

# The Legal Framework of Artificial Intelligence in the European Union: Regulation, Liability, and Sectoral Challenges

Valentina Di Gregorio, Matteo Turci and Monica Gigola

University of Genoa, Italy

[valentina.digregorio@unige.it](mailto:valentina.digregorio@unige.it)

[matteo.turci@giuri.unige.it](mailto:matteo.turci@giuri.unige.it)

[monica.gigola@edu.unige.it](mailto:monica.gigola@edu.unige.it)

**Abstract:** This paper provides a systematic analysis of the emerging legal profiles in the artificial intelligence ecosystem, structured along three interdependent conceptual axes. Firstly, it examines the multi-level regulatory framework taking shape in the European Union. The EU Regulation 2024/1689 is critically explored in its risk-based approach, with particular attention to the categories of high-risk AI systems. The synergies and tensions with the legal framework governing data circulation in the Union are analyzed, with a profound influence in terms of compliance on data-driven technologies. This includes the EU Regulation 2016/679, which directly addresses crucial issues such as automated decisions and profiling; the EU Regulation 2022/868 on data altruism mechanisms and the reuse of public data; the EU Regulation 2023/2854, which introduces rules related to accessing data generated, among others, by IoT and industrial devices, as well as the EU Regulation 2025/327. Secondly, the complex issue of AI liability is evaluated, in the dual dimension of and safety. Particular attention will be paid to the now dismissed EU regulatory proposals. A specific focus will deal with the possible applicability of the product liability discipline. Finally, several sectoral criticalities are identified through case studies in healthcare and transport domains, evaluating for each the difficult balance between potential benefits and risks from algorithmic biases and systemic discrimination. The methodology combines dogmatic analysis, legal comparison, and concrete case studies, contributing to the debate on harmonization between technological innovation, protection of fundamental rights and sustainable legal governance models in the AI era.

**Key words:** AI civil liability, EU AI regulation, High-Risk AI systems, Algorithmic discrimination, Healthcare AI, Autonomous transport, Financial services AI, Product liability directive, Data governance act, Regulatory fragmentation

---

## 1. AI Regulation, Digital Market, and Data Protection/Governance

The transformation of the technological scenario, accelerated since the beginning of the new millennium, has been driven by digital and computational sciences, robotics, and bioengineering, fields relying on algorithms and machine learning within the wider framework of Artificial Intelligence. These advances have enabled sophisticated models capable of self-learning and autonomous decision-making, exploiting the vast amounts of data circulating in the ICT market. Human-machine interaction has thus become a central issue in scientific and philosophical inquiry across domains such as transport, healthcare, social relations, and the IoT (Finocchiaro, 2024).

Beyond questions of safety and reliability, ethical dimensions are increasingly considered both as frameworks guiding technological design and as standards governing the behaviour of AI systems. These aspects reshape the modalities of social and economic interaction.

The wide availability of data—an economic driver and catalyst of digitalisation—has led the EU legislator to establish rules aimed at ensuring AI safety and reliability, while promoting competitiveness and cooperation among Member States (Nitzberg and Zysman, 2022). The AI Act (Regulation (EU) 2024/1869) provides a framework to foster innovation while safeguarding liberty, privacy, security, health, environmental protection, democracy, and the rule of law, in line with the Charter of Fundamental Rights.

EU regulation has evolved from the protection of personal data under Regulation (EU) 2016/679 (GDPR) and non-personal data under Regulation (EU) 2018/1807, towards valuing interoperable data within a broader data-sharing strategy (European Commission, 2020). This shift underpins the Data Governance Act (Regulation (EU) 2022/868) and the Data Act (Regulation (EU) 2023/2854), both central to the Union's data governance architecture. The Council of Europe's 2024 Framework Convention (n.225) on AI and Human Rights, Democracy and the Rule of Law reinforces principles of transparency, trustworthiness, accountability, privacy, and democratic values.

Further initiatives include the 2022 Digital Services Package (Digital Services Act and Digital Markets Act), intended to protect users' fundamental rights and ensure a level playing field for innovation, growth, and competitiveness.

Nonetheless, concerns arise over the coherence between new sectoral rules and existing national legal categories. Tensions are especially visible in the redefinition of the legal status of personal data, contractual obligations linked to networked products, and civil liability for damages caused by AI systems—issues still subject to active debate (Di Gregorio, 2022).

### **1.1 The Circulation of Data: From Data Protection to Data Economy**

As data drives economic activity and is increasingly shaped by artificial intelligence, the EU adopted the Data Governance Act (2022) to establish European data spaces and promote a forward-looking digital economy. Building on the GDPR's focus on protection, the DGA enhances innovation by enabling large-scale data sharing while ensuring safe circulation through rules on re-use of public data, data intermediation services, and voluntary registration of altruistic entities.

Together with the Data Act, which frames data both as a protected asset and as an economic resource, this legislation creates obligations for holders to ensure fair and transparent access. The framework fosters innovation and competitiveness by optimising production processes and enabling AI-based solutions across IoT devices, transport, healthcare, and virtual assistants, while safeguarding trade secrets and reducing contractual imbalances.

