3

Companies developing compliance with requirements

Guide 3. Conformity Assessment

European
Artificial Intelligence Act

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GOBIERNO DE ESPAÑA
MINISTERIO PARA LA TRANSFORMACIÓN DIGITAL Y DE LA FUNCIÓN PÚBLICA
SECRETARÍA DE ESTADO DE DIGITALIZACIÓN E INTELIGENCIA ARTIFICIAL

Plan de Recuperación, Transformación y Resiliencia

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This guide has been developed within the framework of the development of the Spanish pilot for the regulatory AI Sandbox, through collaboration among participants, technical assistance providers, potential competent national authorities, and the sandbox's expert advisory group.

The aim of the guide is to serve as an introductory support to the European Regulation on Artificial Intelligence and its applicable obligations. **Although it is not legally binding and does not replace or develop the applicable legislation, it provides practical recommendations** aligned with regulatory requirements, pending the approval of the harmonised implementing standards for all Member States.

This document is subject to an ongoing **process of evaluation and review**, with periodic updates in line with the development of standards and the various guidelines published by the European Commission, and it will be updated once the Digital Omnibus amending the AI Act is approved.

Among the relevant technical references currently applicable, particular note should be made of I**SO/IEC 17000:2004, *"Conformity assessment – Vocabulary and general principles,"*** and **ISO/IEC 17007:2009, *"Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment."*** Also noteworthy are the technical references currently under development under the prEN XXX AI Conformity **Assessment** Framework. All of these references will establish **the terminological and methodological framework for conformity assessment activities**, providing **the necessary conceptual foundations for the development and application of certification procedures** in the context of **compliance with the European Regulation on Artificial Intelligence.**

Revision date: 10 December 2025

General content

Detailed Index

1. Preamble

1.1 Purpose of the document

This guide within the framework of the artificial intelligence sandbox **aims to provide guidance on the** conformity assessment procedure to which high-risk Artificial Intelligence systems of the European Regulation on Artificial Intelligence (*AI Act*) must be subjected.

1.2 How to read this guide?

The structure of this guide has the following characteristics.

The **first section** addresses the essential notes of this Guide.

Next, the **second section** develops the content of the European Regulation on Artificial Intelligence that refers to the conformity assessment procedure. Because of this, this section is further subdivided into a series of subsections, these are:

a) A general approximation is made to the conformity assessment procedure designed by the EU for products subject to harmonisation legislation.

b) The focus is on the conformity assessment procedure of AI systems set out in the European Regulation on Artificial Intelligence.

c) Some of the tools that are closely related to conformity assessment and that are also covered by the European Regulation on Artificial Intelligence are mentioned.

The **third section** refers to the precepts that regulate the conformity assessment procedure in the European Regulation on Artificial Intelligence.

Finally, the **fourth section** encompasses the sources consulted for the preparation of this guide, as well as others that we consider may be relevant for the implementation of the measures and requirements derived from the European Regulation on Artificial Intelligence in this context.

This guide is based on Regulation 2024/1689 of the European Parliament and of the Council of 13 June 2024 (European Regulation on Artificial Intelligence)

1.3 Who is it for?

It is the responsibility of providers of high-risk AI systems to implement appropriate measures to properly carry out the requirements of the European Regulation on Artificial Intelligence regarding the conformity assessment procedure.

1.4 Use cases and examples throughout the guide

The following use cases have been selected based on the ability to explain the information and procedures detailed in the guide. However, on certain occasions other examples will be mentioned.

The selected cases have been:

- Chronic disease management. Smart insulin pump.
- Control of attendance at work through biometric recognition.

2. Introduction

2.1 Concept of conformity assessment.

AI Act

Art.3.20 - Definitions

"Conformity assessment" means the process of demonstrating whether the requirements set out in Chapter III, Section 2 relating to a high-risk AI system have been fulfilled.

Through this process providers verify that the high-risk AI system complies with the requirements of Articles 8 to 15 of the European Regulation on Artificial Intelligence.

Conformity assessment is the responsibility of the provider, even where design or production is outsourced. In certain cases, the conformity assessment procedure may require the involvement of a notifies body.

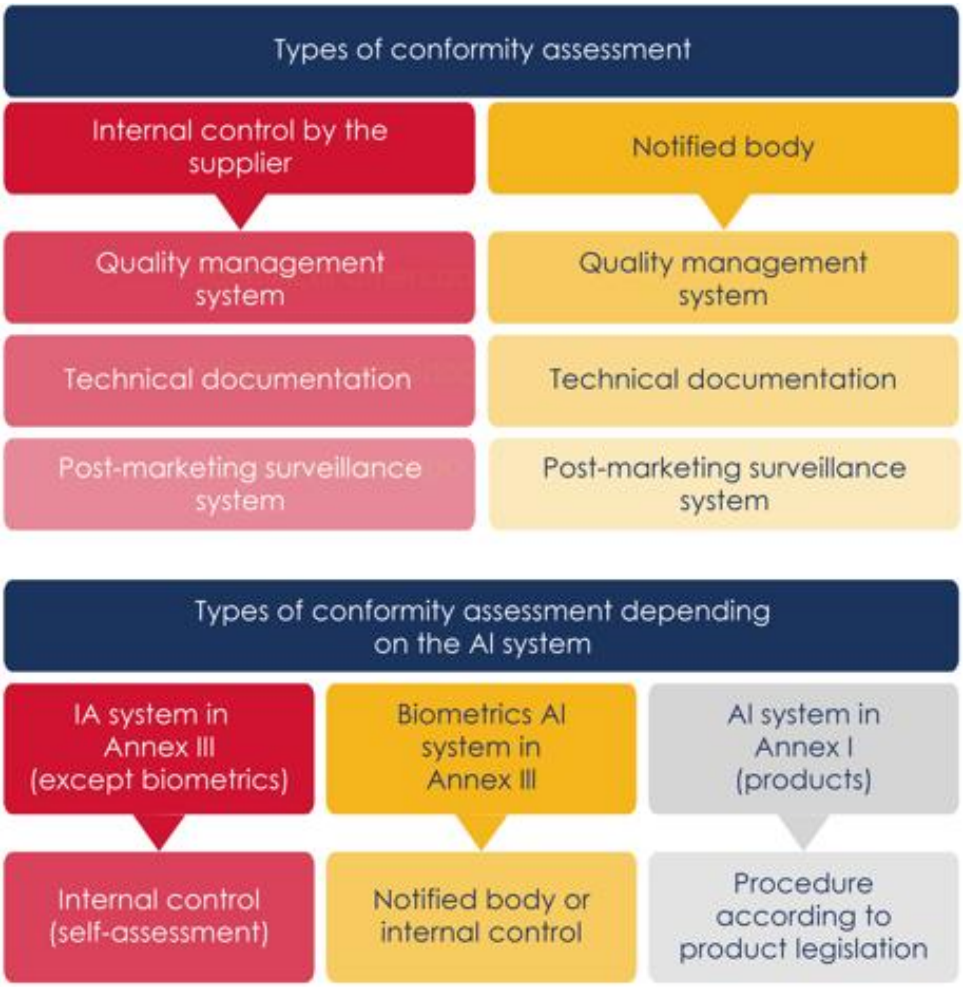
2.2 Ways of conducting the conformity assessment

The European Regulation on Artificial Intelligence sets out two ways of assessing the conformity of **high-risk AI systems** depending on the processes to be carried out and whether or not such conformity assessment involves a notified body.

- Conformity assessment procedure based on an **internal control** of the provider. Annex VI European Regulation on Artificial Intelligence.
- Conformity based on the assessment of the quality management system and the assessment of the technical documentation. **A notified body** intervenes. Annex VII European Regulation on Artificial Intelligence.

The choice of one or the other conformity assessment procedure is linked to the type of AI system developed by the provider. This classification is discussed later in this Guide.

A summarized and visual way to understand the two methods for assessing the conformity of high-risk AI system is:


Types of conformity assessment
Internal control by the supplier
Notified body
Quality management system
Quality management system
Technical documentation
Technical documentation
Post-marketing surveillance system
Post-marketing surveillance system
Types of conformity assessment depending on the AI system
IA system in Annex III (except biometrics)
Biometrics AI system in Annex III
AI system in Annex I (products)
Internal control (self-assessment)
Notified body or internal control
Procedure according to product legislation

2.3 Conformity assessment within the framework of European Union harmonisation legislation

The conformity assessment procedure of the European Regulation on Artificial Intelligence, which we will detail later, is part of the so-called new legislative framework, hereinafter NLF. The NLF is made up of several European legal texts that establish a common basis for the marketing, evaluation and surveillance of products in the European Union[1]. In this way, the European legislator, when legislating on a product, takes the NLF as a reference, which contemplates a structure that ensures a reliable evaluation and placing on the market of such products and goods.

