

# 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*”.

# Sample Of Position Paper

**Thirumalaisamy P.  
Velavancorresponding**

**Sample Of Position Paper:**

## Unveiling the Energy of Verbal Beauty: An Psychological Sojourn through **Sample Of Position Paper**

In a world inundated with displays and the cacophony of immediate connection, the profound energy and mental resonance of verbal beauty usually fade in to obscurity, eclipsed by the constant onslaught of sound and distractions. However, nestled within the lyrical pages of **Sample Of Position Paper**, a fascinating function of literary elegance that impulses with natural thoughts, lies an wonderful journey waiting to be embarked upon. Published with a virtuoso wordsmith, this mesmerizing opus courses visitors on a mental odyssey, delicately exposing the latent possible and profound affect embedded within the delicate web of language. Within the heart-wrenching expanse of the evocative analysis, we can embark upon an introspective exploration of the book is central styles, dissect its fascinating publishing type, and immerse ourselves in the indelible impression it leaves upon the depths of readers souls.

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