2. REGULATION OF DIGITAL TECHNOLOGIES AND ARTIFICIAL INTELLIGENCE

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CE MARKING AND THE DECLARATION OF CONFORMITY FOR HIGH-RISK AI SYSTEMS UNDER THE EU AI ACT: LEGAL NATURE, PROCEDURAL FRAMEWORK AND IMPLICATIONS FOR BUSINESS ENTITIES

Abstract: The CE mark (Conformité Européenne, European Conformity), originally conceived as a market access instrument within the European Union's single market, has undergone significant normative evolution with adoption of Regulation (EU) 2024/1689 on artificial intelligence (the AI Act). For the first time in the history of EU product safety law, the CE marking as procedure is applied to purely digital software system, a development that raises fundamental legal questions about the adequacy of existing conformity assessment mechanisms in the context of high-risk artificial intelligence.

The paper examines the CE mark and the EU Declaration of Conformity as dual instruments of marketing surveillance for high-risk AI systems under Articles 47 and 48 of the AI Act. As AI Act builds directly upon Regulation (EC) No 765/2008 as its foundational legal framework, these

two instruments must be read and applied in coexistence. Finally, the paper addresses legal obligations for business entities operating within the legal framework of the Republic of Serbia, examining how the national Law on Technical Requirements for Products and Conformity Assessment transposed the CE model into domestic law, and identifying the procedural and industrial barriers that Serbian companies face when seeking o place CE-marked high-risk AI systems on the EU market.

The paper concludes that the current conformity assessment architecture of the AI Act, while pragmatic in its proportionality, carries inherent risks of normative formalism that may undermine the fundamental rights protections the regulation in question seeks to achieve. The authors propose targeted recommendations for strengthening the accountability dimension of the CE marking procedure, with particular attention to the needs of small and medium-sized enterprises

Keywords: *CE marking, AI Act, conformity assessment, high-risk AI systems, market surveillance*

1. INTRODUCTION

The regulation of artificial intelligence in the European Union has entered a new and decisive phase with the adoption of Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024, commonly referred to as the EU Artificial Intelligence Act (hereinafter: AI Act).[1] Among the many obligations this landmark regulation imposes for providers of high-risk AI systems, one stands out for its historical novelty and its underexplored legal implications: the obligation to affix the CE mark and draw up an EU Declaration of Conformity before placing a high-risk AI system on the market or putting it into service (Articles 47 and 48 of the AI Act). That means that for the first time in the history of EU product safety law, the CE mark, an instrument born out of the need to facilitate the free circulation of physical goods across Member States, is formally extended to purely digital, software-based systems. Historically, the CE mark was created in 1993. and firstly used in 1995. Today, the CE mark is facing new

[1] The Artificial Intelligence Act – Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828.

areas and challenges. One of the basic questions for products and services that are put on the market is whether these products are safe enough for usage and how can consumers, who do not have the professional knowledge, be qualified to judge whether the product is safe. The extension of the CE marking to purely digital, software-based systems is not merely a technical detail. It represents a fundamental shift in the normative architecture of EU market regulation, one that raises serious and yet insufficiently examined questions about the adequacy, coherence, and practical effectiveness of applying a decades-old physical-product paradigm to the governance of algorithmic systems.

Through a legal analysis of the existing framework in the AI Act, while taking into account legal nature of the CE mark and its regulations, we will try to provide an overview of the legal and practical importance of the CE mark, what it presumably testifies to and how it is applied to software solutions based on AI. This paper derives its scientific benefit from the lack of legal science sources in this area, and its practical benefit from the fact that these are issues that national law-makers must take into account when creating the Legal Act on Artificial Intelligence, and also from the fact that the AI Act applies to companies in Serbia that enter the EU market. This is a practical question of interest to all companies providing AI systems on EU market.

2. CE MARKING IN EU LAW

The EU market includes 27 countries, which makes it very complex economic ecosystem. It is necessary to assess whether a product is complies with relevant regulation (safe for use), while at the same time relevant procedures do not represent a bureaucratic problem. The CE mark is the EU's legal instrument that meets these requirements. The CE mark has been used for decades in the EU as a mechanism that allows a product to be assessed at one point and then circulated in all 27 countries without repeated checks. It would be a major bureaucratic problem if CE mark would need to be revised in each member state again and again. The history of CE marking was not so linear: “The European Commission’s “New Approach” to standardization – launched in 1985. amid hurried efforts to relaunch integration and complete the Single Market – streamlined the process of removing technical barriers to trade by focusing only on “essential requirements” outlined by directives drafted by the European Commission and approved by the Council, delegating the development of standards to European standards bodies, keeping the use of standards voluntary, and

granting presumed legal conformity to products manufactured according to European standards." (Ballor, 2021, p. 12). Yet it took nearly a decade for this vision to take a shape and in 1993. CE mark was created and became mandatory as of 1995. With the creation of AI Act, CE mark been extended to digital products for the first time in its 30 years long history. This may cause some doubts in practice, especially regarding its visibility and transparency.

