

Position Paper

Background

The European Commission has published their proposal for a regulation that covers many aspects of AI (Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS COM/2021/206 final) in April 2021. The draft Artificial Intelligence Act (AIA) is a horizontal regulation implementing a risk-based approach to identify the level of control on AI Systems being placed on the European market. The members of the Team NB, the EU association for Notified Bodies for medical devices and IVDs publish this position-paper with the intention to express their opinion and concerns regarding the upcoming regulations, with a focus on the interface and overlap between the upcoming regulations and the Medical Device Regulation (MDR) and IVD Regulation (IVDR).

Definitions

Article 3(1): ‘artificial intelligence system’ (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with

Annex I:

- (a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;
- (b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;
- (c) Statistical approaches, Bayesian estimation, search and optimization methods.

Team NB Opinion:

The definition used includes terms related to logic and knowledge-based systems. This is an overly broad definition such that it could potentially include non-AI systems leading to confusion for the regulators, manufacturers and notified bodies. Since the goal of standardization is to provide harmonized definitions of technologies for the purpose of exchanges between relevant stakeholders, we recommend to use the definition found in the international standard “ISO/IEC 2382:2015, Information technology – Vocabulary”.

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Table of Contents Sample Of Position Paper

1. Understanding the eBook Sample Of Position Paper
 - The Rise of Digital Reading Sample Of Position Paper
 - Advantages of eBooks Over Traditional Books
2. Identifying Sample Of Position Paper
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Sample Of Position Paper
 - User-Friendly Interface
4. Exploring eBook Recommendations from Sample Of Position Paper
 - Personalized Recommendations
 - Sample Of Position Paper User Reviews and Ratings
 - Sample Of Position Paper and Bestseller Lists

5. Accessing Sample Of Position Paper Free and Paid eBooks
 - Sample Of Position Paper Public Domain eBooks
 - Sample Of Position Paper eBook Subscription Services
 - Sample Of Position Paper Budget-Friendly Options
6. Navigating Sample Of Position Paper eBook Formats
 - ePub, PDF, MOBI, and More
 - Sample Of Position Paper Compatibility with Devices
 - Sample Of Position Paper Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Sample Of Position Paper
 - Highlighting and Note-Taking Sample Of Position Paper
 - Interactive Elements Sample Of Position Paper
8. Staying Engaged with Sample Of Position Paper
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Sample Of Position Paper
9. Balancing eBooks and Physical Books Sample Of Position Paper
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Sample Of Position Paper
10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
11. Cultivating a Reading Routine Sample Of Position Paper
 - Setting Reading Goals Sample Of Position Paper
 - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Sample Of Position Paper
 - Fact-Checking eBook Content of Sample Of Position Paper
 - Distinguishing Credible Sources
13. Promoting Lifelong Learning

- Utilizing eBooks for Skill Development
- Exploring Educational eBooks

14. Embracing eBook Trends

- Integration of Multimedia Elements
- Interactive and Gamified eBooks

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