

Importer: a natural or legal person located or established in the Union that places on the EU market an AI system that bears the name or trademark of a natural or legal person established in a third country.

Distributor: a natural or legal person in the supply chain other than the provider or the importer that makes the AI system available on the EU market.

Note:

- Obligations on importers and distributors only apply to **high-risk AI systems** (mostly Articles 23-24)
- Both importers and distributors are included in the definition of “operator”
- Importers and distributors can become providers of high-risk AI systems and subject to Article 16 obligations where they meet the criteria in Article 25(1).

Obligation	Importers	Distributors
Conformity due diligence	<p>Before putting a high-risk AI system on the market, importers must verify:</p> <ul style="list-style-type: none"> ■ That the relevant provider has: <ul style="list-style-type: none"> ▪ completed the Article 43 conformity assessment ▪ drawn up Article 11 and Annex IV documentation ▪ complied with the Article 22(1) requirement to appoint an authorised representative ■ That the AI system bears the required CE marking and is accompanied by the Article 47 declaration of EU conformity and instructions for use (Article 23(1)). <p>Where the importer has reason to believe a high-risk AI system is not in conformity it must not place it on the market until non-conformity has been rectified (Article 23(2)).</p>	<p>Before making a high-risk AI system available on the market, distributors must verify it:</p> <ul style="list-style-type: none"> ■ Bears the required CE marking ■ Is accompanied by the Article 47 declaration of EU conformity ■ Is accompanied by instructions for use ■ Relevant providers and importers have complied with their obligations under Articles 16(b-c) and 23(3) respectively (Article 24(1)). <p>Where the distributor has reason to believe a high-risk AI system is not in conformity it must not place it on the market until non-conformity has been rectified (Article 24(2)).</p> <p>Where the high-risk system poses a risk of the kind set out in Article 79(1) ie to health and safety or fundamental rights, the distributor must inform the relevant provider or importer (Article 24(2)).</p>
Transparency and identification	<p>Importers must:</p> <ul style="list-style-type: none"> ■ Provide their name, registered trade name or trade mark and contact details on the high-risk system and any accompanying documentation or packaging (Article 23(3)). ■ Ensure that any storage or transport conditions do not jeopardise the high-risk AI system's section 2 compliance while the system is under their responsibility (Article 23(4)). 	<p>Distributors must:</p> <ul style="list-style-type: none"> ■ Ensure that any storage or transport conditions do not jeopardise the high-risk AI system's section 2 compliance while the system is under their responsibility (Article 24(3)). ■ Take corrective actions to bring a high-risk AI system into conformity with section 2 on becoming aware that it is not, or withdraw or recall it or require any relevant provider, importer or operator to take corrective actions (Article 24(4)). ■ Immediately inform the provider or importer of the system and the competent authorities on becoming aware of any Article 79(1) risk, giving details of the non-compliance and any corrective actions taken (Article 24(4)).
Record keeping	<p>For ten years following a high-risk system being placed on the market or into service, importers must keep:</p> <ul style="list-style-type: none"> ■ A copy of the certificate issued by the notified body ■ Instructions for use ■ The Article 47 EU declaration of conformity (Article 23(5)). 	<p>Distributors are not subject to record keeping requirements.</p>
Cooperation with authorities	<ul style="list-style-type: none"> ■ Importers have duties to cooperate with relevant competent authorities in relation to assisting with investigations and actions, providing information and documentation to help demonstrate conformity and reducing and mitigating risk (Articles 23(6-7)). All operators including distributors, have a general duty to cooperate with the market surveillance authority and other specified national public authorities or bodies (Article 79). 	<ul style="list-style-type: none"> ■ Importers have duties to cooperate with relevant competent authorities in relation to assisting with investigations and actions, providing information and documentation to help demonstrate conformity and reducing and mitigating risk (Articles 24(5-6)). All operators including distributors, have a general duty to cooperate with the market surveillance authority and other specified national public authorities or bodies (Article 79).