The main instruments that make up this structure are the following:

- Harmonised standards: are technical specifications adopted at the request of the European Commission for the implementation of Union harmonisation legislation by an European recognised standardisation body.
- Common specifications: these are technical specifications drawn up by the European Commission through implementing acts for the implementation of Union harmonisation legislation. These specifications are adopted where there are no harmonised standards, or if they exist, the European Commission does not consider that they are sufficient to meet the requirements of the harmonisation legislation.
- Declaration UE of Conformity: This is a mandatory document that the manufacturer or his authorised representative must sign to declare that his products meet EU requirements.
- CE marking: The CE marking is a key indicator (but not a test) of a product's conformity with EU legislation and allows for the free movement of products within the European market.
- Technical Documentation: Set of documented evidence containing information (on design, manufacture, operation, etc.) demonstrating the conformity of the product with the applicable requirements. The content of the technical documentation is established, in each Union harmonisation act, according to the products concerned.
- Conformity assessment: A process by which it is demonstrated that the requirements specified in EU legislation relating to a product or process are met.[2]
- Notifying authorities: A notifying authority is the public body responsible for carrying out the procedures necessary for the assessment, designation and

[1] The three legal texts that make up the New Legislative Framework are: Regulation (EC) No. 765/2008 of the European Parliament and of the Council establishing the requirements for accreditation and surveillance of the market for products; Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the placing of products on the market; Regulation (EU) 2019/1020 of the European Parliament and of the Council on market surveillance and conformity of products.

[2] ISO/IEC 17000:2004

notification of conformity assessment bodies under the harmonisation legislation of the Union.

- Notified bodies: Notified bodies are conformity assessment bodies that have been officially designated and notified by the notifying authorities to carry out the procedures for conformity assessment provided for in Union harmonisation legislation. They can be public or private.
- Market surveillance: Market surveillance aims to ensure that products comply with applicable requirements that provide a high level of protection of public interests protected by EU harmonisation legislation.

Among the products or safety components of products whose harmonization legislation presents this structure we find: machines, toys, elevators, equipment and protection systems for use in potentially explosive atmospheres, radio equipment, pressure equipment, recreational craft equipment, cable transport installations, appliances that burn gaseous fuels, medical devices and products toilets for in vitro diagnosis.

Each of these products and product safety components have their own harmonization law that follows the structure set by the NLF. In this way, the product must comply with the legal requirements in force at the time of placing on the market or putting into service. These legal requirements are provided for in each of the harmonization laws[3].

The European Regulation on Artificial Intelligence has the same structure mentioned above, adapted to the requirements of AI systems. The following pages study the integration of all these instruments into the European Regulation on Artificial Intelligence.

[3]The list of products and product safety components along with the laws that regulate each of these can be found here:

https://single-market-economy.ec.europa.eu/single-market/ce-marking/manufacturers_en

3. European Regulation on Artificial Intelligence

The putting into service or use of high-risk AI systems should be subject to compliance with certain mandatory requirements, including compliance. Those requirements aim to ensure that high-risk AI systems available in the Union or whose output outputs are used in the Union do not pose unacceptable risks to important public interests recognised and protected by Union law.

This section includes the articles referring to the conformity assessment of the requirements for high-risk AI systems as defined in Regulation 2024/1689 of the European Parliament and of the Council of 13 June 2024 (European Regulation on Artificial Intelligence) and details which sections of this guide address the different elements of said articles.

3.1 Previous analysis and relationship of the articles

The obligations on conformity, as it is a cross-cutting issue to the requirements established in Chapter III, section 2 of the European Regulation on Artificial Intelligence, are spread over a multitude of articles and annexes, but specifically on the assessment of this conformity, we find it mainly in article 43 of the European Regulation on Artificial Intelligence. In addition, annexes VI and VII must be taken into account in addition to article 43.

Due to the nature and content of this article and in annexes, they will be dealt with, in the specific case of this guide, jointly. In this sense:

- **Article 43 Conformity assessment:** Establishes the necessary conditions to demonstrate compliance with the requirements for high-risk AI systems.
- **Annex VI Conformity assessment procedure based on internal control:** It sets out the requirements for conformity assessment in an internal control, i.e. carried out by the AI system provider itself.
- **Annex VII Conformity based on an assessment of the quality management system and an assessment of the technical documentation:** It focuses on the evaluation of the quality management system and the evaluation of the technical documentation, with the participation of a notified body.

3.2 Content of the articles in the AI Act

AI Act

Art.43 – Conformity assessment

1. For high-risk AI systems listed in point 1 of Annex III, where, in demonstrating the compliance of a high-risk AI system with the requirements set out in Section 2, the provider has applied harmonised standards referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall opt for one of the following conformity assessment procedures based on:

(a) the internal control referred to in Annex VI; or

(b) the assessment of the quality management system and the assessment of the technical documentation, with the involvement of a notified body, referred to in Annex VII.

In demonstrating the compliance of a high-risk AI system with the requirements set out in Section 2, the provider shall follow the conformity assessment procedure set out in Annex VII where:

(a) harmonised standards referred to in Article 40 do not exist, and common specifications referred to in Article 41 are not available;

(b) the provider has not applied, or has applied only part of, the harmonised standard;

(c) the common specifications referred to in point (a) exist, but the provider has not applied them;

(d) one or more of the harmonised standards referred to in point (a) has been published with a restriction, and only on the part of the standard that was restricted.

For the purposes of the conformity assessment procedure referred to in Annex VII, the provider may choose any of the notified bodies. However, where the high-risk AI system is intended to be put into service by law enforcement, immigration or asylum authorities or by Union institutions, bodies, offices or agencies, the market surveillance authority referred to in Article 74(8) or (9), as applicable, shall act as a notified body.

2. For high-risk AI systems referred to in points 2 to 8 of Annex III, providers shall follow the conformity assessment procedure based on internal control as referred to in Annex VI, which does not provide for the involvement of a notified body.

3. For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider shall follow the relevant conformity assessment procedure as required under those legal acts. The requirements set out in Section 2 of this Chapter shall apply to those high-risk AI systems and shall be part of that

assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply.

For the purposes of that assessment, notified bodies which have been notified under those legal acts shall be entitled to control the conformity of the high-risk AI systems with the requirements set out in Section 2, provided that the compliance of those notified bodies with requirements laid down in Article 31(4), (5), (10) and (11) has been assessed in the context of the notification procedure under those legal acts.

Where a legal act listed in Section A of Annex I enables the product manufacturer to opt out from a third-party conformity assessment, provided that that manufacturer has applied all harmonised standards covering all the relevant requirements, that manufacturer may use that option only if it has also applied harmonised standards or, where applicable, common specifications referred to in Article 41, covering all requirements set out in Section 2 of this Chapter.

4. High-risk AI systems that have already been subject to a conformity assessment procedure shall undergo a new conformity assessment procedure in the event of a substantial modification, regardless of whether the modified system is intended to be further distributed or continues to be used by the current deployer.

For high-risk AI systems that continue to learn after being placed on the market or put into service, changes to the high-risk AI system and its performance that have been pre-determined by the provider at the moment of the initial conformity assessment and are part of the information contained in the technical documentation referred to in point 2(f) of Annex IV, shall not constitute a substantial modification.

5. The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend Annexes VI and VII by updating them in light of technical progress.

6. The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend paragraphs 1 and 2 of this Article in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VII or parts thereof. The Commission shall adopt such delegated acts taking into account the effectiveness of the conformity assessment procedure based on internal control referred to in Annex VI in preventing or minimising the risks to health and safety and protection of fundamental rights posed by such systems, as well as the availability of adequate capacities and resources among notified bodies.

AI Act

Annex VI - Conformity assessment procedure based on internal control

1. The conformity assessment procedure based on internal control is the conformity assessment procedure based on points 2, 3 and 4.

2. The provider verifies that the established quality management system is in compliance with the requirements of Article 17.

