



**AI Assurance
Institute**

AI Risk Management System Solution

One Unified Platform.
Full Conformity with the prEN 18228.

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The Requirement

Under the EU AI Act (Regulation 2024/1689), providers of high-risk AI systems must establish, implement, document, and maintain a risk management system throughout the entire AI system life cycle, as mandated by Article 9. This system must systematically identify, analyse, evaluate, and mitigate risks to health, safety, and fundamental rights, taking into account the specific characteristics of the AI system—including its level of autonomy, adaptiveness, and potential for emergent behaviours.

The risk management system must be aligned with the draft European harmonized standard prEN 18228 (“AI Risk Management Systems”), which provides the detailed technical framework for continuous, lifecycle-spanning risk management. Compliance with prEN 18228 can result in a presumption of conformity with Article 9 obligations, covering hazard identification, risk estimation and evaluation, risk control measures, residual risk acceptance, and ongoing post-market monitoring.

The Solution

The AI Assurance Institute’s AI Risk Management System Platform is a purpose-built solution that fully implements prEN 18228 and delivers complete, audit-ready conformity with Article 9 of the EU AI Act in a single, integrated environment.

Designed specifically for providers of high-risk AI systems, the platform automates the full risk management lifecycle—from initial hazard identification through risk control implementation to continuous post-market reassessment. It generates comprehensive, regulator-ready Risk Management Files and provides real-time visibility into evolving risks, ensuring your AI systems remain safe, trustworthy, and compliant throughout their operational life.

Key Capabilities

1. AI Risk Management System (prEN 18228 + Article 9)

- Automated process for identification of hazards and development of comprehensive risk scenarios, explicitly accounting for AI-specific factors such as autonomy, adaptiveness, self-learning capabilities, and potential emergent behaviours
- Systematic risk estimation, evaluation, and prioritization using both quantitative (e.g., severity × probability) and qualitative methods tailored to the unique risk profile of AI systems
- Definition, justification, and documentation of risk acceptability criteria with objective evidence, stakeholder consultation, and alignment to fundamental rights impact assessments
- Implementation of the complete risk control hierarchy—inherent design measures, protective safeguards, and information for use—with full bidirectional traceability to requirements, verification activities, and validation evidence
- Rigorous evaluation of overall residual risk, including cumulative and combined effects, foreseeable misuse scenarios, and direct assessment of impacts on health, safety, and fundamental rights
- Automated generation, versioning, and maintenance of the complete Risk Management File, including risk management plan, risk analysis reports, control traceability matrices, and residual risk acceptance records
- Seamless integration of post-market monitoring data, incident reports, and performance metrics to trigger dynamic risk reassessment and system updates
- Built-in support for human oversight requirements and consideration of the system's level of autonomy when determining risk mitigation strategies

2. Traceability, Documentation & Audit Readiness

- End-to-end, immutable traceability linking every identified hazard through risk controls to residual risk acceptance and verification evidence
- Version-controlled documentation with comprehensive audit trails, electronic signatures, and role-based approval workflows aligned to prEN 18228 requirements
- Automated mapping of all risk management activities to specific clauses of prEN 18228 and obligations under Article 9 of the EU AI Act
- One-click generation of regulator-ready Risk Management Files, technical documentation summaries, and instructions for use with embedded risk information

3. Continuous Risk Assurance & Post-Market Integration

- Real-time risk dashboards displaying current risk status, open issues, and trend analysis with intelligent alerts for new hazards, threshold breaches, or significant system changes
- Closed-loop post-market feedback integration, automatically incorporating operational data, user reports, and incident notifications into the risk management process
- Scheduled and event-triggered risk management reviews with automated recommendations for updates when new evidence or system modifications arise
- Support for bias, robustness, and adversarial testing outputs as inputs to the risk analysis, ensuring comprehensive coverage of AI-specific vulnerabilities

Why Choose the AI Assurance Institute Risk Management Platform?

Benefit	How We Deliver it
Single Source of Truth for Risk	One integrated platform fully implementing all prEN 18228 requirements with complete lifecycle coverage
Audit-Ready Risk Management File	Automatically generated, regulator-ready documentation with full traceability and clause mapping to Article 9 and prEN 18228
Reduce Compliance Burden	Significant time savings through automation of risk identification, analysis, control implementation, and documentation workflows
Continuous Risk Assurance	Real-time monitoring dashboards with post-market feedback integration and dynamic risk reassessment capabilities
Focus on Protection	Built-in tools specifically designed for assessing impacts on health, safety, and fundamental rights throughout the AI lifecycle
Future-Proof Compliance	Regular platform updates aligned with the latest version of prEN 18228, harmonized standards, and evolving regulatory guidance

Who It's For

- Providers of high-risk AI systems that require a robust, standards-aligned risk management system
- Organizations seeking to demonstrate conformity with Article 9 of the EU AI Act through compliance with prEN 18228
- Companies looking to implement an auditable, lifecycle-spanning risk management process efficiently and at scale
- AI development and compliance teams needing integrated tools for hazard analysis, risk control, residual risk evaluation, and continuous monitoring

How It Works

1. **Onboarding** - Import your AI system details, intended purpose, technical characteristics (including autonomy and adaptiveness levels), and known operational context
2. **Risk Identification** - Guided and automated workflows for comprehensive hazard identification and risk scenario development aligned with prEN 18228 methodologies
3. **Risk Analysis & Evaluation** - Step-by-step processes for risk estimation, definition of acceptability criteria, prioritization, and fundamental rights impact consideration
4. **Risk Control Implementation** - Selection and documentation of controls according to the risk control hierarchy, with built-in traceability and verification tracking
5. **Documentation & Review** - One-click generation of the complete Risk Management File, management review packages, and regulatory submission-ready artifacts
6. **Continuous Monitoring** - Ongoing post-market risk tracking with intelligent alerts, automated reassessment triggers, and integration of operational feedback for lifecycle compliance

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Trusted by Forward-Thinking AI Providers

The AI Assurance Institute Risk Management Platform will provide competitive advantage, protect health, safety, and fundamental rights, and maintain full EU AI Act conformity with confidence, efficiency, and audit readiness.

Ready to Accelerate Your EU AI Act Compliance?

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

Contact Us

Email: info@aiassurance.institute

Phone: +353 89 277 7844

Website: www.aiassurance.institute

AI Risk Management System Platform

Conformity. Simplified. Rigorous. Future-Ready