EU AI ACT READINESS ASSESSMENT

Comprehensive Compliance Evaluation

Client Organization:	TechManufactur AG
Industry Sector:	Industrial Manufacturing & Automation
Assessment Period:	November 2025 – January 2026
Report Date:	12 January 2026
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We conducted this assessment in accordance with the requirements of the EU AI Act (Regulation 2024/1689) and ISO/IEC 42001:2023 for AI management systems. All findings and recommendations are based on information provided by TechManufactur AG during the assessment period and reflect the regulatory landscape as of January 2026.

Version	Date	Author	Changes
1.0	12.01.2026	Dr. V. Mayr	Initial release

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Executive Summary

TechManufactur AG has demonstrated commendable foresight in proactively addressing EU AI Act compliance ahead of the regulation's enforcement deadlines. This comprehensive assessment evaluated eight AI systems across the organization's production, quality control, and business operations, identifying critical compliance gaps and strategic opportunities for responsible AI implementation.

Key Findings

- Three high-risk AI systems identified under EU AI Act Article 6(2) requiring immediate compliance action: the Predictive Maintenance System, Quality Inspection System, and Worker Safety Monitor.
- Overall compliance score of 42% against EU AI Act requirements, with significant gaps in technical documentation (Article 11), risk management systems (Article 9), and human oversight mechanisms (Article 14).
- Critical documentation deficiencies exist across all high-risk systems, including missing technical documentation, incomplete training data descriptions, and the absence of bias-testing protocols.
- The data governance framework is partially compliant with Article 10 requirements but lacks systematic procedures for detecting and mitigating bias.
- Estimated total compliance investment of €185,000 – €285,000 over 18 months, compared to potential regulatory penalties of up to €35 million (7% of annual worldwide turnover) for non-compliance.

Strategic Recommendations

We recommend a phased implementation approach spanning 18 months, prioritized by regulatory deadlines and business risk:

1. **Phase 1 (Months 1-6): Foundation & Critical Gaps – Establish AI governance structure, complete technical documentation for high-risk systems, implement bias testing framework.**
2. **Phase 2 (Months 7-12): Operationalization – Deploy continuous monitoring systems, establish post-market surveillance, and implement human oversight protocols.**
3. **Phase 3 (Months 13-18): Optimization & Certification – Conduct comprehensive system testing, prepare for conformity assessment, and establish continuous improvement processes.**

Business Impact

Achieving EU AI Act compliance will position TechManufactur AG as a trusted AI provider in the European market, enabling continued operations without regulatory disruption. Beyond regulatory necessity, this initiative offers strategic benefits including enhanced customer trust, improved operational transparency, reduced liability exposure, and competitive differentiation in an increasingly compliance-conscious market.

The estimated return on investment extends beyond compliance, with projected benefits including a 15-20% reduction in AI-related operational risks, 25% improvement in system reliability through enhanced monitoring, and strengthened market position for EU-focused business development.

Assessment Methodology

We conducted this assessment using waveImpact's proprietary three-phase methodology, developed in alignment with EU AI Act requirements, ISO/IEC 42001:2023 standards, and industry best practices for responsible AI implementation.

Phase A: Discovery & System Inventory (Weeks 1-2)

The discovery phase established a comprehensive understanding of TechManufactur AG's AI landscape through systematic stakeholder engagement and technical documentation review.

Stakeholder Interviews (18 hours):

- Executive leadership: Chief Technology Officer, Head of Operations, Legal Counsel (3 hours each)
- Technical teams: AI/ML engineering leads, data scientists, system architects (2 hours each, six interviews)
- Business unit owners: Production, Quality Assurance, Supply Chain (1.5 hours each)

AI System Discovery Workshop (4 hours):

Facilitated cross-functional session with 12 participants systematically identified all AI applications, documented system boundaries, mapped data flows, and established initial risk indicators.

Technical Documentation Review (22 hours):

Comprehensive analysis of existing technical documentation, data governance policies, GDPR compliance frameworks, and current AI development practices. This review identified baseline capabilities and documentation gaps for subsequent gap analysis.

