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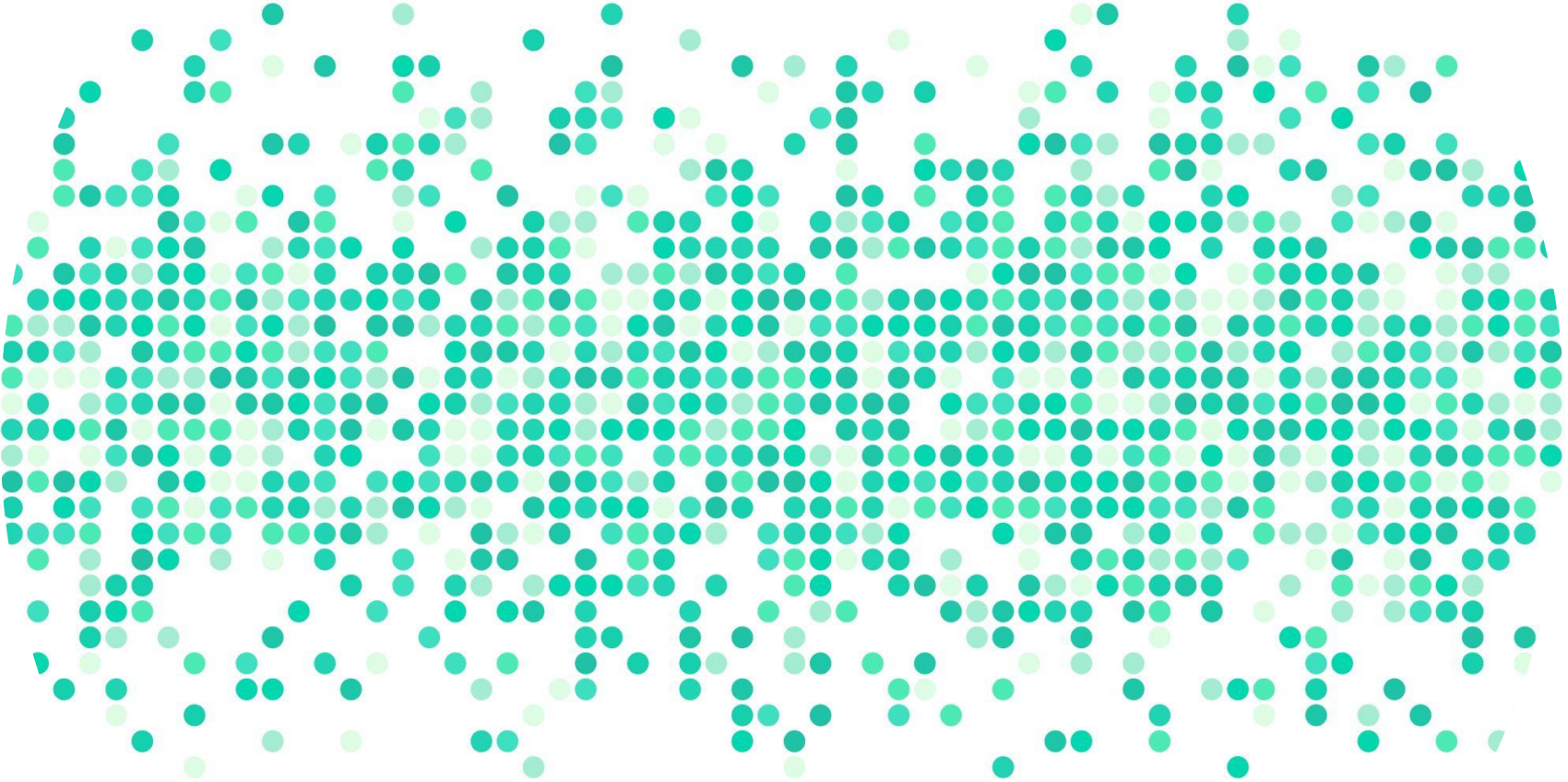

The European Union Artificial Intelligence Act

Green Guide

Guidance on Implementation

August 2024

About

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About AI & Partners

'AI That You Can Trust' - Your trusted advisor for EU AI Act Compliance. Unlock the full potential of artificial intelligence while ensuring compliance with the EU AI Act by partnering with AI & Partners, a leading professional services firm. We specialise in providing comprehensive and tailored software solutions for companies subject to the EU AI Act, guiding them through the intricacies of regulatory requirements and enabling responsible and accountable AI practices. At AI & Partners, we understand the challenges and opportunities that the EU AI Act presents for organisations leveraging AI technologies. Our team of seasoned experts combines in-depth knowledge of AI systems, regulatory frameworks, and industry specific requirements to deliver strategic guidance and practical solutions that align with your business objectives.

To find out how we can help you, email contact@ai-and-partners.com or visit https://www.ai-and-partners.com.

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What is the Green Guide?

The EU AI Act Green Guide is a comprehensive document that provides detailed guidance on the implementation of the AI Act. This guide aims to ensure consistency, clarity, and ease of compliance for stakeholders.

