITS FOR ORGANISATIONS

Regulatory Readiness

Demonstrate compliance with EN 18286, the EU AI Act (including post-market monitoring and fundamental rights obligations), ISO/IEC 13485, and related standards through structured processes and readily available evidence.

Operational Confidence

Provide teams with clear workflows, consistent tools, and immediate visibility into the status of quality management activities, risks, audits, and changes.

Stakeholder Trust

Build credibility with regulators, customers, users, and the public by maintaining transparent, well-documented, and independently verifiable practices.

Efficiency and Consistency

Eliminate fragmented approaches. The same five quality management processes, the same control language, and the same evidence standards apply whether the activity is QMS documentation, an audit, a monitoring event, or a change.

Defensibility

When questions arise — from internal audit, external certification, or regulatory inquiry — the organization can quickly produce complete, timestamped, and cryptographically protected records.

How the System Supports the Full AI Lifecycle

The AI Quality Management System is designed to remain relevant from initial conception through development, deployment, operation, and eventual decommissioning or significant modification.

- During development and initial deployment, quality management system and risk assessments establish the foundation.
- At the point of significant release or change, formal change control and updated risk evaluations are applied.
- During operation, monitoring, auditing, and incident management provide continuous oversight.
- When issues arise, nonconformity processes and corrective actions ensure timely response.
- Throughout, evidence is generated and preserved, and all activities remain traceable to the specific AI systems involved.

A System Built for Accountability

At its heart, this AI Quality Management System is about accountability — to the people whose lives are affected by AI, to regulators, to business stakeholders, and to society at large.

By embedding the protection of health, safety, and fundamental rights into the daily operation of the QMS — through consistent processes, rich traceability, strong evidence practices, and rigorous change control — the system helps organizations move from aspiration to demonstrable, sustainable practice.

Target Users

- AI System Providers & Manufacturers
- Deployers of High-Risk AI Systems
- Quality & Compliance Managers
- Risk & Data Protection Officers
- Legal & Regulatory Affairs Teams
- Internal Auditors & Conformity Coordinators
- Notified Bodies & Consultants

Availability

The Quality Management System is delivered as a secure, cloud-based SaaS platform with enterprise-grade security, regular updates, and dedicated support.

Ready to Accelerate Your EU AI Act Compliance?

Book a personalized demonstration today and discover how we can transform your risk management process and accelerate your journey to EU AI Act conformity.

Contact Us

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Your trusted partner for responsible, compliant, and ethical AI deployment in the European Union.