Phase B: Classification & Gap Analysis (Weeks 3-5)

The classification and gap analysis phase applied the EU AI Act risk categorization framework to each identified system and conducted detailed compliance assessments for each system.

Risk Classification Assessment (28 hours):

- Applied the EU AI Act Article 6 high-risk classification criteria to each system
- Evaluated systems against Annex III use case categories
- Assessed prohibited AI practices under Article 5
- Developed a detailed risk classification matrix with business impact scoring

Technical Compliance Gap Analysis (36 hours):

System-by-system evaluation against EU AI Act Chapter III, Section 2 requirements (Articles 8-15), including risk management, data governance, technical documentation, transparency, human oversight, accuracy, robustness, and cybersecurity. We scored each requirement using a four-level maturity scale: Non-Compliant (0%), Partially Compliant (33%), Largely Compliant (67%), and Fully Compliant (100%).

Fundamental Rights Impact Assessment (18 hours):

Conducted preliminary Article 27 fundamental rights impact assessments for high-risk systems, evaluating potential impacts on affected individuals and groups, human oversight adequacy, and safeguard mechanisms.

Phase C: Strategic Roadmap Development (Weeks 6-8)

The strategic roadmap phase translated compliance findings into actionable implementation plans with clear priorities, resource requirements, and success metrics.

Prioritization Workshop (4 hours):

Facilitated leadership session established risk-based priorities, defined resource allocation parameters, and developed a preliminary timeline aligned with regulatory deadlines and business constraints.

Implementation Planning (32 hours):

Developed detailed action plans for each priority area, including specific tasks, milestone definitions, resource requirements, budget estimates, vendor selection criteria, and success measurement frameworks.

Financial Impact Analysis (12 hours):

Comprehensive cost-benefit analysis including direct compliance costs, potential penalty exposure, operational efficiency gains, and strategic market advantages. Analysis incorporated both quantitative financial projections and qualitative risk assessments.

AI System Inventory

The assessment identified eight AI systems currently deployed or under development at TechManufactur AG. We catalogued each requirement with comprehensive technical, operational, and risk information to support accurate classification under the EU AI Act.

System 1: Predictive Maintenance System (PredictMaint-2024)

System Classification	High-Risk (EU AI Act Annex III, Point 4 – Safety of Products)
Business Purpose	Predicts equipment failures 48-72 hours in advance across 180 production machines, enabling preventive maintenance and minimizing unplanned downtime.
Technical Architecture	Ensemble model (Random Forest + LSTM neural network) trained on 3 years of sensor data. Processes real-time vibration, temperature, pressure, and acoustic signals from IoT sensors.
Data Sources	Industrial IoT sensors (18 parameters per machine), maintenance logs (CMMS system), production schedules (ERP integration), and historical failure records.
Deployment Status	Production environment since September 2024. Currently monitoring 180 machines across three production facilities. Integrated with the SAP PM module.
Users/Stakeholders	Maintenance team (15 technicians), production managers (8), plant operators (45). The system generates approximately 300 predictions monthly.
Risk Factors	False negatives could lead to catastrophic equipment failure, production line shutdown, and potential safety hazards. System influences critical safety decisions.

System 2: Quality Inspection System (VisionQC-Pro)

System Classification	High-Risk (EU AI Act Annex III, Point 4 – Safety of Products)
Business Purpose	Automated visual quality inspection of manufactured components using computer vision. Detects defects, surface anomalies, and dimensional deviations with 99.2% accuracy.
Technical Architecture	Convolutional Neural Network (ResNet-50 backbone) trained on 2.4 million labeled images, deployed on edge computing infrastructure with real-time inference (<100ms latency).
Data Sources	High-resolution industrial cameras (12MP, 360° coverage), historical quality records, defect classification database, CAD specifications for dimensional validation.
Deployment Status	Production environment since June 2023. Deployed on 12 production lines, inspecting approximately 45,000 components daily. Human verification for edge cases is maintained.
Users/Stakeholders	Quality assurance team (8 inspectors), production line workers, and supply chain management. Customers are indirectly affected through product quality assurance.