The CE mark is not a sign of quality or origin (it does not mean that the product is manufactured in the EU). It is not even a sign that product marked with it meets the requirements of safety, health and environmental protection defined in EU regulations that are in force. It is a declaration of conformity, or a statement by the manufacturer, that their product has been manufactured in accordance with the relevant safety regulation. On the European Commission's homepage for the CE marking, everyone can download the original design and find out more about the CE mark. There is an interesting detail at the bottom of the page where European Commission has left a note: "Not all product must gave CE marking. It is compulsory only for most of the products covered by the New Approach Directive. It is forbidden to affix CE marking to other products. Please note that a CE marking does not indicate that a product has been approved as safe by the EU or by another authority. It does not indicate the origin of a product either."[2]

The CE marking is affixed by the provider himself, under his own responsibility. A third party, a notified body, is involved only in certain higher-risk cases, where it carries out an independent conformity assessment and issues a certificate, while the marking itself is still affixed by the provider.

3. AI ACT AND CE MARKING – NORMATIVE ANALYSIS

The goal of developing any software solution is to put it on the market and economically exploit it in different ways (as software as a service, software license, etc.). In order for a company to be able to put such software on the market, it must be sure that it has complied with all regulatory obligations, and that it is a product (in this case software as a digital product) safe for usage. The CE mark is used as the final safety mechanism when it comes to AI-based programs.

[2] Official website of European Commission on CE marking: https://single-market-economy.ec.europa.eu/single-market/goods/ce-marking_en (accessed on 05.07.2026.)

The CE mark is a visible sign by which the provider (manufacturer) declares that the AI-based program meets all requirements in accordance with the EU AI Act. It is a legal mechanism of consumer protection, and at the same time proof that the provider has guaranteed compliance and thereby assumed responsibility in the event that compliance does not exist or when problems arise with system users.

It should be noted that that the CE mark only covers compliance with product regulations, it does not refer to acts such as GDPR. However, in a broader context, personal data regulation bears importance for AI systems (Reljić, Tul, 2025, p.600). CE mark is a tool that enables two essential principles of personal data protection: transparency and the principle of responsibility (Tul, 2024, p.759-770). The CE mark is a declaration by the provider which stipulates under legal responsibility that he has checked the system in question and claims that it is compliet with the law. However, as this is an obligation imposed on the providers, the main aim is not to burden the providers of all AI-based systems, but a distinction has been carefully made in favor of those systems that can cause more severe and far-reaching consequences for users. Thus, this obligation under the AI Act is stipulated for high-risk systems, while GPAI models[3] have a separate regime and model providers who are rated as limited and minimal risk systems do not have this obligation.

Therefore, the CE mark is reserved only for high-risk AI systems, throughout the whole lifecycle of the product. "Compliance with the requirements is not a one-time obligation. The system must be assessed for conformity throughout its lifecycle. The CA must evaluate whether the AI system is designed and used according to its intended purpose while also accounting for reasonably foreseeable misuse." (Serban, Rovilos, Demetzou, 2025, p.24). The way post-market monitoring is working is described by Mokander, J. and coauthors: "The post-market monitoring plan is complementary to the conformity assessment because it is based on a different logic. In the academic literature, a distinction is often made between three complementary yet distinct approaches to AI auditing: functionality audits focus on the rationale behind using an AI system; code audits entail reviewing the source code of an algorithm; and impact audits

[3] General-Purpose AI (GPAI) models are highly versatile, foundation-style AI systems trained on vast datasets and capable of competently performing a wide range of distinct tasks, such as generating text, audio, images, or code. Prime examples include GPT-4, Gemini, Claude, and Llama.

investigate the types, severity, and prevalence of effects of an AI system's outputs."(Mokander et. al, 2021, p.13).

The relevant legal sources are Article 47 of the AI Act, which deals with the declaration of conformity as a document accompanying the CE mark, and Article 48 of the AI Act, which prescribes the rules for affixing the CE mark. Also, as relevant and related articles can be considered article 43 of the AI Act, which regulates the conformity assessment procedure, since it is a prerequisite for placing the mark, and article 16 of the AI Act which is considered to be a base, as it states that the provider is obligated to mark his digital product with CE mark before releasing it on EU market. One provision also relevant is recital 129 of the AI Act preamble which explains the logic of the CE mark. We will analyze these provisions.