3. The provider examines the information contained in the technical documentation in order to assess the compliance of the AI system with the relevant essential requirements set out in Chapter III, Section 2.

4. The provider also verifies that the design and development process of the AI system and its post-market monitoring as referred to in Article 72 is consistent with the technical documentation.

AI Act

Annex VII - Conformity based on an assessment of the quality management system and an assessment of the technical documentation

1.Introduction

Conformity based on an assessment of the quality management system and an assessment of the technical documentation is the conformity assessment procedure based on points 2 to 5.

2. General Presentation

The approved quality management system for the design, development and testing of AI systems pursuant to Article 17 shall be examined in accordance with point 3 and shall be subject to surveillance as specified in point 5. The technical documentation of the AI system shall be examined in accordance with point 4.

3. Quality management system

3.1. The application of the provider shall include:

(a) the name and address of the provider and, if the application is lodged by an authorised representative, also their name and address;

(b) the list of AI systems covered under the same quality management system;

(c) the technical documentation for each AI system covered under the same quality management system;

(d) the documentation concerning the quality management system which shall cover all the aspects listed under Article 17;

(e) a description of the procedures in place to ensure that the quality management system remains adequate and effective;

(f) a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality management system shall be assessed by the notified body, which shall determine whether it satisfies the requirements referred to in Article 17.

The decision shall be notified to the provider or its authorised representative.

The notification shall contain the conclusions of the assessment of the quality management system and the reasoned assessment decision.

3.3. The quality management system as approved shall continue to be implemented and maintained by the provider so that it remains adequate and efficient.

3.4. Any intended change to the approved quality management system or the list of AI systems covered by the latter shall be brought to the attention of the notified body by the provider.

The proposed changes shall be examined by the notified body, which shall decide whether the modified quality management system continues to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

The notified body shall notify the provider of its decision. The notification shall contain the conclusions of the examination of the changes and the reasoned assessment decision.

4. Control of the technical documentation.

4.1. In addition to the application referred to in point 3, an application with a notified body of their choice shall be lodged by the provider for the assessment of the technical documentation relating to the AI system which the provider intends to place on the market or put into service and which is covered by the quality management system referred to under point 3.

4.2. The application shall include:

(a) the name and address of the provider;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) the technical documentation referred to in Annex IV

4.3. The technical documentation shall be examined by the notified body. Where relevant and limited to what is necessary to fulfil its tasks, the notified body shall be granted full access to the training, validation, and testing data sets used, including, where appropriate and subject to security safeguards, through API or other relevant technical means and tools enabling remote access.

4.4. In examining the technical documentation, the notified body may require that the provider supply further evidence or carry out further tests so as to enable a proper assessment of the conformity of the AI system with the requirements set out in Chapter III, Section 2. Where the notified body is not satisfied with the tests carried out by the provider, the notified body shall itself directly carry out adequate tests, as appropriate.

4.5. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Chapter III, Section 2, after all other reasonable means to verify conformity have been exhausted and have proven to be insufficient, and upon a reasoned request, the notified body shall also be granted access to the training and trained models of the AI system, including its relevant parameters. Such access shall be subject to existing Union law on the protection of intellectual property and trade secrets.

4.6. The decision of the notified body shall be notified to the provider or its authorised representative. The notification shall contain the conclusions of the assessment of the technical documentation and the reasoned assessment decision.

Where the AI system is in conformity with the requirements set out in Chapter III, Section 2, the notified body shall issue a Union technical documentation assessment certificate. The certificate shall indicate the name and address of the provider, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for the identification of the AI system.

The certificate and its annexes shall contain all relevant information to allow the conformity of the AI system to be evaluated, and to allow for control of the AI system while in use, where applicable.

Where the AI system is not in conformity with the requirements set out in Chapter III, Section 2, the notified body shall refuse to issue a Union technical documentation assessment certificate and shall inform the applicant, accordingly, giving detailed reasons for its refusal.

Where the AI system does not meet the requirement relating to the data used to train it, re-training of the AI system will be needed prior to the application for a new conformity assessment. In this case, the reasoned assessment decision of the notified body refusing to issue the Union technical documentation assessment certificate shall contain specific considerations on the quality data used to train the AI system, in particular on the reasons for non-compliance.

4.7. Any change to the AI system that could affect the compliance of the AI system with the requirements, or its intended purpose shall be assessed by the notified body which issued the Union technical documentation assessment certificate. The provider shall inform such notified body of its intention to introduce any of the abovementioned changes, or if it otherwise becomes aware of the occurrence of such changes. The

intended changes shall be assessed by the notified body, which shall decide whether those changes require a new conformity assessment in accordance with Article 43(4) or whether they could be addressed by means of a supplement to the Union technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the provider of its decision and, where the changes are approved, issue to the provider a supplement to the Union technical documentation assessment certificate.

5. Surveillance of the approved quality management system.

5.1. The purpose of the surveillance carried out by the notified body referred to in Point 3 is to make sure that the provider duly complies with the terms and conditions of the approved quality management system.

5.2. For assessment purposes, the provider shall allow the notified body to access the premises where the design, development, testing of the AI systems is taking place. The provider shall further share with the notified body all necessary information.

5.3. The notified body shall carry out periodic audits to make sure that the provider maintains and applies the quality management system and shall provide the provider with an audit report. In the context of those audits, the notified body may carry out additional tests of the AI systems for which a Union technical documentation assessment certificate was issued.

3.3 Correspondence of the articles with the sections of the guide

Article	AI Act requirement	Section
43.1	Conformity assessment for high-risk AI systems referred to in points 1 of Annex III. (biometrics)	Section 4.3.1
43.2	Conformity assessment for high-risk AI systems referred to in points 2 to 8 of Annex III.	Section 4.3.2
43.3	Conformity assessment for high-risk AI systems regulated by Union harmonisation legislation listed in Section A of Annex I.	Section 4.3.3
43.4	Conformity assessment in the event of substantial modification.	Section 4.4
Annex VI	Conformity assessment procedure based on internal control. (evaluation by the provider)	Section 4.2.1
Annex VII	Conformity based on an assessment of the quality management system and an assessment of the technical documentation. (assessment by the notified body)	Section 4.2.2

4. How to approach the requirements?

4.1 Conformity assessment during the development and placing on the market of products

The conformity assessment procedure consists of a whole series of processes and phases through which it is verified that a product complies with the requirements of harmonisation legislation required so that such a product can be placed on the market with certain guarantees.

It is up to each provider/manufacturer to be very clear about the intended purpose of the product to be designed, the end users to whom it is intended and the essential characteristics of the product. This is because the first essential step is to assess whether there is indeed a harmonization law on the product that is intended to be developed or, where appropriate, placed on the market.

Once it has been detected that the product that is being designed or intended to be designed will be affected by one of these harmonisation laws, the next step will be to analyse the minimum compliance requirements of the product, and the conformity assessment process contemplated in that law.

The latter is extremely relevant, since many of the requirements and evidence that must be demonstrated and verified as part of the conformity assessment of a product must be integrated and contemplated from the first phases of conception of said product.

Providers participating in regulatory sandboxes:

The European Regulation on Artificial Intelligence stipulates that providers participating in controlled testing environments may use documentation extracted from these environments for the purpose of demonstrating that their AI systems comply with this standard. Both market surveillance authorities and notified bodies will take into account reports derived from providers' participation in these environments with a view to speeding up conformity assessment procedures.

4.2 The conformity assessment procedure in the AI Act for high-risk AI systems

As mentioned previously in the introduction, the regulation establishes two ways of assessing the conformity of high-risk AI systems based on the procedure to be carried out and whether or not a notified body is involved in the conformity assessment. Both possibilities are detailed below.

4.2.1 Internal control by the provider

The internal control procedure is encompassed by three actions that the **provider itself** must carry out to assess the conformity of its AI system.

These are:

1. Quality management system verification.
2. Checking the technical documentation.
3. Verification of the design and development process of the AI system and its post-market surveillance.

These actions are revealed.

4.2.1.1 Quality Management System Verification

AI Act

> ANNEX VI – Procedure for conformity assessment based on internal control
>
> 2. The provider verifies that the established quality management system is in compliance with the requirements of Article 17.

The AI Sandbox has a specific guide dedicated to analysing the quality management system.

As regards the **conformity assessment procedure**, it is up to the provider to check that each of the elements referred to in Article 17 of the European Regulation on Artificial Intelligence are incorporated into the quality management system that the provider has had to develop within the framework of this sandbox taking as a reference the Quality Management System Guide provided.

