16

Checklist Manual for Requirements Guidelines

European Artificial Intelligence Act

Companies in improvement of their quality

Financiado por la Unión Europea
NextGenerationEU

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

España | digital 2026

This manual has been developed within the framework of the development of the Spanish AI regulatory sandbox pilot, in collaboration between the participants, technical assistance, potential national competent authorities and the sandbox expert advisory group.

The manual aims to serve as an introductory support to the European Regulation on Artificial Intelligence and their applicable obligations. Although **it is not binding and does not replace or develop the applicable regulations, it provides practical recommendations** aligned with regulatory requirements pending the approval of harmonised implementing rules for all member states.

This document is subject to a **permanent evaluation and review process**, with periodic updates in accordance with the development of the standards and the different guidelines published by the European Commission and will be updated once the Digital Omnibus amending the Artificial Intelligence Act is approved.

NIPO: 230260293

Revision date: 30, June 2026

- Document version control:

Version	Revision date	Major changes
1.0	10/12/2025	First official release
1.1.	30/06/2026	Minor editorial changes

General content

Detailed Index

1. Context

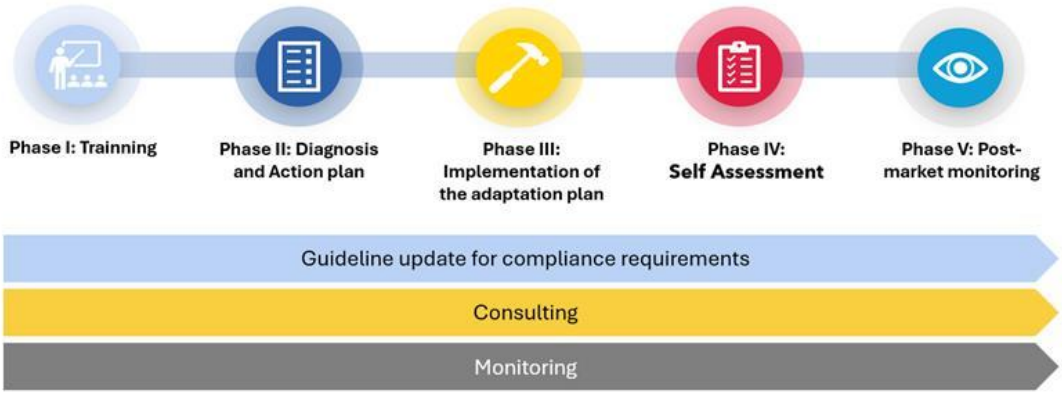
Regulatory sandboxes play a key role in the experimentation and validation of regulatory frameworks, allowing participating entities to develop and implement innovative solutions in a controlled and supervised environment. This approach facilitates early risk detection, agile adaptation to regulatory requirements, and the generation of practical knowledge for continuous regulatory improvement.

In the specific case of the Spanish sandbox, the initiative is a theoretical testing environment that promotes the development and use of responsible AI, focusing on training, support and advice for compliance with the obligations of the Regulation by entities that develop high-risk artificial intelligence systems, in the context of the European Regulation on Artificial Intelligence (Regulation (EU) 2024/1689 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL - hereinafter "RIA"-), and including a conformity assessment simulation.

This sandbox pursues the objectives detailed below:

- Provide clarity on the requirements established in the Regulation.
- Assess the impact of the Regulation and its obligations in a controlled environment.
- Validate the applicability of the technical guides of requirements and the rest of the material made available to the participating entities.
- Transfer knowledge about compliance with the Regulation to entities developing AI solutions.
- Encourage the development of innovative and reliable AI systems.
- To increase the capacities and knowledge in the field of Artificial Intelligence supervision, which will then be reusable by the Spanish Agency for the Supervision of Artificial Intelligence (AESIA).
- Influence the development of the European implementing acts and standardisation processes of the Regulation.
- To make Spain a benchmark for the development of responsible AI in the EU and in the world

For all this, the *sandbox* has been carried out throughout different phases.



1.1 Diagnosis and Action plan

The diagnostic phase has **two objectives**:

- That the entities carry out a **self-diagnosis** of their system, in accordance with the requirements of the AI Act, based on the measures proposed to facilitate their compliance. After this self-diagnosis, each entity will know the **theoretical** gap that remains for compliance with the AI Act.
- Design the Adaptation Plan (ADP) that will allow **planning** the implementation of the measures necessary for such compliance, and which will be executed at a later stage.