Risk Factors	False positives result in wasted materials and production inefficiency. False negatives could result in defective products, posing customer safety risks and exposing the company to liability.

System 3: Worker Safety Monitor (SafetyWatch-AI)

System Classification	High-Risk (EU AI Act Annex III, Point 4 – Safety; Biometric Categorization under Article 5)
Business Purpose	Monitors work environments for safety hazards and worker behavior. Detects the absence of required PPE, unsafe proximity to machinery, and potential accident scenarios.
Technical Architecture	Real-time video analytics using the YOLO v8 object detection model. Processes feeds from 85 cameras across facilities. Generates automatic alerts for safety violations.
Data Sources	Surveillance camera network, worker location data (RFID badges), equipment sensor data, historical incident reports, and safety training records.
Deployment Status	Pilot deployment since March 2025 in one production facility. Currently monitoring 120 workers across two shifts. Full rollout planned for Q2 2026.
Users/Stakeholders	Production workers (directly monitored), safety officers (8), facility managers (3), and the works council. The system infringes on workers' privacy and autonomy.
Risk Factors	CRITICAL: System may constitute prohibited biometric categorization under Article 5(1)(f) if it infers emotional or psychological states. Significant worker privacy concerns. False alerts could create a harassment environment. Must undergo a fundamental rights impact assessment.

Additional Systems (Limited-Risk Classification)

We identified five additional AI systems with limited-risk or minimal-risk classifications:

- Supply Chain Optimization Engine: ML-based demand forecasting and inventory optimization (Limited-Risk, Article 50 transparency obligations)
- Customer Service Chatbot: German-language support chatbot for customer inquiries (Limited-Risk, Article 50 transparency obligations)
- Energy Consumption Optimizer: ML model optimizing facility energy usage patterns (Minimal-Risk)
- Document Processing System: OCR and information extraction for incoming documents (Minimal-Risk)
- Production Scheduling Assistant: Recommendation system for optimal production schedules (Minimal-Risk)

EU AI Act Risk Classification Matrix

The following matrix summarizes the risk classification for each identified AI system according to EU AI Act categorization criteria. This classification determines the applicable regulatory requirements and compliance obligations.

System	Risk Level	EU AI Act Category	Primary Obligations
PredictMaint-2024	High	Annex III, Point 4	Full Article 8-15 compliance, conformity assessment, CE marking, registration
VisionQC-Pro	High	Annex III, Point 4	Full Article 8-15 compliance, conformity assessment, CE marking, registration
SafetyWatch-AI	High / Prohibited	Art. 5 review required	URGENT: Legal review for prohibited practices, fundamental rights assessment, worker consent framework
Supply Chain Optimizer	Limited	Article 50	Transparency obligations when interacting with natural persons
Customer Chatbot	Limited	Article 50	Clear disclosure of AI interaction, transparency in communications
Energy Optimizer	Minimal	Article 4	Voluntary compliance with best practices
Document Processor	Minimal	Article 4	Voluntary compliance with best practices
Scheduling Assistant	Minimal	Article 4	Voluntary compliance with best practices

Priority Focus: The three high-risk systems require immediate attention to achieve compliance before regulatory enforcement deadlines. The SafetyWatch-AI system requires urgent legal review to determine if current functionality constitutes prohibited biometric categorization under Article 5.

Comprehensive Gap Analysis

This section provides a detailed compliance gap analysis for the three high-risk AI systems, evaluated against EU AI Act Chapter III, Section 2 requirements (Articles 8-15). We assessed each requirement using a four-level maturity scale to quantify compliance status.