Article 17 of the European Regulation on Artificial Intelligence establishes 13 sections that must have been documented at least beforehand when developing the quality management system.

SMEs and start-ups:

It should be noted that the regulatory compliance requirements of the quality management system will be proportionate to the size of the provider's organisation. However, providers shall respect the degree of rigour and level of protection required to ensure that their high-risk AI systems comply with the AI Act.

4.2.1.2 Checking the technical documentation

AI Act

> ANNEX VI – Procedure for conformity assessment based on internal control
>
> 3. The provider examines the information contained in the technical documentation in order to assess the compliance of the AI system with the relevant essential requirements set out in Chapter III, Section 2.

The AI Sandbox has different specific guides that develop compliance with articles 8 to 15 of the European Regulation on Artificial Intelligence. In addition, there is a specific guide dedicated to the technical documentation to be prepared by providers participating in this sandbox.

As regards the **conformity assessment procedure**, the provider should take as a reference the information contained in the technical documentation that it has prepared in the framework of the sandbox to assess whether the system complies with the essential requirements set out in Articles 8 to 15 of the European Regulation on Artificial Intelligence.

Checking and examining technical documentation:

1. Collect all the technical documentation you have produced. Remember that there is a specific Guide on technical documentation.
2. Check that the technical documentation produced covers the various essential requirements set out in Articles 8 to 15.
3. Assess the conformity of your system with the requirements of Articles 8 to 15 by reference to the technical documentation. Depending on the requirement being assessed, you will need to implement different assessment measures such as document checking, trials, testing of your AI system, etc.
4. Evaluation measures should be documented.

SMEs and start-ups:

The European Regulation on Artificial Intelligence allows SMEs and start-ups to submit the technical documentation of their AI systems in simplified manner. To this end, the European Commission will develop a standard form. Where a provider chooses to use this form, it shall be sufficient for the purposes of the conformity of the technical documentation of the AI system.

4.2.1.3 Verification of the system design and development process

AI Act

ANNEX VI – Procedure for conformity assessment based on internal control

The provider also verifies that the design and development process of the AI system and its post-market monitoring as referred to in Article 72 is consistent with the technical documentation.

There is specific guide dedicated to the deployment of the post-market surveillance system in Article 72 of the European Regulation on Artificial Intelligence. In addition, there is another specific guide dedicated to the technical documentation to be prepared by the provider.

As regards **the conformity assessment procedure**, the provider should verify that the design process and post-market surveillance of its AI system are consistent with the part of the technical documentation that refers to those paragraphs. To this end, **the provider will entrust** this task to personnel with the necessary qualifications and knowledge of the AI system to carry out this verification.

Once the three actions have been carried out by the provider mentioned above, the conformity assessment will be understood to have been carried out and passed.

The implementation of this entire internal procedure **must be fully documented** and must **always be available** to the competent market surveillance authority when required.

Member States' authorities have a legal obligation to ensure that the technical documentation they collect during market surveillance activities remains confidential. Therefore, providers should have no reason to believe that the information provided could be disclosed.

4.2.2 Conformity assessment in the presence of a notified body.

Annex VII of the European Regulation on Artificial Intelligence establishes various actions and processes in which both **the provider and the notified body intervene** when carrying out the conformity assessment.

The Annex VII conformity assessment procedure essentially comprises the examination of:

- The quality management system in Article 17.
- The technical documentation referred to in Annex IV.

The AI Sandbox has a specific guide dedicated to analysing the quality management system and another specific guide dedicated to technical documentation.

SMEs and start-ups:

Notified bodies should take into account the size of the provider and the sector in which it operates during their conformity assessments. All with the aim of minimizing administrative burdens and compliance costs for SMEs and start-ups.

When setting the fees for the conformity assessment process, these shall be reduced proportionally to the size of SMEs and start-ups.

4.2.2.1 Analysis of the quality management system with the presence of a notified body

Evaluation Request:

In order for the notified body to be able to evaluate the quality management system, the provider must submit a duly prepared request to that body.

In accordance with section 3.1 of Annex VII of the European Regulation on Artificial Intelligence, such an application shall contain the following information:

- the name and address of the provider and, if the application is submitted by the authorised representative, also their name and address;
- the list of AI systems to which the same quality management system applies;
- the technical documentation of each AI system to which the same quality management system applies;
- documentation relating to the quality management system, which shall cover all aspects listed in Article 17;
- a description of the procedures in place to ensure that the quality management system remains adequate and effective;
- a written statement that the same application has not been submitted to any other notified body.

Each notified body shall establish its own application, which shall contain at least the information indicated above**. As an example**, the notified body in Spain on medical devices has designed a specific application to be completed by manufacturers of medical devices when requesting the evaluation of the quality management system[4].

Quality System Assessment:

The notified body shall assess the quality system and decide whether it complies with the requirements of Article 17 of the European Regulation on Artificial Intelligence.

Decision of the notified body on conformity assessment:

The decision on the conformity of the system shall be notified to the provider or its authorised representative. It shall be duly reasoned and shall include the conclusions of the assessment of the quality management system and the reasoned assessment decision.

The decision on the conformity of the system shall determine whether or not the quality management system complies with the requirements of Article 17 of the European Regulation on Artificial Intelligence. It is the responsibility of the notified body to approve or reject that quality management system.

Quality Management System Maintenance:

Once the quality management system has been approved by the notified body, the provider shall implement and maintain it to ensure that it remains adequate and effective.

Possible modifications:

Where the provider intends to amend the approved quality management system or the list of AI systems to which it applies, this shall be communicated to the notified body.

The notified body shall examine the proposed changes and decide whether the amended quality management system continues to comply with the requirements mentioned initially and for which the quality management system was approved or whether a new evaluation is necessary.

The notified body shall notify the provider of its decision. The notification shall include the conclusions of the review of the changes and the reasoned evaluation decision.

Monitoring of the approved quality management system:

To ensure that the provider duly complies with the conditions of the approved quality management system, the notified body:

[4] This is the case of the National Centre for the Certification of Medical Devices, the only notified body in Spain for the conformity assessment of medical devices regulated in Regulation 2017/745, of 5 April, on medical devices. The application for the evaluation of the quality management system can be consulted on the following website.

https://certificaps.gob.es/docs/R_DEX_05-solicitud-de-evaluacion-del-sistema-de-gestion-de-calidad.pdf

- You will gain access to the facilities where the design, development, or testing of the AI system is taking place.
- Will regularly conduct audits to ensure that the provider maintains and implements the approved quality management system. In these cases, a report shall be issued by the notified body on that audit.
- In addition, as part of these audits, additional tests may be carried out on AI systems for which an EU Technical Documentation Assessment Certificate has been issued.

For example, the monitoring of the quality management system of a medical device within the framework of the Medical Device regulation once it has received the CE certificate from a notified body is made up of various actions carried out by that body, including:

- Conducting annual follow-up audits that may lead to the suspension, limitation, or withdrawal of the certificate.
- Unannounced, unscheduled on-site audits.
- Every five years, the conformity assessment of the products is reviewed and recertified.
- Significant changes in the intended purpose or design of the product require a new conformity assessment procedure.

SMEs and start-ups:

It should be noted that the regulatory compliance requirements of the quality management system will be proportionate to the size of the provider's organization. However, providers shall respect the degree of rigor and level of protection required to ensure that their high-risk AI systems comply with this regulation.

4.2.2.2 Analysis of technical documentation in the presence of a notified body

Evaluation Request:

In order for the notified body to be able to assess the technical documentation, the provider must submit a request to that body.

In accordance with section 4.2 of Annex VII of the European Regulation on Artificial Intelligence, such application shall contain the following information:

- the name and address of the provider;
- a written statement that the same application has not been submitted to any other notified body;
- the technical documentation provided for in Annex IV.

When submitting the application, the provider must check whether the notified body to which it has requested the assessment has a specific application form, and whether the scope of its designation includes the type of product for which the technical documentation assessment is requested.

Evaluation of technical documentation

The notified body shall evaluate the technical documentation in a variety of ways. (Sections 4.3, 4.4 and 4.5 of Annex VII)

1. Section 4.3: The technical documentation shall be examined by the notified body. Where relevant and limited to what is necessary to fulfil its tasks, the notified body shall be granted full access to the training, validation, and testing data sets used, including, where appropriate and subject to security safeguards, through API or other relevant technical means and tools enabling remote access.