It is designed to ensure the safe and ethical development, deployment, and use of AI systems within the European Union. The Green Guide offers clear, practical, and comprehensive guidance to all stakeholders, ensuring effective and consistent implementation of the AI Act across the Union.

This is based on the @European Commission's Blue Guide on the implementation of the product rules 2022'. This is accessible at: https://single-market-economy.ec.europa.eu/news/blue-guide-implementation-product-rules-2022-published-2022-06-29_en.

Content

Product Safety: The Green Guide contains information on provisions that help AI stakeholders better navigate the complex landscape of EU regulations, ensuring their AI products are compliant and safe for the market.

AIvoiding redundancy, maximising adherence

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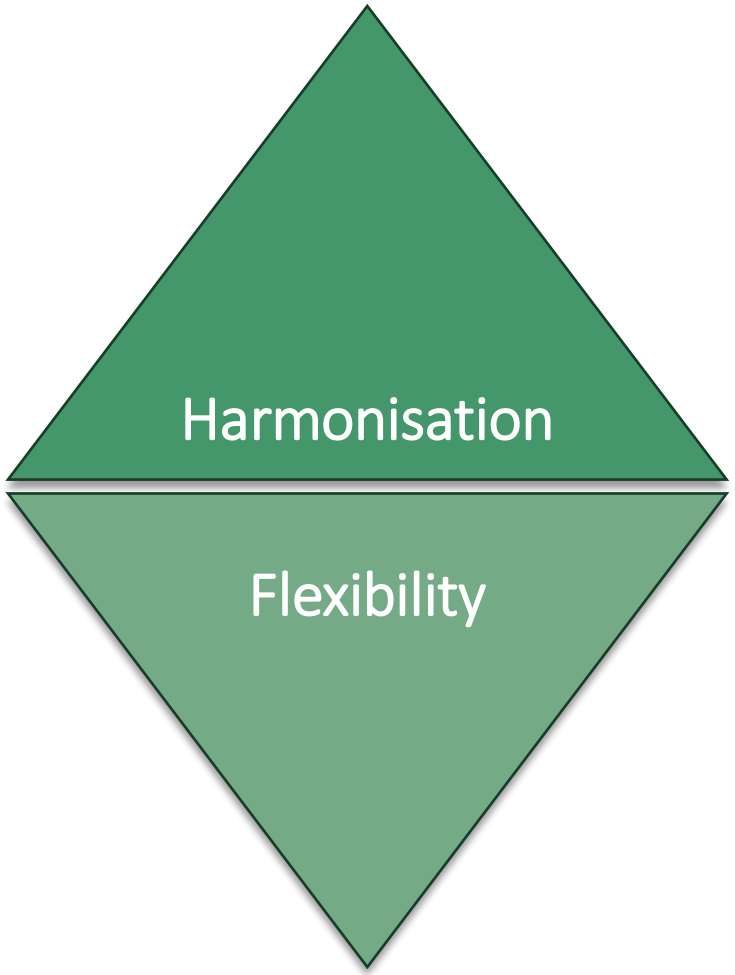

Importance
Harmonizing AI regulations with existing Union legislation is crucial to avoid redundancy and ensure comprehensive compliance.

Consistency
Ensures that AI systems comply with all applicable Union harmonization legislation, promoting a unified regulatory framework.

Reference
The EU AI Act emphasizes the need for consistency with other Union laws to protect public interests such as health, safety, and fundamental rights.

Integration
Providers are allowed flexibility to integrate necessary testing, reporting, and documentation processes with existing procedures under other Union harmonization legislation.

Optimisation
This approach helps in optimizing compliance efforts, reducing administrative burdens, and fostering innovation.

Reference
The Act allows for the integration of AI-specific requirements with existing regulatory frameworks, ensuring that providers can efficiently meet all necessary standards.

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High-Risk AI Systems

Requirements

- **Risk Management**: High-risk AI systems must have a robust risk management system in place, identifying and mitigating potential risks throughout the lifecycle.
- **Data Governance**: Ensure high standards of data quality and integrity, complying with data protection regulations.
- **Transparency**: High-risk AI systems must be transparent, providing clear information on their capabilities, limitations, and the data used.

Compliance

Step-by-step instructions

1. **Risk Assessment**: Conduct a thorough risk assessment to identify potential hazards and implement mitigation measures.
2. **Data Management**: Establish data governance protocols to ensure data quality and compliance with privacy laws.
3. **Documentation**: Maintain comprehensive documentation, including technical specifications and user instructions.
4. **Testing**: Perform rigorous testing to ensure the system meets all regulatory requirements before deployment.
5. **Monitoring**: Continuously monitor the system's performance and update it as necessary to maintain compliance.

Codes of Conduct and Guidelines

Voluntary Codes

- **Encouragement**: Promote the creation of voluntary codes of conduct for AI systems not classified as high-risk, fostering ethical and trustworthy AI practices.
- **Elements**: Include elements such as environmental sustainability, AI literacy, and inclusive design.

Guidelines

- **Commission Guidelines**: Follow the guidelines issued by the Commission for practical implementation, focusing on transparency obligations and the definition of AI systems.
- **Transparency**: Ensure that AI systems are developed and used in a way that allows appropriate traceability and explainability.