To carry out this diagnostic phase, a ***checklist*** tool has been designed as a guideline that allows entities to meet the objectives described:

- Self-diagnosing their compliance with the AI Act **in a simple way,** also being able **to extract indicators** on the **degree of progress of** the same and **conclusions** about the state of their systems at the beginning of the process.
- Designing an **Adaptation Plan** (ADP) which consists of the work plan that each entity will execute to implement the measures that lead to compliance with the AI Act.

There is a checklist tool for each of the 12 requirements on which the diagnosis needs to be made: quality management system, risk management system, human oversight, data and data governance, transparency, accuracy, robustness, cybersecurity, records, technical documentation, post-market monitoring and serious incident management.

2. Introduction

These *checklists* have been successfully tested in the *sandbox*, but their use is not restricted to it, and can be used by any entity to achieve the objectives mentioned above: to carry out a self-diagnosis of compliance with the requirements established by the Regulation by its high-risk AI systems, and to design a plan to adapt its systems to the requirements established by it.

The use of this tool is simple and intuitive, and in addition, it is supported by the requirements guides that accompany it and which detail each of the proposed measures and the reason for their choice to comply with each of the requirements of the AI Act for high-risk AI systems.

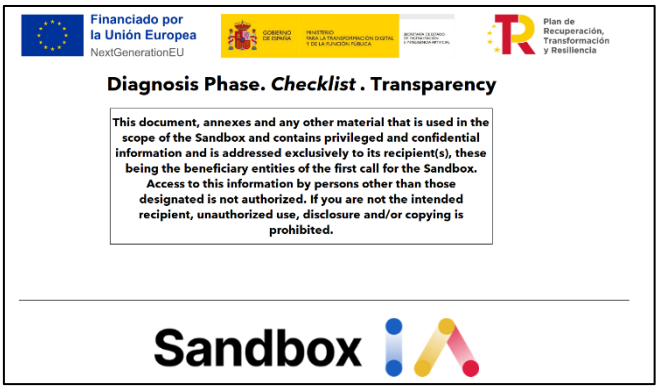
3. Checklist Tool Structure

Such a tool is an Excel document that has the **same structure** for all requirements.
It consists of **9 tabs**, **5 of them informative** with instructions for use and context information, and another 4 operational tabs in which you fill in the required information. To ensure that their use is aligned with the operating procedure of this phase, **it is recommended** to approach the tabs in the order in which they appear in the tool itself.

The information and functionality of each of the tabs is described below, indicating in square brackets the nature of the same (informative or operational).

3.1 Cover [Informational]

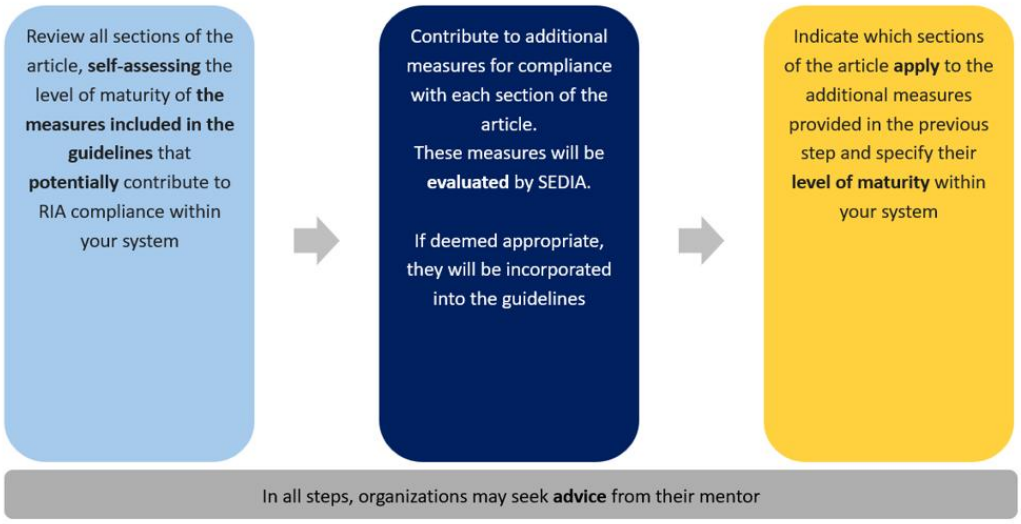
It contains the mandatory confidentiality reminder for SEDIA (Secretary of State for Digitalization and Artificial Intelligence) and all entities participating in the *sandbox*, which includes the use and distribution of this *checklist*.