Remember that within the framework of the sandbox, a Technical Documentation Guide has had to be developed. The technical documentation shall be provided in a clear and organised manner taking as reference the requirements set out in the European Regulation on Artificial Intelligence.

- Clear: The information must follow a coherent structure.
- Organized: Provide the detailed documentation taking as a reference the different sections that make up Annex IV of the European Regulation on Artificial Intelligence. It will be essential to take as a reference the Technical Documentation Guide that brings together in an organized way all the documentation required by the European Regulation on Artificial Intelligence.

This documentation is the support used by the provider to demonstrate the compliance of its AI system with the requirements of the AI Act. For some products, the competent notified bodies have designed specific guidelines on how manufacturers should submit such technical documentation. **As an example**, the notified body in Spain on medical devices in order to carry out the evaluation of technical documentation has developed a specific guide to submit this documentation[5]. This guide indicates that the documentation must be incorporated into different folders, each folder corresponds to the different sections provided for by the regulation on medical devices.

Where appropriate, the notified body will be able **to access the** training, validation and test **datasets** used. This access may be made through application programming interfaces (APIs) or other tools that allow remote access.

5 See the Guide on the technical documentation to be submitted by the manufacturers of these medical devices prepared by the National Centre for the Certification of Medical Devices within the framework of Regulation 2017/745, of 5 April, on medical devices. This guide can be consulted on the following website.

https://certificaps.gob.es/wp-content/uploads/CertificacionMDR/R_DEX_18-Gu%C3%ADa-para-la-documentacion-tecnica.pdf

2. Section 4.4: In examining the technical documentation, the notified body **may require that the provider supply further evidence or carry out further tests** so as to enable a proper assessment of the conformity of the AI system with the requirements set out in Chapter III, Section 2. Where the notified body is not satisfied with the tests carried out by the provider, the notified body shall itself directly carry out adequate tests, as appropriate.
3. Section 4.5: Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Chapter III, Section 2, after all other reasonable means to verify conformity have been exhausted and have proven to be insufficient, and upon a reasoned request, **the notified body shall also be granted access to the training and trained models of the AI system**, including its relevant parameters. Such access shall be subject to existing Union law on the protection of intellectual property and trade secrets.

The aim of all these actions is for the notified body to be able to adequately verify compliance with the requirements of the European Regulation on Artificial Intelligence by an AI system through different evidence.

SMEs and start-ups:

The European Regulation on Artificial Intelligence allows SMEs and start-ups to submit technical documentation for their AI systems in a simplified manner. To this end, the European Commission will develop a form. When a provider opts for this form, notified bodies are obliged to accept the submission of technical documentation through it for the purposes of assessing the conformity of the AI system.

Decision of the notified body on conformity assessment:

Once the notified body has evaluated the technical documentation, they must notify the provider or its authorised representative of the decision to evaluate the technical documentation.

The decision shall be reasoned and shall include the conclusions of the evaluation of the technical documentation and the reasoned evaluation decision.

The evaluation decision may indicate that[6]:

a) The AI system **complies** with the requirements set out in the European Regulation on Artificial Intelligence for High-Risk systems. In such cases, the notified body **shall issue** the EU certificate for the assessment of the documentation.

[6] See Section 4.6 Annex VII of the EUROPEAN REGULATION ON ARTIFICIAL INTELLIGENCE.

b) The AI system **does not meet** the requirements set out in the European Regulation on Artificial Intelligence for High-Risk systems. In such cases, the notified body **shall not issue** the EU certificate for the assessment of the documentation.

c) The system **does not meet** the requirements relating to the data used for its training. In such cases, the notified body shall not issue the EU certificate and shall also **set out specific considerations relating** to the quality of the data used to train the AI system, paying particular attention to the reasons for non-compliance.

Once all the aforementioned actions have been carried out, the conformity assessment shall be deemed to have been passed. If the decision is not positive, the provider may request a new assessment or appeal the decision. However, if a notified body determines that a system does not pass the conformity assessment, a new application may not be submitted without modifications having been made to the system or to the technical documentation demonstrating its conformity.

The duration of the conformity assessment procedure for the different products where the participation of a notified body is envisaged will vary depending on various factors such as the type of product, notified body to which the application is submitted, stages of the conformity assessment provided for in harmonisation legislation, etc.

In the case of the evaluation of medical devices in Spain, from the time the application is submitted until the conformity is finally approved, the approximate average time has ranged from 6 to 12 months, although, with the entry into force of the AI Act on medical devices, these periods are reaching 18 months.

In many cases, from the initial request for conformity assessment submitted by the manufacturer, the notified body may not accept it because it realizes that the product will not be able to pass the conformity assessment. In this way, this application is rejected until the initial deficiencies detected are perfected.

4.3 Form of conformity assessment according to the type of AI system

Article 43 of the European Regulation on Artificial Intelligence establishes the conformity assessment process to be carried out by each provider taking into account the type of AI system it holds.

4.3.1 Biometric identification AI systems classified as High Risk

The conformity assessment of remote biometric identification systems referred to in point 1 of Annex III of the European Regulation on Artificial Intelligence presents differentiated assessment processes depending on whether or not the provider has applied harmonised standards (Article 40 of the AI Act) or common specifications (Article 41 of the AI Act).

4.3.1.1 The provider has applied harmonised standards or common specifications

When the provider, in demonstrating compliance with the requirements of the AI Act for High-Risk systems, **has applied** harmonised standards or common specifications, **they must opt** for one of the two procedures for conformity assessment as follows:

- Conformity assessment carried out by the provider itself. Internal control. Internal self-assessment of conformity[7].
- Conformity assessment in the presence of a notified body[8].

4.3.1.2 The provider has not applied harmonised standards or common specifications

When the provider, when demonstrating compliance with the requirements set out in the AI Act for High-Risk systems, **has not applied** harmonised standards or these have been partially applied or does not have common specifications, **they must carry out** the conformity assessment in the presence of a notified body.

4.3.1.3 The notified bodies competent to carry out the conformity assessment for biometric identification systems

Example – Attendance control using biometric recognition

The provider of this AI system will have to assess the conformity of the product.
Have I applied harmonised standards or common specifications to meet the requirements of the AI Act?
YES: I can choose to assess conformity through internal control or through external control carried out by the notified body.
NO: I have to carry out the conformity assessment with the participation of the notified body.

As a general rule, for this conformity assessment procedure involving the notified body, the provider may choose the notified body it deems appropriate.

[7] Annex VI. A conformity assessment procedure based on internal control.
[8] Annex VII. Conformity based on the evaluation of the quality management system and the evaluation of the technical documentation.

However, several specific rules are established depending on the authority that puts the AI system into operation.

Thus, when the system is expected to be put into service by:

(A) The law enforcement authorities or the immigration or asylum authorities, the notified bodies to carry out the conformity assessment shall be the relevant market surveillance authorities[9].

B) The EU institutions, bodies or agencies, the notified body will be the European Data Protection Supervisor.

4.3.2 Other high-risk AI systems

The conformity assessment of the AI systems provided for in points 2 to 8 of Annex III shall be based on the internal control carried out by the provider.

It should be recalled that the AI systems provided for in points 2 to 8 of Annex III are:

- Critical infrastructures.
- Education and vocational training.
- Employment, worker management and access to self-employment.
- Access to and enjoyment of essential private services, essential public services and benefits.
- Law enforcement, to the extent that its use is permitted by applicable Union or national law.
- Migration, asylum and border control management.
- Administration of Justice and Democratic Processes.

For example, an AI system whose main function is to grant aid falls within the high-risk systems referred to in point 5 of Annex III, therefore, in order to assess its compliance with the requirements of the AI Act, the provider's internal control must be carried out.

4.3.3 AI system that are products or safety components of products of harmonisation legislation.

As noted above, there are a whole range of products and product safety components that have been regulated following the NLF. The European legislation regulating these products is mentioned in Section A of Annex I of the AI Act.

It is possible that an AI system may be a product or safety component of a product as indicated in the harmonisation legislation in Section A of Annex I of the AI Act.

[9] Specifically, these authorities may be: (i) national authorities that supervise the activities of law enforcement authorities, (ii) border control, immigration or asylum authorities, (iii) judicial authorities or, (iv) supervisory authorities responsible for data protection under Directive (EU) 2016/680 or Regulation 2016/679.

