

Legal Alert: Mandatory AI Documentation Rules—What Providers OF High- Risk AI Systems Need to Know Before August 2026

Tina Kamilaki, Senior Associate | 7 May 2026

From 2 August 2026 onwards, the creation and maintenance of technical documentation for high-risk AI systems becomes a mandatory obligation. According to Article 11 of the AI Act, providers of such systems must compile comprehensive documentation before making them available on the market, and ensure that it remains continuously updated. This documentation should clearly demonstrate compliance with the requirements set out in the AI Act and cover key elements such as an overview of the system, its intended use, design and development details, as well as performance assessment information. For small and medium-sized enterprises (SMEs), the European Union allows a simplified format for presenting this information.

Well-structured documentation plays an important role in enhancing understanding for both users and practitioners—including deployers and implementers—thereby facilitating effective interaction with the system and supporting the identification and troubleshooting of unexpected behavior during operation. Technical documentation also contributes to transparency throughout the lifecycle of an AI system. It helps clarify architectural choices and design decisions, supports faster onboarding of new team members, and enables continuous reassessment of key decisions as the project evolves.

Annex IV provides a detailed and comprehensive list of elements that must be included in the Technical Documentation referred to in Article 11 of the AI Act, which should include the following:

1. A general description of the AI system including

(a) its intended purpose, the name of the provider and the version of the system reflecting its relation to previous versions;
(b) how the AI system interacts with, or can be used to interact with, hardware or software, including with other AI systems, that are not part of the AI system itself, where applicable;

(c) the versions of relevant software or firmware, and any requirements related to version updates;

(d) the description of all the forms in which the AI system is placed on the market or put into service, such as software packages embedded into hardware, downloads, or Application Programming Interfaces (APIs);

(e) the description of the hardware on which the AI system is intended to run;

(f) where the AI system is a component of products, photographs or illustrations showing external features, the marking and internal layout of those products;

(g) a basic description of the user-interface provided to the deployer;

(h) instructions for use for the deployer, and a basic description of the user-interface provided to the deployer, where applicable;

2. A detailed description of the elements of the AI system and of the process for its development, including:

(a) the methods and steps performed for the development of the AI system,

(b) the design specifications of the system, namely the general logic of the AI system and of the algorithms;

(c) the description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing; the computational resources used to develop, train, test and validate the AI system;

(d) where relevant, the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used, including a general description of these data sets, information about their provenance, scope and main characteristics; how the data was obtained and selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection);

(e) assessment of the human oversight measures needed;

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(f) where applicable, a detailed description of pre-determined changes to the AI system and its performance, together with all the relevant information related to the technical solutions adopted to ensure continuous compliance;

(g) the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; metrics used to measure accuracy, robustness and compliance with other relevant requirements, as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons;

(h) cybersecurity measures put in place;

3. Detailed information about the monitoring, functioning and control of the AI system

(a) its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose;

(b) the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI system; t

(c) the human oversight measures needed, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the deployers; specifications on input data, as appropriate;

4. A description of the appropriateness of the performance metrics for the specific AI system

5. A detailed description of the risk management system in accordance with Article 9 of the AI Act;

6. A description of relevant changes made by the provider to the system through its lifecycle;

7. A list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union

(where no such harmonised standards have been applied, a detailed description of the solutions adopted to meet the requirements set out in Chapter III, Section 2, of the AI Act including a list of other relevant standards and technical specifications applied)

8. A copy of the EU declaration of conformity referred to in Article 47 of the AI Act

9. A detailed description of the system in place to evaluate the AI system performance in the post-market phase in accordance with Article 72, including the post-market monitoring plan referred to in Article 72(3) of the AI Act.

Key contacts



Tina Kamilaki
Senior Associate
t.kamilaki@tsibanoulis.gr

Tsibanoulis & Partners Law Firm

18 Omirou St.
106 72 Athens | Greece
T: +30 210 3675 100
W: tsibanoulis.gr



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