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Initiatives

Regulatory Sandboxes: SMEs, including start-ups, are given priority access to AI regulatory sandboxes, provided they meet eligibility conditions and selection criteria. These sandboxes offer a controlled environment for testing and experimentation, helping SMEs navigate regulatory requirements and innovate safely.

Guidance on Compliance: Member States are tasked with organizing specific awareness-raising and training activities tailored to the needs of SMEs. These activities include providing advice and responding to queries about the implementation of the AI Act, ensuring SMEs understand and comply with the regulations

Standardization Participation: Efforts are made to facilitate the participation of SMEs in the standardization development process, ensuring their needs and perspectives are considered in the creation of standards.

Templates

Standardized Documentation: The AI Office provides standardized templates for areas covered by the AI Act. These templates help SMEs reduce compliance costs by offering clear and consistent formats for required documentation and communication.

Single Information Platform: A single information platform is maintained to provide easy-to-use information related to the AI Act, helping SMEs access necessary resources and support.

Substantial Modification

Definition

A substantial modification occurs when a change affects the compliance of a high-risk AI system with the EU AI Act, such as changes to the operating system, software architecture, or intended purpose.

Management

- New Conformity Assessment: Any substantial modification requires the AI system to undergo a new conformity assessment to ensure continued compliance.
- Pre-Determined Changes: Changes that have been pre-determined and assessed during the initial conformity assessment do not constitute a substantial modification.

Obligations

- User Information: High-risk AI systems must be designed to ensure sufficient transparency, enabling users to interpret the system's output and use it appropriately.
- Instructions for Use: Provide clear, concise, and comprehensive instructions, including:
  - Provider Details: Identity and contact information of the provider.
  - System Characteristics: Capabilities, limitations, and intended purpose.
  - Performance Metrics: Accuracy, robustness, and cybersecurity levels.
  - Human Oversight: Measures to facilitate the interpretation of outputs by users.
  - Data Specifications: Information on training, validation, and testing data sets used.

Transparency

Incident Reporting

Procedures

- **Immediate Reporting**: Providers of high-risk AI systems must report any serious incident to the market surveillance authorities of the Member States where the incident occurred immediately after establishing a causal link or the reasonable likelihood of such a link.

Timelines:

- **General Incidents**: Report within *15 days* after becoming aware of the incident.
- **Widespread Infringement or Serious Incident**: Report within *2 days*.
- **Incidents Involving Death**: Report immediately, but not later than *10 days* after becoming aware.
- **Responsible Parties**: Providers and, where applicable, deployers are responsible for reporting.
- **Initial and Complete Reports**: Providers may submit an initial incomplete report followed by a complete report if necessary.

Continuous Monitoring

Importance

- **Ongoing Compliance**: Continuous monitoring ensures that AI systems remain compliant with regulatory requirements throughout their lifecycle.
- **Safety and Performance**: Regular updates and monitoring help identify and mitigate risks, ensuring the AI system operates safely and effectively.
- **Post-Market Monitoring System**: Providers must establish a post-market monitoring system to actively and systematically collect, document, and analyse relevant data on the performance of high-risk AI systems.
- **Interaction Analysis**: Monitoring should include an analysis of the interaction with other AI systems and devices, where relevant.

Documentation = PAIn reliever

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General Description

- **Intended Purpose**: The AI system is designed for medical diagnostics, assisting healthcare professionals in identifying diseases from medical images. Provider: MedTech AI Solutions, Version 2.1.
- **Interaction with Hardware/**Software: The system interacts with hospital imaging equipment and electronic health record (EHR) systems, integrating seamlessly with existing medical software.

Data Used

- **Training Data**: The system was trained on a dataset of 100,000 labelled medical images sourced from various hospitals, ensuring diverse and representative data.
- **Validation and Testing Data**: Validation was performed using a separate dataset of 20,000 images, with detailed records of data provenance and characteristics.

Risk Management Process

- **Risk Assessment**: A comprehensive risk assessment identified potential hazards, such as misdiagnosis, and implemented mitigation measures, including regular updates and human oversight.
- **Post-Market Monitoring**: A post-market monitoring plan is in place to continuously evaluate system performance, including user feedback and incident reporting mechanisms.

System Architecture and Design

- **Design Specifications**: The AI system uses a convolutional neural network (CNN) architecture optimized for image recognition tasks. Key design choices include the use of transfer learning and data augmentation techniques.
- **System Architecture**: The software components include a preprocessing module, the CNN model, and a post-processing module that integrates with EHR systems.

Human Oversight Measures

- **Oversight Mechanisms**: The system includes features that allow healthcare professionals to review and validate AI-generated diagnoses, ensuring human oversight and accountability.

Compliance and Certification

- **EU Declaration of Conformity**: A copy of the EU declaration of conformity is included, certifying that the AI system meets all regulatory requirements.
- **Validation and Testing Procedures**: Detailed records of validation and testing procedures, including metrics for accuracy, robustness, and compliance, are maintained.

Thank you!

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