The assessment of the requirements applicable to high-risk AI systems will be part of the conformity assessment provided for in each of the laws harmonising those products or components. The aim is to reduce the burden on operators whose products or product safety components are subject to both the harmonisation legislation specific to each product and the AI Act [10].

4.3.3.1 Conformity assessment of harmonisation legislation

To sum up, the conformity assessment provided for in each act of harmonisation legislation depends in most cases on the product. In other words, within the same act of legislation, there are products that have a conformity assessment based on internal control by the manufacturer itself, while other products are required to intervene by a third party[11]. Some laws also allow manufacturers to opt for conformity assessment based on internal control or the involvement of a notified body depending on whether or not they have implemented harmonised standards covering the requirements of that harmonisation legislation.

Standard and product	Conformity assessment
Directive 2006/42/EC on **machinery[12].**	**Depending on the product**, conformity assessment by the Notified Body or internal evaluation by the manufacturer will be necessary.
Directive 2009/48/EC on **toys.**	The involvement of a Notified Body **is foreseen** in the event that the toy in question does not fully (or partially) comply with the harmonised standards in question.
Directive 2013/53/EU on **recreational craft and personal watercraft.**	**Depending on the product**, conformity assessment by the Notified Body or internal evaluation by the manufacturer will be necessary.
Directive 2014/33/EU on **lifts** and safety components thereof	The participation of a notified body **is mandatory in all cases.**
Directive 2014/34/EU on **equipment and protective systems intended for use in potentially explosive atmospheres**	**Depending on the product**, conformity assessment by the Notified Body or internal evaluation by the manufacturer will be necessary.
Directive 2014/53/EU on the **market of radio equipment**	**Depending on the type of conformity assessment** that the manufacturer chooses, it

[10] Recital 63 of the European Regulation on Artificial Intelligence.

[11] For more information on the conformity assessments for each of these products, please see the following website:

https://single-market-economy.ec.europa.eu/single-market/ce-marking/manufacturers_en

[12] This Directive will expire on 14 January 2027. Article 51.2 of Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery, repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC.

	will be carried out by a Notified body or the manufacturer's internal assessment.
Directive 2014/68/EU on the marketing of **pressure equipment.**	**Depending on the product**, conformity assessment by the Notified Body or internal evaluation by the manufacturer will be necessary.
Regulation (EU) 2016/424 on **cableway installations**	The involvement of a notified body **is mandatory in all cases.**
Regulation (EU) 2016/425 on **personal protective equipment**	**Depending on the product**, conformity assessment by the Notified Body or internal evaluation by the manufacturer will be necessary.
Regulation (EU) 2016/426 on **appliances burning gaseous fuels and repealing**	**Depending on the product**, conformity assessment by the Notified Body or internal evaluation by the manufacturer will be necessary.
Regulation (EU) 2017/745 on **medical devices**	**Depending on the product**, conformity assessment by the Notified Body or internal evaluation by the manufacturer will be necessary[13].
Regulation (EU) 2017/746 on **in vitro diagnostic medical devices**	**Depending on the product**, conformity assessment by the Notified Body or internal evaluation by the manufacturer will be necessary.
Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 **on machinery** and replacing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC.	**Conformity assessment by the Notified Body for:** **Machines that incorporate systems with a wholly or partially self-evolving behaviour that use machine learning approaches that guarantee safety functions.** **Safety components with wholly or partially self-evolving behaviour that use machine learning approaches that ensure safety features**

Therefore, the assessment of the requirements of the European Regulation on Artificial Intelligence will be carried out taking into account the methodology and structure contemplated in the conformity assessment of each of the harmonisation legislative acts.

[13] Recital 60 of European Regulation on Artificial Intelligence (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

The **integration of the requirements** provided for in the AI Act into the methodology designed by each harmonization standard **is not expressly specified** in the AI Act throughout its articles.

However, Recital 64 of that regulation does refer to **Regulation 2023/1230 on machinery.** According to this recital, although the European Regulation on Artificial Intelligence addresses the safety risks of AI systems performing safety functions on machines, some of the specific requirements set out in the Machinery Regulation will ensure the safe integration of the AI system in the general machine. This justifies that the assessment of the requirements of the AI Act is carried out in accordance with the conformity assessment provided for in the Machinery Regulation. According to this standard, the conformity assessment of these systems will be carried out in the presence of a notified body[14].

In turn, Recital 64 of the AI Act also mentions the integration of the requirements provided for in the European Regulation on Artificial Intelligence with respect to **MSA 745/2017 and Regulation 746/2017 on medical devices**. For these cases, it is indicated that the integration of these requirements must be done in compliance with the logic of risks management and the evaluation of the benefit-risk relationship that is carried out in the framework of medical devices.

Therefore, **two conclusions** must be drawn from this process of integration between the AI Act and the rest of the harmonisation legislation with regard to the conformity assessment of an AI system:

- The assessment of the requirements arising from the European Regulation on Artificial Intelligence shall be carried out in accordance with the structure envisaged for the conformity assessment indicated in the applicable product legislation.
- Such an assessment of the requirements of the European Regulation on Artificial Intelligence cannot affect the overall structure of the conformity assessment designed in accordance with the harmonisation legislation applicable to each product or safety component of the product.[15]

For example, Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations states that the conformity assessment of these products may be carried out through different conformity assessment procedures in the presence of a notified body chosen by the manufacturer[16]. If that cableway installation incorporates an AI system or is a safety component thereof, the requirements of the European Regulation on Artificial Intelligence must form part of the conformity assessment provided for in the Cableway Installations Regulation.

[14] Recital 54, Article 25.2 and Annex I. Part A of European Regulation on Artificial Intelligence (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC.

[15] See Article 43 and recital 63 of the European Regulation on Artificial Intelligence.

[16] See Article 18 of European Regulation on Artificial Intelligence (EU) 2016/424.

4.3.3.2 Technical documentation analysed by a notified body

In addition to the above, the European Regulation on Artificial Intelligence provides for the following specific obligations related to conformity assessment for AI systems that are products, or a safety component of a product referred to in Section A of Annex II.

Specifically, a whole series of actions are established that the notified bodies of the different harmonisation laws must carry out. These actions are indicated in sections 4.3, 4.4, 4.5 and 4.6 fifth paragraph of Annex VII of the AI Act and have already been previously explained. Now we briefly mention them[17]:

These are:

- Section 4.3: **The notified body** shall in any case **examine the technical documentation** provided by the provider. In addition, in certain circumstances, the notified body may access the training, validation and test data sets used.
- Section 4.4: After examining the technical documentation, **the notified body may require** the provider **to provide further supporting evidence** or, where appropriate, to carry out additional tests.
- Section 4.5: In certain circumstances, the notified body may access the training model and the trained model of the AI system.
- Paragraph 5 of paragraph 4.6: When the AI system does not meet the requirements relating to the data used for its training, it will be necessary to retrain the system before requesting a new conformity assessment. In this case, the **reasoned decision** on the assessment **by the notified body** refusing to issue the Union certificate of assessment of the technical documentation s**hall contain specific considerations regarding the quality of the data used** to train the AI system, in particular regarding the reasons for non-compliance.

[17]More detailed information can be found in the section of this Guide entitled "Analysis of technical documentation with the presence of a notified body".

Example – Chronic disease management. Smart Insulin Pump

The conformity assessment of the requirements provided for in the AI Act shall be carried out:

- Taking into account the conformity assessment procedure provided for in Article 52 et seq. of Regulation (EU) 2017/745 on medical devices.
- Incorporating the requirements derived from the AI Act but respecting the structure of the conformity assessment provided for in the Medical Device Regulation.
- Carrying out the actions provided for in sections 4.3, 4.4, 4.5 and 4.6, fifth paragraph of Annex VII of the AI Act.

4.3.3.3 The non-need for a notified body to carry out the conformity assessment of the product

Where an AI system is a product or safety component of a product of the harmonisation legislation referred to in Section A of Annex I to the European Regulation on Artificial Intelligence, **the manufacturer may** avoid the third-party conformity assessment provided that these two conditions are met cumulatively[18]:

- The harmonisation legislation act provides for the possibility for the manufacturer to dispense with the conformity assessment if the manufacturer has applied harmonised standards that meet all the permitting requirements laid down by that legislation.
- The manufacturer has applied harmonised standards or common specifications covering the requirements for high-risk AI systems.