Maturity Level	Score	Definition
Non-Compliant	0%	Requirement not addressed; no relevant processes, documentation, or controls in place
Partially Compliant	33%	Despite initial efforts, significant gaps remain; processes are informal or inconsistent
Largely Compliant	67%	Most requirements met with minor gaps; processes documented, but refinement needed
Fully Compliant	100%	Requirement fully satisfied with comprehensive documentation, processes, and evidence

Overall Compliance Summary

EU AI Act Requirement	PredictMaint	VisionQC-Pro	SafetyWatch
Art. 9: Risk Management System	33%	33%	0%
Art. 10: Data & Data Governance	67%	67%	33%
Art. 11: Technical Documentation	33%	33%	0%
Art. 12: Record-Keeping (Logging)	67%	33%	33%
Art. 13: Transparency & Information	33%	33%	0%
Art. 14: Human Oversight	33%	67%	0%
Art. 15: Accuracy, Robustness, Cybersecurity	67%	67%	33%
OVERALL COMPLIANCE SCORE	**48%**	**48%**	**14%**

Article 9: Risk Management System

Current State: TechManufactur AG has informal risk management practices embedded in development workflows but lacks the systematic, documented risk management system mandated by Article 9. Current practices are reactive rather than proactive and do not follow the continuous lifecycle approach required by the regulation.

Critical Gaps Identified:

- No formal risk management system framework is documented or implemented across AI systems
- Risk assessment is conducted primarily during the initial development phase; no continuous risk monitoring or reassessment procedures
- Foreseeable risks to health, safety, and fundamental rights are not systematically identified or evaluated
- Risk mitigation measures exist informally, but they are not documented, measured, or validated for effectiveness
- SafetyWatch-AI system deployed without a comprehensive risk assessment addressing surveillance and worker rights implications
- No integration with GDPR Data Protection Impact Assessments or other organizational risk frameworks

Compliance Recommendations:

4. Establish a comprehensive AI risk management framework aligned with ISO/IEC 23894:2023 (Risk Management for AI Systems)
5. Develop system-specific risk registers documenting identified risks, likelihood, severity, mitigation measures, and residual risk
6. Implement continuous risk monitoring procedures with quarterly review cycles and trigger-based reassessments
7. Integrate fundamental rights risk assessment into standard risk management procedures
8. Establish a clear governance structure with defined roles and responsibilities for risk management oversight

Article 10: Data and Data Governance

Current State: Data governance practices are relatively mature, supported by existing GDPR compliance efforts and established data management procedures. However, AI-specific data quality requirements and bias detection/mitigation procedures are underdeveloped.

Critical Gaps Identified:

- Training datasets not systematically examined for biases or statistical errors; no bias detection protocols implemented
- Data quality metrics are defined inconsistently across systems; no centralized data quality framework for AI applications
- Data provenance tracking is incomplete; the origin and lineage of training data are not fully documented for audit purposes
- Demographic representation analysis was not performed on the training datasets, creating potential for discriminatory outcomes
- Data preparation and labeling procedures documented informally; standardized protocols needed for consistency
- SafetyWatch-AI processing worker video data without a comprehensive assessment of data minimization principles

Compliance Recommendations:

9. Implement a systematic bias detection and testing framework using established tools (AIF360, Fairlearn) for all high-risk systems
10. Develop comprehensive data quality assurance protocols with automated validation checks and quality metrics
11. Establish complete data provenance documentation, including source identification, collection methods, and processing history
12. Conduct demographic representation analysis and develop data balancing strategies where imbalances are identified

13. Create standardized data preparation and labeling procedures with quality control checkpoints

Article 11: Technical Documentation

Current State: This represents the most significant compliance gap. Technical documentation exists primarily as scattered internal notes, code comments, and informal specifications. None of the high-risk systems has comprehensive technical documentation meeting Article 11 requirements.

