

Malta's AI Regulations

LN 226 of 2025: Malta Digital Innovation Authority Act (Cap. 591): AI Regulations 2025

[Link to the new Regulations](#) - published 10th October 2025



Market Surveillance Authority

Malta Digital Innovation Authority (MDIA) has been designated a Market Surveillance Authority (MSA) for the purposes of the EU AI Act - enforcement & supervisory role.

MDIA has been designated as the SPOC for the EU AI Act - ie primary contact for the EU Commission, other Member States & stakeholders on AI regulation. Also, co-ordinating between national competent authorities.

Single Point of Contact (SPOC)



Scientific experts

MDIA may call upon experts of the scientific panel established under Article 68 of the EU AI Act, to support national enforcement activities.

If a provider (developer) or their Authorised Representative in Malta*, becomes bankrupt or ceases operation, it must still retain the relevant documents required under the EU AI Act for a 10-year period.

Documents - 10 years



Importers & high-risk systems

Importers must, upon request, provide national competent authorities with all necessary docs, to demonstrate the conformity of a high-risk AI system with the requirements of the EU AI Act, in the Maltese or English language.

MDIA designated as the Notifying Authority, provided that the assessment & monitoring shall be carried out by **the National Accreditation Board (Malta)**.

Conformity Assessments



Registration of High-Risk systems

A provider (developer) or its Authorised Representative*, shall register high-risk AI systems referred to in point 2 of Annex III EU AI Act (critical infrastructure) in the manner as may be prescribed by MDIA.

MDIA shall be the sole national competent authority responsible for establishment & functioning of a national AI regulatory sandbox. SMEs & start-ups will have priority access.

AI Regulatory Sandbox



Penalties

- **Administrative Penalty:** up to **€350,000** per violation or 1% of worldwide annual turnover.
- **Daily Penalty** up to **€12,000** per day for ongoing breaches.
- Daily Penalty can be given in addition to Administrative Penalty or as an alternative.
- **Public authorities:** up to €50,000 per infringement and €50 per day for ongoing breaches.
- **Non-monetary measures:** MDIA may issue reprimands, warnings, or other measures
- Proceedings must be initiated within **2 years** of the alleged infringement.

* Providers outside the EU must appoint an Authorised Representative within the EU