TRANSPARENCY REQUIREMENT CHECKLIST COVER PAGE EXAMPLE

3.2 Intro [Informative]

It describes in a summarized way the steps and what the tool allows to be done.



3.3 AI Act Article [Informative]

It shows the sections of the article on which the entity is going to make the self-diagnosis. The "*Summary description*" field is a summary of each section to facilitate its contextualization in subsequent tabs.

Section	Description	Summarized Description
13.1	High-risk AI systems shall be **designed and developed** in such a way as to ensure that their operation is sufficiently transparent to enable deployers to interpret a system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured with a view to achieving compliance with the relevant obligations of the provider and deployer set out in Section 3.	Design and development
13.2	High-risk AI systems shall be accompanied by **instructions for use** in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to deployers.	Instructions of use
13.3	The instructions for use shall contain at least the following information	Specific Information
13.3.a	The identity and the **contact details of the provider** and, where applicable, of its authorised representative;	Specific Information.Contact
13.3.b	The **characteristics, capabilities and limitations** of performance of the high-risk AI system, including:	Specific information. Characteristics
13.3.b.i	Its **intended purpose**, including the specific geographical, functional or behavioural environment in which the high-risk AI system is intended to be used	Specific information. Characteristics. Purpose
13.3.b.ii	The **level of accuracy**, including its metrics, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;	Specific information. Characteristics. Level of accuracy

EXAMPLE OF THE TRANSPARENCY CHECKLIST
(THE CONTENT OF THE IMAGE IS PART OF THE EXISTING ONE IN THE TOOL)

3.4 Guiding Measures (MG) [Informative]

It sets out the guideline measures **explained in detail, included in the corresponding guide**, which:

- They have been collected from good practices in the *software industry* and **have been validated** by national and European entities.

- They are expected to be more **detailed** than the standards **expected to** be released by the EC, as these will be more aimed at describing WHAT needs to be done to comply with the AI Act, while the measures described in the guides (and in the checklists) give guidelines on HOW to reach compliance with each requirement (or article).
- **Not all** of them have to be applied in any system according to its characteristics.
- Based on experience, it has been detected *that* there may be **additional measures** that companies are already using in their systems and that are equally valid for AI Act compliance. That is why in the "*Additional Measures (MA)*" tab, described later in this document, they can be added.

In addition, for each measure, some **guiding questions have been defined** in order to contextualize it, so that the answer to them can give an idea of whether or not the system already complies with the measure in question.

ID-Measure	Description	Guiding questions to contextualize the measures
MG01	Provide provider contact	* Is the system accompanied by a channel that allows the management of requests and incidents online? * Does the governance model associated with the system have within its organizational structure a clear point of contact for the supplier available to those deployers?
MG02	Catering to the business domain	* Does the system meet the transparency-related requirements that apply to the use cases supported by the system? * Does the system provide detailed information on its functional scope, also specifying the possible risks due to unforeseen uses of it?
MG03	Ensure the functional objective of the system	* Does the system provide information about foreseeable circumstances where it could be used for purposes other than the one for which it was designed? * Is the system accompanied by a risk plan for such uses? * Does the system have an associated procedure to be able to monitor that such uses do not occur during the operation of the system?
MG04	Transparency about the data used	* Does the system identify the data sources used both in its learning and in its use, also providing the meaning of these sources and data, their usefulness and the implication in their use? * Is the system accompanied by tools that allow a detailed exploratory analysis of data (EDA) of these sources, to know their essence, their associated meta-information, their critical or atypical values, etc.?
MG05	Detailing from the most global to the most particular	* Does the system provide technical mechanisms that facilitate the understanding of its global reasoning mechanism? * Does the system provide technical mechanisms that facilitate the understanding of its actions on a subset of information with similar characteristics to ensure the homogeneity of its operation? * Does the system provide technical mechanisms that facilitate the understanding of each of these actions?
MG06	Adapting the language	* Does the system provide mechanisms that facilitate the understanding of its global reasoning under a language understandable by all the actors that interact with the system throughout its life cycle? * Does the system provide technical mechanisms that facilitate the understanding of its actions on a subset of information with similar characteristics to ensure the homogeneity of its operation, in a language understandable by all the actors that interact with the system throughout its life cycle? * Does the system provide technical mechanisms that facilitate the understanding of your individual actions of the AI system in a language understandable by all actors interacting with the system throughout its entire life cycle?

