Obligations for Importers / Distributors / Authorized Representatives of High-risk AI systems

For a refresher on the notions of "Importer", "Distributor", "Authorized Representative" and "High-risk AI systems", please consult our previous EU AI Act Decoded issues on "Who will the EU AI Act apply to?" and "Classification of AI Systems and GPAI Models"

Importers

Verify Provider's compliance with the EU AI Act prior to placing the AI system on the EU market

(Art. 23)

- The Importer must verify that the Provider has:
  - undergone the relevant **conformity assessment procedure**;
  - drawn up the **technical documentation** in accordance with the EU AI Act;
  - affixed the required **CE marking** on the AI system and has accompanied the AI system with the **EU declaration of conformity** and **instructions for use**;
  - where relevant, designated an **Authorized Representative**.

⚠ Where the Importer has sufficient reason to consider that the AI system is not in conformity with the EU AI Act / is falsified / is accompanied by falsified documentation, it must not place the AI system on the EU market until it has been brought into conformity.

Inform relevant stakeholders in case of risk

(Art. 23)

Where the **AI system presents a risk** (= could affect adversely individuals' health / safety / fundamental rights to a degree which goes beyond that considered reasonable and acceptable in relation to its intended purpose or under the normal or reasonably foreseeable conditions of use), the Importer must **inform**:

- the Provider;
- where relevant, the Authorized Representative;
- the relevant market surveillance authority(ies).

Indicate Importer's name, registered trade name / trade mark, address on the AI system

(Art. 23)

These must also be indicated on the AI system's packaging / its accompanying documentation, where applicable.

Ensure the AI system's compliance with the EU AI Act while being under the Importer's responsibility

(Art. 23)

While the AI system is under its responsibility, the Importer must ensure that the storage / transport conditions of the AI system do not jeopardize its compliance with the EU AI Act.

Keep relevant documentation for 10 years after the placing on the EU market / putting into service of the AI system

(Art. 23)

The Importer must keep a copy of:

- where applicable, the certificate issued by the notified body;
- the instructions for use; and
- the EU declaration of conformity.

Distributors

Verify Provider's and Importer's compliance with the EU AI Act prior to making the AI system available on the EU market

(Art. 24)

- The Distributor must verify that:
  - the AI system bears the **required CE marking**, and is accompanied by **a copy of the EU declaration of conformity** and **instructions for use**;
  - the Provider and the Importer have complied with their respective obligations related to (i) the indication of their name, registered trade name / trade mark, and address; and (ii) the implementation of a quality management system.

⚠ Where the Distributor has sufficient reason to consider that the AI system is not in conformity with the EU AI Act, it must not make the AI system available on the EU market until it has been brought into conformity.

Ensure the AI system's compliance with the EU AI Act while being under the Distributor's responsibility

(Art. 24)

While the AI system is under its responsibility, the Distributor must ensure that the storage / transport conditions of the AI system do not jeopardize its compliance with the EU AI Act.

Inform relevant stakeholders and implement corrective actions in case of non-conformity / risk

(Art. 24)

- Where it has reason to consider that the AI system made available on the EU market **is not in conformity with the EU AI Act**, the Distributor must:
  - take the necessary **corrective actions** to bring the AI system into conformity / withdraw / recall it; or
  - ensure that the Provider / Importer / any other relevant operator take these corrective actions.
- Where the AI system presents **a risk** (= could affect adversely individuals' health / safety / fundamental rights to a degree which goes beyond that considered reasonable and acceptable in relation to its intended purpose or under the normal or reasonably foreseeable conditions of use), the Distributor must immediately **inform** and give details about the non-compliance and any corrective actions taken to:
  - the Provider / Importer; and
  - the competent authority(ies).

Authorized Representatives

Ensure that the appointment as Authorized Representative is made through a written mandate from the Provider

(Art. 22)

- The written mandate must enable the Authorized Representative to perform all of the tasks assigned to it by the EU AI Act (detailed below).
- The written mandate must empower the Authorized Representative to be addressed, in addition to / instead of the Provider, by competent authorities on all issues related to compliance with the EU AI Act, and to provide them with all required information and documentation (incl. logs when relevant).

Provide a copy of the written mandate to competent market surveillance authority(ies) upon request

(Art. 22)

This must be provided in one of the EU official languages as indicated by the competent authority(ies).

Verify Provider's compliance with the EU AI Act

(Art. 22)

The Authorized Representative must verify that the Provider has:

- drawn up the EU declaration of conformity and the technical documentation;
- undergone the appropriate conformity assessment procedure.

Keep relevant documentation for 10 years after the placing on the EU market / putting into service of the AI system

(Art. 22)

The Authorized Representative must keep at the disposal of competent authorities / bodies:

- the Provider's contact details;
- a copy of the EU declaration of conformity;
- the technical documentation; and
- where applicable, the certificate issued by the notified body.

Register in the EU Database

(Art. 22 & 49)

- Before placing on the market / putting into service an AI system listed in Annex III (except those used for critical infrastructures listed under Annex III 2. which must be registered at national level), the Provider/ Authorized Representative must register itself and the AI system in the EU database for High-risk AI systems.
- Before its placing on the market / putting into service, the Provider / Authorized Representative must also register itself and register the AI system in the EU Database when the Provider has concluded that the AI system is not High-risk according to Article 6 (3) of the EU AI Act.

⚠ If the Provider is doing the registration itself, the Authorized Representative must ensure that the Provider is providing the Authorized Representative's correct contact details.

Authorized Representatives

Terminate mandate if Provider is infringing the EU AI Act

(Art. 22)

⚠ The Authorized Representative must terminate the mandate if it has reason to consider that the Provider is acting contrary to its obligations pursuant to the EU AI Act.

⚠ In such a case, the Authorized Representative must immediately inform the relevant market surveillance authority, and, where applicable, the relevant notified body, about the termination of the mandate and the reasons therefor.

⚠ Deadline to comply with these obligations:

August 2 2026

For High-risk AI systems referred in Annex III

August 2 2027

For High-risk AI systems intended to be used as a safety component of a product/which are themselves products (i) covered by EU legislations listed under Annex I; and (ii) subject to a third-party conformity assessment procedure

Notes:

- Compliance with all of the above obligations must be **documented**.
- In certain situations, an **operator could act in more than one role at the same time** and must therefore fulfil cumulatively all the relevant obligations associated with those roles. For example, an organization could cumulatively act as Distributor and Importer.
- Importers / Distributors / Authorized Representatives bear an **obligation of cooperation** with competent authorities, which notably entails the obligation to provide all the information and documentation necessary to demonstrate compliance.
- Importers / Distributors / Authorized Representatives must **closely monitor regulatory developments** including any templates to be issued by the European Commission / EU AI Office / national competent authorities.

⚠ Depending on what they do with the AI system, the Importer / Distributor may be requalified as Provider and be subject to the obligations listed under Article 16 of the EU AI Act. Please see EU AI Act Decoded issue on "Who will the EU AI Act apply to?" for more information.

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