Recital 129

We leave a note that the recitals are not of a normative character, they do not contain legal rules, but serve as a tool for interpretation, that is, the most common tool for the most refined type of purposive interpretation. The goal is to understand the intention of the legislator and to read the normative part correctly.

In a logical order, we will start from the analysis of recital 129, which reads: "High-risk AI systems should bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the internal market. For high-risk AI systems embedded in a product, a physical CE marking should be affixed, and may be complemented by a digital CE marking. For high-risk AI systems only provided digitally, a digital CE marking should be used. Member States should not create unjustified obstacles to the placing on the market or the putting into service of high-risk AI systems that comply with the requirements laid down in this Regulation and bear the CE marking."

Analyzing this article, four points are distinguished. Firstly, the CE mark applies to high-risk AI-based systems, as we have already established. Secondly, the CE mark is a signal of compliance with the AI Act and its ultimate goal is free movement of products within the EU single market. Thirdly, the CE mark is traditionally physical (because it is related to products), but in this case it can be digital, as only digital mark will be applicable for digital products that have no physical materialization. Fourth, if the system has a CE mark and meets the requirements, a member state must not arbitrarily block it from its market.

Article 47: EU Declaration of Conformity

The EU Declaration of Conformity (DoC) is a legal document by which a provider certifies in writing that a high-risk AI-based system meets the requirements of the AI Act. It should contain a list of responsibilities (risk management system, data management, technical documentation, keeping log records, transparency, human supervision, accuracy, robustness and cyber security) and it precedes the CE mark, because one needs to know what the obligations are in order to be able to say that a certain company has harmonized its AI system with the AI Act and to be able to then apply the CE mark.

This article consists of 5 paragraphs. Some are related to technical matters, but it is essential that we address certain points. Paragraph 1 of Article 47 of the AI Act lays the groundwork for further elaboration and gives us basic information about DoC. It is a written and machine-readable physical or electronically signed document for each highly critical AI system, which is kept for 10 years from the release of the AI system to the market. Authorities may request access to this document, within the framework of the supervisory function. Paragraph 2 of the article in question is perhaps the most important, but in combination with Annex V (EU Declaration of Conformity - DoC). This paragraph refers to the content and links this document to section 2 (requirements for High-Risk AI Systems). The exact content is prescribed in Annex V. Michele Finck emphasizes that legal obligation from section 2 extends only to an affirmation that the requirements are met, but not to the specific methods by which they are met (Finch, 2026, p. 455). Paragraph 4 is of particular importance because it says that by creating the DoC, the provider assumes responsibility for compliance and must keep it up-to-date. Michele Finck concluded: "Thus, the declaration functions not merely as a formal administrative step but as an express acknowledgment and assumption of regulatory accountability by the provider." (Finch, 2026, p. 456).

Article 47 is preceded by Article 43, which regulates how Conformity Assessment is done and it states that there are two types of assessment (which aligns with CE marking rules): internal assessment according to Annex VI and external assessment according to Annex VII – Assessment with the notified body. There are situations when the provider must go through Annex VII and do a Conformity Assessment with the help of a notified body, in the following situations: when harmonized standards do not exist, and common specifications are not available, when the provider did not implement them or has implemented them only partially, when common specifications exist, but the provider has not implemented them, or when the standard is published with a limitation, and only for that part

which is limited. The provider itself chooses the notified body that will conduct the Conformity Assessment.

The requirements for high-risk AI systems, which are the object of the conformity assessment, exist to effectively mitigate risks to health, safety, and fundamental rights. There are few groups of requirements (Demotzou, 2021). Also, we should note that pre-market conformity regime also applies to machine learning training, testing and validation datasets on the basis of article 10 (Kop, 2021, p.5).

In essence, the EU DoC is the document in which the provider formally assumes responsibility for the systems compliance with the requirements of Section 2. Once this declaration is in place, it needs to become visible on the system itself, and that is precisely the role of the CE marking under Article 48, to which we now turn.

Article 48: CE Marking

When the provider company has a DoC and through that document has assessed the compliance of its system, it approaches the further procedure, i.e. strives for the final result. And that result is that they can mark his software with the CE mark. That is why Article 48 is essential for our work, and we will analyze it step by step.

The first paragraph refers directly to the Regulation on market surveillance in the EU. Basically, those principles say that the mark is placed by the producer or his authorized representative, and that by placing the mark, responsibility for compliance is assumed (as provider is stating that his product is compliant). These regulations also establish that the CE mark is the only sign that confirms conformity and that no signs may be added that would have the purpose of misleading the user. Illegal use may be sanctioned. Michele Finck put it this way: “These forsee, inter alia, that only the manufacturer/provider or their representative may affix the CE marking to products for which this is foreseen by EU harmonizing legislation or that the manufacturer/provider takes responsibility for the conformity of the product with all applicable requirements by affixing the marking.” (Finch, 2026, p.458).