EXAMPLE OF THE TRANSPARENCY CHECKLIST
(THE CONTENT OF THE IMAGE IS PART OF THE EXISTING ONE IN THE TOOL)

3.5 MG-Apart Ratio. [Informative]

It summarises in an executive way the potential application of the measures set out in the previous tab (Guiding measures (MG)) to each of the sections of the article. It is a visual summary of the relationship between the proposed measures and all the sections of the article.

	Measures															
Sections	MG01	MG02	MG03	MG04	MG05	MG06	MG07	MG08	MG09	MG10	MG11	MG12	MG13	MG14	MG15	MG16
13.1. Design and development		X	X	X	X	X	X	X	X	X	X					
13.2. Instructions of use												X				
13.3. Specific Information																
13.3.a. Specific Information.Contact	X															
13.3.b. Specific information. Characteristics																
13.3.b.i. Specific information. Characteristics. Purpose		X														
13.3.b.ii. Specific information. Characteristics. Level of accuracy			X				X	X		X					X	
13.3.b.iii. Specific information. Characteristics. Risks from unintended uses			X										X			
13.3.b.iv. Specific information. Characteristics. Explaining its Output				X	X	X			X		X					
13.3.b.v. Specific information. Characteristics. Impact on people and groups				X	X											
13.3.b.vi. Specific information. Characteristics. Input data				X	X	X			X		X					
13.3.b.vii. Specific information. Characteristics. Output				X	X				X		X					
13.3.c. Specific information. Changes	X							X								
13.3.d. Specific information. Human Oversight		X	X	X	X	X	X	X	X	X	X			X		
13.3.e. Specific information. HW/SW Resources & Maintenance								X								
13.3.f. Specific information. Log files					X	X										X

EXAMPLE OF THE TRANSPARENCY CHECKLIST

3.6 Autoeval MG. [Operational]

This is the first operational tab of the tool, which will identify both the level of maturity of the implementation of the proposed measure in the system, and the level of perceived difficulty to carry it out. From the completion of this tab will emerge the design of the Adaptation Plan mentioned above, which will be completed with deadlines and efforts, and which will constitute the planning tool for the subsequent phase.

This tab **is pre-reported** with a row for each of the described relationships between measures and subsections of the article.

Section	Summarized section description	ID - Measure	Measure description	Perceived difficulty level	Maturity level	Diagnostic status	Adaptation plan
13.1.	Design and development	MG02	Catering to the business domain			00. Pending Diagnosis	00. Pending Diagnosis
13.1.	Design and development	MG03	Ensure the functional objective of the system			00. Pending Diagnosis	00. Pending Diagnosis
13.1.	Design and development	MG04	Transparency about the data used			00. Pending Diagnosis	00. Pending Diagnosis
13.1.	Design and development	MG05	Detailing from the most global to the most particular			00. Pending Diagnosis	00. Pending Diagnosis
13.1.	Design and development	MG06	Adapting the language			00. Pending Diagnosis	00. Pending Diagnosis
13.1.	Design and development	MG07	Manage complexity			00. Pending Diagnosis	00. Pending Diagnosis
13.1.	Design and development	MG08	Use built-in metrics in the system lifecycle			00. Pending Diagnosis	00. Pending Diagnosis
13.1.	Design and development	MG09	Apply prudence			00. Pending Diagnosis	00. Pending Diagnosis
13.1.	Design and development	MG10	Use causation, minimize correlations			00. Pending Diagnosis	00. Pending Diagnosis
13.1.	Design and development	MG11	Use counterfactuality			00. Pending Diagnosis	00. Pending Diagnosis

EXAMPLE OF THE TRANSPARENCY CHECKLIST
(THE CONTENT OF THE IMAGE IS PART OF THE EXISTING ONE IN THE TOOL)

If the entity also considers that any measure may be used to be applied to an additional section, it may indicate this at the end of the pre-informed rows. For each list, **only two columns must be completed:**

- ***Perceived level of difficulty***, indicating what is the difficulty that the entity understands that the application of said measure would have in its system for that section, based on the following qualitative values:
  - *00. High*
  - *01. Medium*
  - *02. Low*
- ***Maturity level***, indicating what the maturity level of said measure is in your system for the indicated section, using the following values depending on the status of your documentation and implementation in the system:
  - *L1. Not documented or implemented*
  - *L2. Ongoing and unimplemented documentation*
  - *L3. Documented and not implemented*
  - *L4. Documented and Ongoing Implementation*
  - *L5. Documented and Implemented*
  - *L6. Undocumented and Implemented*
  - *L7. Ongoing and Implemented Documentation*
  - *L8. Measure not necessary*, in case the proposed measure is considered not necessary for compliance with the paragraph since, as indicated above, not all measures may have to apply to all types of intelligent systems.

