AI ACT
OBLIGATIONS OF PROVIDERS OF HIGH RISK SYSTEMS

- 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 3
OBLIGATIONS OF PROVIDERS AND USERS OF HIGH-RISK AI SYSTEMS AND OTHER PARTIES

Chapter 3
Art. 16
Obligations for providers

Providers of high-risk AI systems shall:

a. ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title;

b. have a quality management system in place which complies with Article 17;

c. draw-up the technical documentation of the high-risk AI system;

d. when under their control, keep the logs automatically generated by their high-risk AI systems;

e. ensure that the high-risk AI system undergoes the relevant conformity assessment procedure, prior to its placing on the market or putting into service;

Chapter 3
Art. 16
Obligations for providers

Providers of high-risk AI systems shall:

f. comply with the registration obligations referred to in Article 51;

g. take the necessary corrective actions if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title;

h. inform the national competent authorities of the Member States in which they made the AI system available or put it into service and, where applicable, the notified body of the non-compliance and of any corrective actions taken;

i. to affix the CE marking to their high-risk AI systems to indicate the conformity with this Regulation in accordance with Article 49;

j. upon request of a national competent authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title.

Chapter 3
Art. 17
Quality management system

1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

a. a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the high-risk AI system;

b. techniques, procedures and systematic actions to be used for the design, design control and design verification of the high-risk AI system;

c. techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system;

Chapter 3
Art. 17
Quality management system

d. examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, and the frequency with which they have to be carried out;

e. technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, the means to be used to ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title;

f. systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market or putting into service of high-risk AI systems;

Chapter 3
Art. 17
Quality management system

g. the risk management system referred to in Article 9;

h. the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 61;

i. procedures related to the reporting of serious incidents and of malfunctioning in accordance with Article 62;

j. the handling of communication with national competent authorities, competent authorities, including sectoral ones, providing or supporting the access to data, notified bodies, other operators, customers or other interested parties;

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Quality management system

k. systems and procedures for record keeping of all relevant documentation and information;

l. resource management, including security of supply related measures;

m. an accountability framework setting out the responsibilities of the management and other staff with regard to all aspects listed in this paragraph.

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Art. 17
Quality management system

2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation.
3. For providers that are credit institutions regulated by Directive 2013/36/ EU, the obligation to put a quality management system in place shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to Article 74 of that Directive. In that context, any harmonised standards referred to in Article 40 of this Regulation shall be taken into account.

Chapter 3
Art. 19
Conformity assessment

1. Providers of high-risk AI systems shall ensure that their systems undergo the relevant conformity assessment procedure in accordance with Article 43, prior to their placing on the market or putting into service. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity assessment, the providers shall draw up an EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49.
2. For high-risk AI systems referred to in point 5(b) of Annex III that are placed on the market or put into service by providers that are 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 to101 of that Directive.

- HumanE-AI-NET

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