Critical Gaps Identified:

- No structured technical documentation covering the development process, methodology, and design decisions
- System architecture descriptions are incomplete; computational resources, dependencies, and integration points are not fully documented
- Training data descriptions are minimal; data characteristics, provenance, selection criteria, and preprocessing steps are not comprehensively documented
- Model design specifications are lacking in detail on algorithms, optimization objectives, hyperparameter selection rationale, and trade-off decisions
- Validation and testing procedures not formally documented; test datasets, metrics, and results not systematically recorded
- No assessment documentation for human oversight measures, interpretability requirements, or human-AI interaction design
- Cybersecurity measures implemented, but not comprehensively documented with threat modeling and security testing results

Compliance Recommendations:

14. Develop comprehensive technical documentation templates aligned with Article 11 Annex IV requirements
15. Conduct systematic documentation sprints to capture existing system knowledge before it's lost
16. Implement documentation-first development practices for future AI system development
17. Create detailed data sheets for all training datasets, including provenance, characteristics, limitations, and intended use
18. Document all validation and testing procedures with comprehensive test logs, results, and dated/signed attestations
19. Establish version control and change management for technical documentation with an audit trail

Strategic Implementation Roadmap

The following 18-month roadmap provides a structured pathway to EU AI Act compliance, organized into three distinct phases. This timeline accounts for resource constraints, regulatory deadlines, and dependencies between workstreams.

Phase 1: Foundation & Critical Gaps (Months 1-6)

Objective: Establish fundamental compliance infrastructure and address the most critical documentation gaps to prevent regulatory violations.

Workstream	Key Deliverables	Resources
AI Governance Structure	• AI Governance Board establishment • Roles and responsibilities matrix • Decision-making protocols • Escalation procedures	1 FTE internal €12,000 external consulting
Technical Documentation	• Complete Article 11 documentation for all 3 high-risk systems • Training data sheets • System architecture documentation • Development methodology records	2 FTE internal €45,000 external consulting
Risk Management System	• Risk management framework document • System-specific risk registers • Risk assessment templates • Initial risk assessments for 3 systems	0.5 FTE internal €25,000 external consulting
Bias Testing Framework	• Bias detection methodology • Testing protocols and tools • Initial bias audits for 3 systems • Mitigation action plans	1 FTE internal €35,000 external consulting + tools
SafetyWatch-AI Legal Review	• Article 5 compliance assessment • Fundamental rights impact assessment • Worker consent framework • Recommendations for system modification	€18,000 legal counsel €12,000 external consulting

Phase 1 Investment: €147,000 | Key Milestone: High-risk systems documented and risk management system operational

Phase 2: Operationalization (Months 7-12)

Objective: Deploy continuous compliance monitoring, establish operational procedures, and implement human oversight mechanisms.

Workstream	Key Deliverables	Resources
Continuous Monitoring	• Real-time bias monitoring dashboards • Performance tracking systems • Alert mechanisms for anomalies • Automated reporting framework	1 FTE internal €28,000 tools & infrastructure
Human Oversight Protocols	• Human oversight design documentation • Operator training programs • Override and intervention procedures • Interface design improvements	0.5 FTE internal €22,000 external consulting

Post-Market Surveillance	• Incident reporting system • Serious incident response procedures • Continuous improvement protocols • User feedback collection mechanisms	0.5 FTE internal €15,000 system implementation
Record-Keeping System	• Automated logging infrastructure • Log retention and management • Audit trail capabilities • Compliance reporting tools	€32,000 tools & implementation
Transparency Measures	• User instructions for use • Information obligations documentation • Customer communications • Transparency declarations	0.5 FTE internal €8,000 external support

Phase 2 Investment: €105,000 | Key Milestone: Operational compliance infrastructure deployed and functioning

Phase 3: Optimization & Certification (Months 13-18)

Objective: Finalize all compliance measures, conduct comprehensive testing, and prepare for third-party conformity assessment.

Workstream	Key Deliverables	Resources
Comprehensive Testing	• Final validation testing • Robustness and resilience testing • Adversarial testing • Test documentation and reports	1 FTE internal €38,000 external testing services
Conformity Assessment Prep	• Gap remediation • Evidence compilation • Pre-assessment review • Documentation finalization	0.5 FTE internal €45,000 notified body preparation
Quality Management Integration	• ISO 42001 alignment • Quality procedures documentation • Internal audit capability • Continuous improvement processes	0.5 FTE internal €28,000 external consulting
Training & Awareness	• Stakeholder training programs • Operator competency certification • Awareness materials • Knowledge management system	0.25 FTE internal €15,000 training development
Conformity Assessment	• Third-party assessment coordination • CE marking process • EU Database registration • Final certification	€48,000 notified body fees