Paragraph 2 of the article states that the digital CE mark must be used only in such a way that it is accessible and legible, which is followed by paragraph 3, which points out that the CE mark should be visible, but also available in the documentation that accompanies the software solution or the provision of information society services.

Paragraph 4 prescribes that the identification number of the notified body is added to the CE mark, but only when the body participated in the

conformity assessment, while there is no such number in case of internal control. This indicates that it is possible to have internal and external conformity assessment.

Paragraph 5 determines situations when high-risk AI systems simultaneously fall under other EU regulations that also require a CE mark, and stipulates that a single CE mark covering all regulatory requirements is then affixed. The aim of this provision is certainly to avoid duplication of marks. One mark confirms the complete regulatory safety of the product (AI system).

Therefore, the digital CE mark that is marking high-risk AI system can be placed internally and externally. Internal placement of the CE mark means that the provider applies it himself when he assesses compliance in accordance with the DoC. External implies that some external entity carries out the verification and issues the certificate, and then the CE mark is added based on the identification number. In both cases, the CE mark is actually placed by the provider. The difference is in the level of responsibility, because the external entity is responsible only for what it has assessed, for the quality and accuracy of its verification.

What do we not know in the end by reading and analyzing the articles in question? We do not know how the CE mark should actually be presented, that is, the technical details of the CE mark (format, display method). This is likely to be further considered through the European Commission's guidelines for the implementation of the AI Act. This is very important for companies to know how to act in practice in future. For this reason, we currently view the process of bringing an AI-based system to market as a bit unclear. We lack the last step.

CONCLUSION

All companies are responsible for ensuring that the products they put on the market are safe for use. The goal is to protect the interests of citizens and mitigate all possible risks. The EU has devised a way for companies to clearly and transparently confirm to citizens that their products comply with regulations (which usually regulate safety, health, basic rights). That way is the CE mark, which was introduced in 1993 as a mark of product conformity. The CE mark is used in many areas, and in each it means one thing, that the product complies with the regulations that apply to that area.

Nowdays, with the development of technology, new challenges arise. New technologies must also be safe to use. The AI Act for AI-based systems uses the CE mark infrastructure that already exists. The challenges

arise because this is the first time that the CE mark will be used on digital software solutions and not on a tangible physical product.

What does this mean for companies creating AI systems? In order for a company to put an AI system on the market, it must provide a Declaration of Conformity (state that their AI system is compliant with all obligations from AI Act). It must then affix the CE mark that is legible and visible to the user. In the majority of cases, this mark can be applied by the provider himself, but in certain cases he can or must obtain a certificate (or consent) from the body participating in the assessment (still provider is affixing the CE mark).

The CE mark is an obligation of the company and at the same time one of the last obligations before placing the high-risk AI system on the market in the EU. It is important for all previous obligations from AI Act. The CE mark is a guarantee that the process of compliance with the AI Act has been carried out and that the company claims that its AI-based system complies with the regulation. Therefore, all companies that want to economically exploit high-risk AI systems (software solutions based on AI) will encounter this in practice. For them it is of major importance that EU establishes rules on how CE mark should be presented in digital products.

Republic of Serbia is in the process of passing the Legal Act on Artificial Intelligence. It is of the utmost importance that it be done according to the principles of the AI Act, because companies operating in Serbia are often oriented towards cooperation on the EU market. This is facilitated by the fact that Serbian regulation has the same infrastructure as the EU regarding the CE mark (although the CE mark given in Serbia is not valid on the EU market). Republic of Serbia has the Legal Act on Technical Requirements for Products and Conformity Assessment[4], and the designation is AAA (three A's in an equilateral triangle).

The AI Act has an extraterritorial effect, so it will be applied in the Serbian market to companies that place AI systems on the EU market, regardless of the place of establishment and if the provider or deployer established in a third country providers the output of the system that will be used in the EU. Therefore, software companies based in Serbia, if they are exporters of IT services, that sell or provide AI services to clients in the EU must comply with the AI Act as if they were established in the EU. And we know that today, in fact, many IT companies tend to operate in foreign markets and that software services are rarely tied to one market, given that

[4] Legal Act on Technical Requirements for Products and Conformity Assessment ("Sl. glasnik RS" br. 49/2021).

the Internet enables easier placement on other markets, which many companies use more and more.

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