When you select any of the above Maturity *Level values*, you **will automatically**:

- The *Diagnostic Status column* is updated with the value *01. Already diagnosed* (by default, this column appears with the value *00. Diagnosis File*), which **will allow** us to know the degree of progress of the diagnosis.
- The *Adaptation Plan column* is updated with a value that will be used to design the Adaptation Plan for each system, based on the following relationship:

Maturity Level	Adaptation Plan
L1. Not documented or implemented	01. Document and implement
L2. Documentation in progress and not implement	01. Document and implement
L3. Documented and not implemented	02. Implement
L4. Documented and implementation in progress	02. Implement
L5. Documented and implemented	03. Complete Adaptation
L6. Not documented and implemented	04. Document
L7. Documentation in progress and implemented	04. Document
L8. Measure not necessary in my system	05. No Adaptation Required

RELATIONSHIP BETWEEN MATURITY LEVELS AND THE ADAPTATION PLAN TO BE CARRIED OUT

3.7 Additional Measures (MA). [Operational]

From this tab, together with the following two, the self-diagnosis consists of the information from the entities about measures that they themselves propose as possible for compliance with the AI Act and of which SEDIA evaluates their suitability.

This tab **appears without informing**, so that the entity indicates the measures that, in its experience, allow compliance with sections of the article.

To do this, you must add a row for each of these measurements, indicating the following information:

- *Short description:* An identifying description of the measure. It is recommended to use the **same specification** as that used in the Half Guides (MG).
- *File name:* where said measurement will be detailed by the entity. When this field is reported, the "*Additional Documented Measurement*" column will automatically update with the value "*01. Already provided*" (by default, as the field is blank it will appear with the value "*00. Pending contribution*")

Additional measures must be validated by the corresponding institution (SEDIA in the case of the sandbox), which will report the following columns:

- *SEDIA evaluation. Status,* which includes the following values:
  - *00. Evaluation of Additional Measure SEDIA. Pending*, for when the measure is pending assessment by SEDIA.
  - *01. Evaluation of additional SEDIA measure. OK.*, when SEDIA has given its OK to the measure. This will be a success for the entity, as it will have provided a hitherto unidentified measure that will allow its application in Spain and Europe.
  - *02. Evaluation of additional SEDIA measures. NO_OK,* by the time SEDIA rejects the measure after, in addition to using the criteria of its internal experts, it has resorted to external experts and entities for its evaluation.

- *SEDIA evaluation. Comments,* where SEDIA includes additional comments to any of the three states listed above.

ID-Measure	Summarized Description	Name of the file where the measurement is described (template linked)	**Additional Documented Measure**
MA01	Additional measure test1	Additional measurement detail test1	01. Already Contributed
MA02	Additional measure test2	Additional measurement detail test2	01. Already Contributed
MA03	Additional measure test3	Additional measurement detail test3	01. Already Contributed
			00. Pending contribution
			00. Pending contribution

Additional Testing Measures

3.8 MA-Apart. [Operational]

It allows **for an executive summary of the potential application** of the measures reported in the tab before each of the sections of the article.

The identifiers of the measures provided in the previous tab automatically appear in the upper columns.

It is only necessary to mark with an **X (capital letter)** to which section of the article each measure applies.

	Additional Measures															
Sections	MA01	MA02	MA03													
17.1. Minimum QMS requirements	X															
17.1.a. Compliance Strategy	X															
17.1.b. Design procedures	X	X														
17.1.c. Development procedures		X														
17.1.d. Validation procedures		X	X													
17.1.e. Standards applied		X	X													
17.1.f. Data Management System		X	X													
17.1.g. RMS		X	X													
17.1.h. Post-market surveillance system		X	X													
17.1.i. Reporting of Major Incidents		X	X													
17.1.j. Communication Management		X	X													
17.1.k. Registration procedures			X													
17.1.l. Resource management	X															
17.1.m. Accountability	X															
17.2. QMS proportion	X															
17.3. Existing QMS by sectoral regulations																
17.4. QMS in financial institutions			X													

