Application of European AI Regulations to Healthcare

- Establish a foundation for the safe and ethical use of AI
- Classify AI systems according to their potential risk
- Formulate requirements, obligations and deadlines adapted to the risk levels

APPLICABLE TO:

- **Suppliers, importers and distributors** of AI healthcare technology
- **Healthcare centre and medical professionals** that use it clinically

MORE INFORMATION

- **European Regulation** on Artificial Intelligence - (EU) 2024/1689
- **Complete guide** to the application of European AI Regulation to Healthcare
- **Website** of the Health/AI Programme

CLASSIFICATION OF AI SYSTEMS

UNACCEPTABLE RISK
Tools used for certain **practices prohibited by the** EU. For example, human behaviour manipulation or social scoring tools

→ **Prohibited. Off the market**
02 February 2025

HIGH RISK
A. Products falling under the use cases described in **Annex III** of the European AI Regulation, such as patient triage or emergency call classification
B. Products regulated by the Medical Devices and In Vitro Diagnostic Regulations **(MDR/IVDR)** that require third-party conformity assessment

→ **Requirements and obligations**
A: 02 August 2026
B: 02 August 2027

LIMITED RISK
A. Tools that **interact with users** (patients or professionals) that are not considered high risk
B. Tools that use **Generative AI** and are not considered high risk

→ **Transparency obligations**
02 August 2026

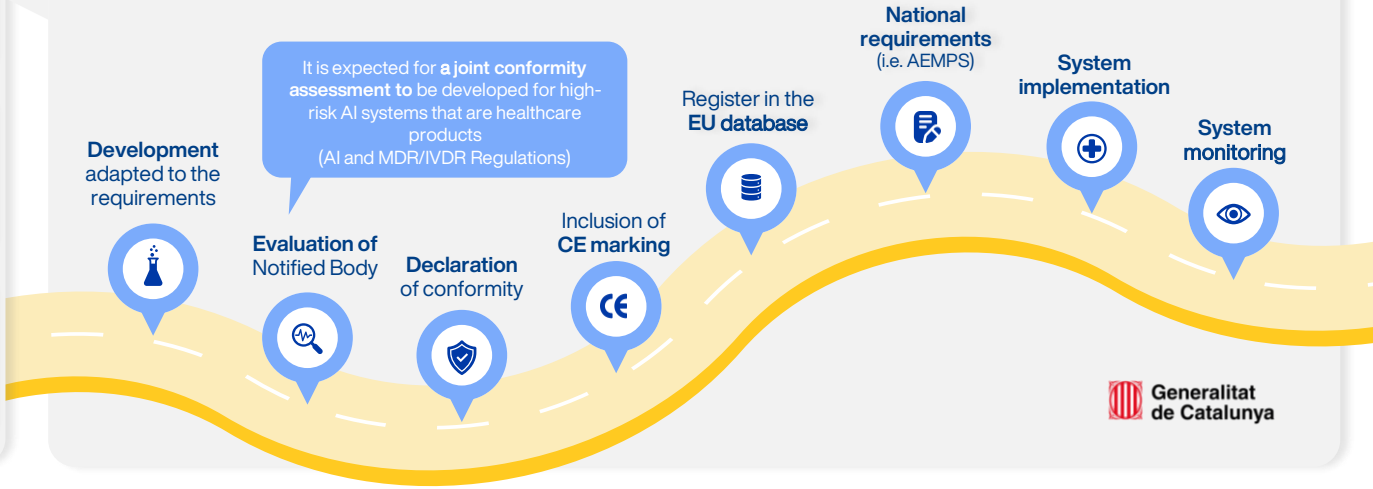
MINIMUM RISK
Tools that do not fall under any of the previous levels. For example, tools for administrative purposes

→ **Voluntary codes of conduct**

DEPLOYMENT OF HIGH-RISK AI SYSTEMS

Requirements to be met:

- Risk management system
- Data and data governance
- Technical documentation
- Compliance record-keeping
- Transparency and information
- Human supervision measures
- Precision, robustness and cybersecurity



Generalitat de Catalunya