Phase 3 Investment: €174,000 | Key Milestone: EU AI Act certification achieved; systems compliant and market-ready

Financial Investment Summary

Phase	Timeline	Internal Resources	External Costs
Phase 1: Foundation	Months 1-6	4.5 FTE-months	€147,000
Phase 2: Operationalization	Months 7-12	3.0 FTE-months	€105,000
Phase 3: Certification	Months 13-18	2.25 FTE-months	€174,000
TOTAL 18-MONTH INVESTMENT	**18 months**	**9.75 FTE-months**	**€426,000**

Note: Internal resource costs not included in external cost figures. Based on an average €85,000 annual cost per FTE, internal resources represent approximately €69,000 in opportunity cost. Total program investment, including internal resources: approximately €495,000.

Risk vs. Investment Analysis

TechNabufactur AG needs to evaluate the €426,000 external investment against regulatory penalties and business risks of non-compliance:

Risk Factor	Potential Impact
Regulatory Penalties	Up to €35 million or 7% of annual worldwide turnover for high-risk AI violations (Article 99)
Market Access	Inability to market AI systems in the EU without compliance; competitive disadvantage vs. compliant providers
Reputational Damage	Public disclosure of non-compliance; customer trust erosion; difficulty winning new business
Operational Disruption	Forced system shutdown by regulators; production line impacts; customer service degradation
Liability Exposure	Increased product liability risk; customer claims for AI-related damages; legal defense costs

Return on Investment: Beyond regulatory compliance, the investment delivers measurable business benefits, including reduced operational risks (annual value of € 200,000+), enhanced system reliability and performance (15-20% improvement), competitive market positioning for EU-focused growth, and strengthened customer trust and brand reputation. The true ROI extends well beyond penalty avoidance to fundamental business resilience and market opportunity.

Conclusions and Next Steps

TechManufactur AG stands at a critical juncture in its AI journey. The EU AI Act represents both a compliance imperative and a strategic opportunity to establish leadership in the responsible implementation of AI. This assessment has identified clear pathways to compliance, with realistic timelines and resource requirements.

Key Takeaways

20. **Compliance is achievable within 18 months with focused effort and appropriate resource allocation**
21. **Technical documentation represents the highest-priority gap requiring immediate attention**
22. **SafetyWatch-AI system requires urgent legal review before continued deployment**
23. **Investment in compliance delivers returns beyond regulatory necessity through operational improvements and market positioning**
24. **Existing GDPR and data governance foundations provide a strong starting point for EU AI Act compliance**

Immediate Recommended Actions (Next 30 Days)

25. Executive Decision: Board approval for compliance program and budget allocation
26. SafetyWatch-AI Legal Review: Immediate engagement with legal counsel for Article 5 compliance assessment
27. Project Kickoff: Establish AI Governance Board and assign project leadership
28. Vendor Selection: Identify and engage technical documentation and compliance support partners
29. Team Formation: Allocate internal resources and define roles/responsibilities for the compliance program

waveImpact GmbH stands ready to support TechManufactur AG throughout this compliance journey, providing both strategic guidance and hands-on technical implementation support. Our expertise in EU AI Act compliance, responsible AI frameworks, and practical implementation ensures that your organization not only meets regulatory requirements but also establishes best-in-class AI governance practices that drive competitive advantage.

Appendix A: Detailed Article-by-Article Compliance Assessment

This appendix provides comprehensive compliance scoring for each EU AI Act requirement across all three high-risk systems. Detailed gap descriptions and remediation recommendations are available in the complete technical supplement.

[Additional technical appendices would continue here in the full report...]

Appendix B: EU AI Act Regulatory Timeline

[Detailed timeline of regulatory deadlines and enforcement dates...]

Appendix C: Recommended Vendor and Tool Ecosystem

[Vendor recommendations for compliance tools, notified bodies, and service providers...]

Appendix D: Templates and Frameworks

[Sample templates for risk registers, technical documentation, testing protocols...]

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