Evidence of the Additional Measures provided in the previous tab with the sections

3.9 Autoeval MA. [Operational]

This is the last step. The tab is automatically **pre-reported** with a row for each of the relationships described in the previous tab. As in the "*Autoeval MG"* tab, only two columns must be reported **for each relationship:** "*Perceived Difficulty Level*" and "*Maturity Level*". The "*Diagnostic Status*" and "*Adaptation Plan*" columns are **automatically** updated when reporting the previous two columns in the same way as in the *"Autoeval MG"* tab described above.

Section	Summarized Section Description	IDMeasure	Measure Description	Perceived Difficulty Level	Maturity Level	Diagnostic Status	Adaptation Plan
17.1.	Minimum QMS requirements	MA01	Additional measure test1			00. Pending Diagnosis	Pendiente de evaluación
17.1.a.	Compliance Strategy	MA01	Additional measure test1			00. Pending Diagnosis	Pendiente de evaluación
17.1.b.	Design procedures	MA01	Additional measure test1			00. Pending Diagnosis	Pendiente de evaluación
17.1.b.	Design procedures	MA02	Additional measure test2			00. Pending Diagnosis	Pendiente de evaluación
17.1.c.	Development procedures	MA02	Additional measure test2			00. Pending Diagnosis	Pendiente de evaluación
17.1.d.	Validation procedures	MA02	Additional measure test2			00. Pending Diagnosis	Pendiente de evaluación
17.1.d.	Validation procedures	MA03	Additional measure test3			00. Pending Diagnosis	Pendiente de evaluación
17.1.e.	Standards applied	MA02	Additional measure test2			00. Pending Diagnosis	Pendiente de evaluación
17.1.e.	Standards applied	MA03	Additional measure test3			00. Pending Diagnosis	Pendiente de evaluación
17.1.f.	Data Management System	MA02	Additional measure test2			00. Pending Diagnosis	Pendiente de evaluación
17.1.f.	Data Management System	MA03	Additional measure test3			00. Pending Diagnosis	Pendiente de evaluación
17.1.g.	RMS	MA02	Additional measure test2			00. Pending Diagnosis	Pendiente de evaluación
17.1.g.	RMS	MA03	Additional measure test3			00. Pending Diagnosis	Pendiente de evaluación
17.1.h.	Post-market surveillance system	MA02	Additional measure test2			00. Pending Diagnosis	Pendiente de evaluación
17.1.h.	Post-market surveillance system	MA03	Additional measure test3			00. Pending Diagnosis	Pendiente de evaluación
17.1.i.	Reporting of Major Incidents	MA02	Additional measure test2			00. Pending Diagnosis	Pendiente de evaluación
17.1.i.	Reporting of Major Incidents	MA03	Additional measure test3			00. Pending Diagnosis	Pendiente de evaluación
17.1.j.	Communication Management	MA02	Additional measure test2			00. Pending Diagnosis	Pendiente de evaluación
17.1.j.	Communication Management	MA03	Additional measure test3			00. Pending Diagnosis	Pendiente de evaluación
17.1.k.	Registration procedures	MA03	Additional measure test3			00. Pending Diagnosis	Pendiente de evaluación
17.1.l.	Resource management	MA01	Additional measure test1			00. Pending Diagnosis	Pendiente de evaluación
17.1.m.	Accountability	MA01	Additional measure test1			00. Pending Diagnosis	Pendiente de evaluación
17.2.	QMS proportion	MA01	Additional measure test1			00. Pending Diagnosis	Pendiente de evaluación
17.4.	QMS in financial institutions	MA03	Additional measure test3			00. Pending Diagnosis	Pendiente de evaluación

TEST SELF-ASSESSMENT OF THE ADDITIONAL MEASURES PROVIDED IN THE PREVIOUS TAB WITH THE SECTIONS

4. Conclusion

The *checklist tool* allows institutions to easily carry out **the self-diagnosis** of their system in accordance with the measures proposed for compliance with the requirements of the AI Act, which are included in the guides in a more exhaustive way.

This will allow companies to design a work plan (Adaptation Plan) that facilitates the planning of the development of the measures they apply to their systems, as well as the preparation of the technical documentation required by the AI Act.

Financiado por la Unión Europea
NextGenerationEU

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

España | digital 2026