




AI ACT


NOTIFYING AUTHORITIES AND NOTIFYING BODIES

**STANDARDS, CONFORMITY ASSESSMENT,
CERTIFICATES, REGISTRATION**

- Title I: General Provisions
- Title II: Prohibited AI Practices
- Title III: **High-risk systems**
- Title IV: Transparency obligations for certain systems
- Title V: Measures in support of innovation 
- Title VI: Governance
- Title VII: EU database for stand-alone high-risk AI systems
- Title VIII: Post-market monitoring, information sharing, market surveillance
- Title IX: Codes of Conduct
- Title X: Confidentiality and penalties

Chapter 4

Notifying authorities and notifying bodies

- **Notifying authority** shall be set up  to set up conformity assessment bodies
- **Notified body**, a conformity assessment body if notified by the notifying authority will verify the conformity assessment

Chapter 5

Standards, conformity assessment, certificates, registration

- Harmonised standards
- Common specifications
- Presumption of conformity



Chapter 5

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 Chapter 2 of this Title, the provider has applied harmonised standards referred to in Article 40, or, where applicable, common specifications referred to in Article 41, the provider shall follow one of the following procedures:
 - a. **the conformity assessment procedure based on internal control referred to in Annex VI;**
 - b. **the conformity assessment procedure based on assessment of the quality management system and assessment of the technical documentation, with the involvement of a notified body, referred to in Annex VII.**

(...)

Chapter 5

Art. 43

Conformity assessment

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.***



For high-risk AI systems referred to in point 5(b) of Annex III, placed on the market or put into service by **credit institutions** regulated by Directive 2013/36/EU,

- *the conformity assessment shall be carried out as part of the procedure referred to in Articles 97 to 101 of that Directive.*

Chapter 5

Art. 43

Conformity assessment

3. For high-risk AI systems, to which legal acts listed in Annex II, section A, apply, the provider shall follow the relevant conformity assessment as required under those legal acts.

Chapter 5

Art. 43

Conformity assessment

4. High-risk AI systems **shall undergo a new conformity assessment procedure whenever they are substantially modified**, regardless of whether the modified system is intended to be further distributed or continues to be used by the current user.



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.**

Chapter 5

Art. 48

EU declaration of conformity

1. The provider shall draw up a written EU declaration of conformity for each AI system and keep it at the disposal of the national competent authorities for 10 years after the AI system has been placed on the market or put into service. The EU declaration of conformity shall identify the AI system for which it has been drawn up. A copy of the EU declaration of conformity shall be given to the relevant national competent authorities upon request.

The EU declaration of conformity shall state that the high-risk AI system in question meets the requirements set out in Chapter 2 of this Title. The EU declaration of conformity shall contain the information set out in Annex V and shall be translated into an official Union language or languages required by the Member State(s) in which the high-risk AI system is made available.

Chapter 5

Art. 49

CE marking for conformity

1. The CE marking shall be affixed **visibly, legibly and indelibly for high-risk AI systems**. Where that is not possible or not warranted on account of the nature of the high-risk AI system, it shall be affixed to the packaging or to the accompanying documentation, as appropriate.
2. The CE marking referred to in paragraph 1 of this Article shall be **subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008**.

Art. 30.3: By affixing or having affixed the CE marking, the manufacturer indicates that **he takes responsibility for the conformity of the product** with all applicable requirements set out in the relevant Community harmonisation legislation providing for its affixing.



- HumanE-AI-NET

- AI Act: enables, prohibits, restricts
 - *Reasonable?*
 - *Pertinent?*