There **are currently no** harmonised standards or common specifications covering the requirements set out in the European Regulation on Artificial Intelligence for AI systems, so this option to avoid the conformity assessment indicated is not yet possible.

In such cases, even if the manufacturer could avoid the conformity assessment of his product by a notified body in accordance with harmonisation legislation, **that notified body would have to intervene** under the European Regulation on Artificial Intelligence if there are no harmonised standards or common specifications covering the requirements of that standard.

As an example, let's assume that harmonised standards that meet the requirements of the **Machinery Directive 2006/42/EC[19]** have been applied for the manufacture of an intelligent

[18]The third paragraph of Article 43 provides that: In the case of high-risk AI systems regulated by the Union harmonisation legislation listed in Section A of Annex I, the provider shall comply with the conformity assessment procedure required by such legislative acts. The requirements set out in Section 2 of this Chapter shall apply to such high-risk AI systems and shall form part of that assessment. Points 4.3, 4.4 and 4.5 of Annex VII and the fifth paragraph of point 4.6 of that Annex shall also apply.

[19] As already indicated above, this Directive will expire on 14 January 2027.

robot, but there are no harmonised standards to implement the compliance requirements of the European Regulation on Artificial Intelligence.

Article 12(3) of Directive 2006/42/EC on machinery provides that in cases where the machinery has been manufactured in accordance with harmonised standards covering all the relevant essential health and safety requirements of that Directive, the manufacturer may choose the conformity assessment procedure based on the internal control of the manufacturer that is contemplated (Article 12.3.a), being able to dispense with the conformity assessment process carried out by a notified body.

However, because there are currently no harmonized standards covering the requirements set out in the European Regulation on Artificial Intelligence for High-Risk systems, **the manufacturer would not be able** to avoid external control by a notified body.

Another example can be found in Article 19.2 of Directive **2009/48/EC on the safety of toys**, which also provides for the possibility for the manufacturer of these products to dispense with the conformity assessment carried out by notified bodies if it has applied harmonised standards covering all relevant requirements provided for in that Directive.

Thus, if an AI system is a toy or a safety component of a toy, **given that there are no harmonised standards** or common specifications yet to apply the requirements established by the AI Act for high-quality systems, risk, **the manufacturer** of that toy **would not be able to avoid** the notified body even though the legislative act on the harmonisation of toys contemplates this possibility.

4.4 Conformity assessment in the event of substantial modification.

Once the AI system has undergone the conformity assessment and has passed such a verification process it will most likely undergo alterations after its deployment.

The European Regulation on Artificial Intelligence establishes that when that high-risk AI system undergoes a substantial modification, it must undergo a **new conformity assessment**.

A substantial modification **of the AI system** is understood to exist when[20]:

- a change occurs that may affect the compliance of a high-risk AI system (e.g. a change of operating system or software architecture) that has not been foreseen or planned by the provider, or
- the intended purpose of the system is changed.

For **high-risk AI systems that continue to learn** after placing on the market or putting into service, the changes that have been foreseen by the provider at the time of the initial conformity assessment and are included in the information set out in the technical documentation shall not be considered as substantial modifications.

[20] Recital 128 and Article 3.23. European Regulation on Artificial Intelligence.

4.5 Tools related to conformity assessment in the AI Act

The European Regulation on Artificial Intelligence provides for a whole series of instruments that are particularly related to the conformity assessment procedure of high-risk AI systems that should be analysed.

Some of these instruments are also applicable to general-purpose AI models.

4.5.1 Harmonised standards, common technical specifications, other specifications and specific presumptions of conformity

4.5.1.1 Harmonised standards

These are those technical specifications adopted following a request from the Commission for the implementation of European Union harmonisation legislation[21].

The harmonised standards are adopted by one of the following bodies: CEN, CENELEC or ETSI. Generally, a period of approximately three years usually elapses from the request of the European Commission to the drafting of these standards.

Harmonised standards are essential tools for the proper implementation of harmonisation legislation due to their highly technical nature. Despite their name, harmonised standards **are not mandatory**. When references to harmonised standards are published in the Official Journal of the European Union (OJEU), **the application** of their specifications confers a **presumption of conformity** with the essential requirements laid down in that harmonisation legislation.

The harmonised standards do not always cover each and every one of the regulatory compliance requirements required by harmonisation legislation, hence it is common for the manufacturer or provider not only to use this type of standard to demonstrate compliance with the requirements of their product, but also to refer to other instruments to demonstrate the conformity of the product.

[21] Article 2(1)(c) of European Regulation on Artificial Intelligence (EU) No 1025/2012.

AI Act

Art.40.1 – Harmonised standards and standardisation deliverables

High-risk AI systems or general-purpose AI models which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 shall be presumed to be in conformity with the requirements set out in Section 2 of this Chapter or, as applicable, with the obligations set out in of Chapter V, Sections 2 and 3, of this regulation, to the extent that those standards cover those requirements or obligations.

Therefore, providers of high-risk AI systems or providers of general-purpose AI models applying harmonised standards providing for the requirements set out in Section 2 of the Chapter III or in sections 2 and 3 of Chapter V of the European Regulation on Artificial Intelligence respectively shall bear the presumption of conformity of their AI systems.

It is important to note that **the presumption of conformity** granted by the harmonised standards referred to in the European Regulation on Artificial Intelligence and the rest of the harmonisation legislation **never means** that the provider avoids the conformity assessment procedure.

The application of harmonised standards facilitates and speeds up the process of verifying the product conformity assessment, as these rules are drafted and developed to meet the specific requirements of harmonisation legislation.

In some harmonization laws, compliance with harmonized standards allows the manufacturer to choose between conducting the conformity assessment internally or with the involvement of a notified body. However, it is always mandatory to perform the conformity assessment; what changes is the procedure, not the obligation to comply.

This is contemplated, for example, in:

- Directive 2006/42/EC on machinery. (Article 12.3)
- Directive 2009/48/EC on the safety of toys. (Article 19.2)
- Regulation (EU) 2023/1230 on machinery (Article 25.3)
- European Regulation on Artificial Intelligence. (Article 43)[22].

[22] Article 43.1 of the European Regulation on Artificial Intelligence. See the section of this Guide entitled "Annex III remote biometric identification AI systems.

Example – Attendance control using biometric recognition

A provider that has applied harmonised standards that are in line with the requirements of the AI Act for high-risk AI systems may choose to assess the conformity of its AI system through internal control or control by a notified body.

There are currently no harmonised standards covering the requirements of the European Regulation on Artificial Intelligence[23].

4.5.1.2 Common Technical Specifications

The common specifications **are adopted by** the **European Commission**. Within these specifications, express mention is made of the products for which they are intended and the compliance requirements that they cover with respect to the harmonisation legislation on which these specifications have been developed.

As **an example**, the European Commission has developed common technical specifications for certain devices in Regulation (EU) 2017/745 on medical devices[24].

AI Act

Art.41.3 – Common specifications

High-risk AI systems or general-purpose AI models which are in conformity with the common specifications referred to in paragraph 1, or parts of those specifications, shall be presumed to be in conformity with the requirements set out in Section 2 of this Chapter or, as applicable, to comply with the obligations referred to in Sections 2 and 3 of Chapter V, to the extent those common specifications cover those requirements or those obligations.

Thus, and as with harmonised standards, if the common technical specifications cover the requirements of Chapter III, Section 2 (high-risk systems) or the requirements set out in Sections 2 and 3 of Chapter V (general-purpose AI models) indicated in the European Regulation on Artificial Intelligence, the AI system that complies with those specifications **shall be deemed to comply** with the requirements of the AI Act. That is, the application of

[23]The list of harmonised standards can be found on the following website:

https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards_en

[24]See Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of devices with no intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices.

these by providers confers a **presumption of conformity** with the essential requirements provided for in the AI Act.

The common specifications covering the requirements of the European Regulation on Artificial Intelligence **are not mandatory,** however, providers that do not implement them in their AI systems must duly justify that they have adopted technical solutions that demonstrate that they comply with the requirements of the AI Act.

There are currently **no common technical specifications** on the requirements set out the European Regulation on Artificial Intelligence for high-risk AI systems.

4.5.1.3 Other technical specifications

The conformity of a product with the requirements of the AI Act or other harmonisation legislation can be demonstrated not only by harmonised standards or common specifications but also by the use of other specifications or technical standards.

This is essential because, as indicated above, not all harmonised standards or common technical specifications cover each of the compliance requirements provided for in the harmonisation legislation applicable to each product.

These technical specifications may be documented in national or international standards. Unlike harmonised standards or common specifications, **the application of these standards does not presume** the conformity of the product with the harmonisation legislation act, although they can be used to demonstrate that the product complies with that legislation. It will be up to the provider to indicate the evidence that demonstrates that through the application of these technical standards its product complies with the requirements provided for by that legislation.

4.5.1.4 Specific presumptions of conformity

The AI Act provides for several specific presumptions of conformity referring to certain requirements for high-risk AI systems. These requirements are related to data and cybersecurity.

Thus, Article 42 establishes two presumptions:

- On the one hand, when AI systems have been trained and tested **with data** that reflects the specific geographical, behavioural or functional environment of their use, it will be presumed that **such system complies with** the requirement provided for in **Article 10.4 of the AI Act.** There is a specific Guide on Data and Data Governance that discusses this requirement.
- On the other hand, when a high-risk or general-purpose AI system has been certified or issued with a declaration of conformity with a cybersecurity scheme and whose references have been published in the OJEU[25],

[25] Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act).

compliance with the requirements set out in Article 15 of the AI Act on cybersecurity shall be presumed to the extent that such cybersecurity certificate or declaration of conformity provides for such requirements.

4.5.2 Declaration UE of conformity

Through this instrument, **the provider declares** that its product complies with the relevant harmonization legislation.

Article 47 of the AI Act establishes a series of **obligations** to be imposed on the **provider** of high-risk AI systems derived from the declaration of conformity, these are:

- It must be written or electronically signed.
- It shall keep it available to the national competent authority for a period of 10 years after the placing of the AI system on the market or its putting into service.
- A copy shall be provided to the relevant national competent authorities upon request.
- The information it contains shall be as specified in Annex V of the AI Act It shall be translated into a language that can be easily understood by the competent national authorities of the Member State or Member States in which the high-risk AI system is placed on the market or marketed.
- It will be expressly mentioned that the AI system complies with the requirements established by the European Regulation on Artificial Intelligence for High-Risk systems.

The declaration of conformity **is not intended** for general-purpose AI models.

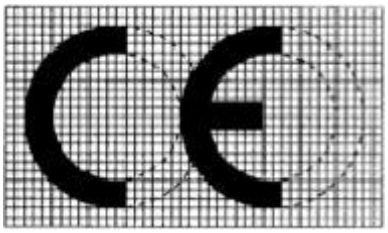
4.5.3 The CE marking

The CE marking is a key indicator (but not a test) of a product's compliance with EU legislation.

AI Act

Art.3.24 – Definitions

"CE marking" means a marking by which a provider indicates that an AI system is in conformity with the requirements set out in Chapter III, Section 2 and other applicable Union harmonisation legislation providing for its affixing.



In accordance with Article 48 of the European Regulation on Artificial Intelligence, the CE marking shall be affixed in a visible, legible and indelible manner on high-risk AI systems. If this is not possible, it shall be placed in the packaging or in the enclosed documents.

For high-risk AI systems that are provided digitally, a digital CE marking shall be used, only if it is readily accessible through the interface from which such a system is accessed or by means of an easily accessible machine-readable code or other electronic means.

This marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures described in this Guide and regulated in Article 43 of the European Regulation on Artificial Intelligence.

Where high-risk AI systems are subjects to other provisions of Union law that also require the affixing of the CE marking, they shall indicate that the high-risk AI systems also meet the requirements of those other provisions.

CE marking **is not intended** for general-purpose AI models.

4.5.4 The notifying authorities and the notified bodies

4.5.4.1 Notifying authorities

The notifying authority is the **public authority** responsible for carrying out the procedures necessary for the assessment, designation and notification of conformity assessment bodies under Union harmonisation legislation.

Each Member State should designate at least one notifying authority that will be responsible for the assessment, notification and monitoring of conformity assessment

bodies. In Spain there is a single notifying authority for each of the harmonisation legislative acts[26].

Therefore, **through the notification**, the notifying authority informs the Commission and the other Member States that a conformity assessment body has been designated to carry out the conformity assessment pursuant to a Union harmonisation act and which meets the requirements for notified bodies set out in that EU harmonisation act.

Member States may decide that the assessment and supervision of notified bodies shall be carried out by the National Accreditation Body, in the case of Spain, ENAC.

4.5.4.2 The notified bodies

Notified bodies are conformity assessment bodies that **have been officially designated and notified** by the notifying authorities to carry out conformity assessment procedures provided for in Union harmonisation legislation where these legal texts provide for the involvement of a third party. They can be either public or private entities.

Therefore, they are responsible for carrying out the different processes and phases that are part of the conformity assessment, these are: presentation of documents, testing, testing, access and inspection of products, etc.

It is important to note that a notified body will not normally be designated for all conformity assessment procedures for the same product, even for the same harmonisation law.

By way of example, in Spain, there are currently 5 notified bodies that can carry out the conformity assessment provided for in Article 12.3.b) and 12.4.a) of Directive 2006/42/EC on **machinery**[27]. On the other hand, there are only 3 notified bodies that can carry out the conformity assessment provided for in Articles 12(3)(c) and 12(4)(b) of the same Directive.

In turn, in the field of **medical devices**, the National Centre for the Certification of Medical Devices is the only notified body in Spain to evaluate the conformity of medical devices and in vitro diagnostic medical devices[28].

Another example can be found in the toys sector, currently there is only one notified body accredited by ENAC to carry out the conformity assessment of the products of Directive 2009/48/EC on the **safety of toys**[29].

The lists of Notified Bodies for the different harmonisation legislative acts can be found on the following website of the European Union: Nando (New Approach Notified and Designated Organisations) Information System.

[26] The notifying authorities in Spain of the different harmonisation legislative acts are the following: https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies/notifying-authorities?filter=countryId:724

[27] As already indicated above, this Directive will expire on 14 January 2027.

[28] https://certificaps.gob.es/

[29] This information can be found at:

https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notification.pdf&dir_id=140521&ntf_id=310342

Articles 29 to 39 of the AI Act regulate everything related to the procedure for a conformity assessment body to become a notified body for the purposes of this standard. There **is currently no** such notified body.

5. References, Standards and Norms

Various sources have been used for the preparation of this guide.

Providers and deployers are particularly encouraged to read the "**Blue Guide on the Implementation of European Product Rules** prepared by the European Commission in 2022.

5.1 Guide Reference Standards

The following standards have been consulted when developing some of the contents indicated in this Guide.

- ISO/IEC 17000:2004, "Conformity assessment – Vocabulary and general principles"
- ISO/IEC 17007:2009, "Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment"
- prEN XXX AI Conformity assessment framework. WIP).

5.2 Standards recommended

It recommends the relevant international standards and guidelines by ISO and IEC known as the CASCO toolbox. Some of these Guides are:

[1] ISO/IEC 23053:2022, "Framework for Artificial Intelligence (AI) Systems Using Machine Learning (ML)"

[2] ISO 9001:2015, "Quality management systems – Requirements"

[3] UNE-ISO/IEC 42001:2025. Tecnología de la información. Inteligencia artificial. Sistema de gestión.

5.3 Standards related to conformity assessment not intended for providers of AI systems.

[4] ISO/IEC 17021-3:2018, "Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 3: Competence requirements for auditing and certification of quality management systems" (Standard intended for notified bodies)

[5] ISO/IEC 17021-1:2015, "Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements". (Standard intended for notified bodies)

[6] ISO/IEC 17029:2019, "Conformity Assessment – General principles and requirements for validation and verification bodies". (Standard intended for notified bodies)

[7] ISO/IEC 17065:2012, "Conformity Assessment - Requirements for bodies certifying products, processes and services". (Standard intended for notified bodies)

[8] ISO/IEC 17011, "Conformity assessment – General requirements for accreditation bodies carrying out accreditation of conformity assessment bodies". (Standard intended for notified bodies)

5.4 Relevant web links

[9] List of product harmonization legislation: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.main

[10] List of harmonised standards on products subject to harmonisation legislation: https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards_en

[11] List of notified bodies for the conformity assessment of products subject to harmonisation legislation: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notifiedbody.notifiedbodies&num=1&text=0001-0100

[12] List of market surveillance authorities of products subject to harmonisation legislation by sector and country: https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/market-surveillance/organisation_en

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