Overall, the EU's data strategy seeks to balance innovation with protection, empowering individuals and businesses and supporting the delivery of high-quality, personalised products and services through data-driven AI.

### **1.2 The AI Act within the Framework of the EU Single Market for Data**

Within the digital market, the AI Act (Regulation (EU) 2024/1869) provides a central regulatory framework for a rapidly expanding sector. Building on earlier scepticism but now recognising AI's economic potential, the Act adopts a risk-based approach inspired by product safety law and aims to promote human-centric, trustworthy AI.

It differentiates obligations according to system risk level, prohibiting certain practices and imposing stricter requirements on high-risk systems while maintaining lighter duties for others. Its scope also covers non-EU providers, reflecting a rationale distinct from the GDPR. Risk assessment is supported by Fundamental Rights and Conformity Assessments, often linked to harmonised standards, with sanctions and liability in cases of non-compliance.

For high-risk systems, the Act requires robust data governance covering training, validation, and testing to prevent bias, especially in sensitive areas such as healthcare and credit scoring, while reaffirming the primacy of the GDPR. Obligations extend to general-purpose and generative AI, which must meet transparency and documentation duties, with models of systemic impact subject to enhanced oversight, including incident reporting and cybersecurity safeguards.

Together, algorithms, data, and computing power form the foundation of the AI ecosystem. The AI Act, alongside EU data regulation, embodies the Union's strategic vision of a digital society, positioning Europe as a global leader in trustworthy AI governance.

## **2. Navigating the Maze of AI Liability: The European Approach to AI Liability and the Risk of Fragmentation**

Since the early 2000s, scientific advances in technology have raised complex liability issues concerning robotics and Artificial Intelligence (AI), yet the European legislator has not provided a comprehensive regulatory framework, leaving rules fragmented among Member States and derived from national legal systems; this section reviews successive European legislative proposals on AI liability, explains their withdrawal or failure, and considers the current reform of producer liability. The Commission has long recognised liability as central to Europe's AI strategy (European Commission, 2018). A reform should simplify liability by clarifying responsibility to users, reduce litigation costs (Bertolini, 2020), create recourse mechanisms across the value chain, limit overlapping regimes, and achieve harmonisation to prevent market fragmentation (Palmerini and Bertolini, 2016). However, EU rules operate within a wider framework left to Member States (Expert Group on Liability and New Technologies, 2019), reflecting a policy choice to avoid deep harmonisation; unlike regulation-based proposals, Commission texts were directives, culminating in the 2025 withdrawal of the directive on AI civil liability (European Parliament Legislative Train, 2025). A uniform approach remains crucial to sustain the 'Brussels Effect' (Bradford, 2020), as partial interventions risk disciplinary and market fragmentation (Bertolini

and Riccaboni, 2020), thereby weakening user protection and limiting technological dissemination. In the absence of harmonisation, some Member States have adopted sectoral rules: Germany amended its Road Traffic Act (Straßenverkehrsgesetz) for autonomous vehicles, Estonia debated specific legislation, and Italy's Draft Bill on AI (2024) includes 'sectoral provisions'. Such bottom-up rules contrast with the Commission's technological neutrality, risk creating entrenched path-dependencies (Podsiadla, 2013), and may generate irreversible legal and market fragmentation, with differing by-design product requirements shaping the very architecture of AI technologies.

### 2.1 Technological Neutrality and Expanding Liability: From Producers to Operators

The European product liability regime, reinforced by recent reform, remains central to AI liability. Although the Commission in 2018 deemed Directive 85/374/EEC "consistent with EU consumer protection legislation, relevant and future-proof" (Commission Staff Working Document, 2018), persistent shortcomings justified reform. Yet the legislator has resisted revising the principle of technological neutrality, which insists on functional equivalence and treats AI no differently from human helpers, thereby neglecting issues specific to self-learning systems and excluding other actors such as the "operator" envisaged in the European Parliament's 2020 proposal. Victims of technological harm should not be disadvantaged compared to victims of human conduct, but legislators are not obliged to provide superior remedies (Castronovo, 1981). Nonetheless, innovative approaches—expanding strict liability, easing causation, introducing automatic indemnity, or lowering evidentiary burdens—are essential to protect victims effectively.

The 2020 Parliament proposal (European Parliament, 2020) introduced strict liability for operators, defined as those controlling AI risks, whether frontend (direct users) or backend (shaping features and providing data). It applied to high-risk AI, coupled with mandatory insurance and joint liability, while other cases followed fault-based rules with reversed burden of proof. Producers had to cooperate by disclosing information. Despite its innovation, the proposal struggled with distinguishing liability types, coordinating EU and national rules, and resolving causal uncertainty (Gabielli and Ruffolo, 2019). Accidents with automated vehicles illustrated the difficulty of attributing fault when human and machine factors overlap. By broadening responsibility to multiple operators, the scheme sought simplification but still required identifying risk within each sphere of control. The absence of a designated liable party, unlike consumer sales guarantees (Barcellona, 2009), left compensation uncertain.

The 2024 reform of the Product Liability Directive (COM (2022) 495 final; European Parliament legislative resolution, 2024) confirmed technological neutrality, retained the Directive's structure, and extended "product" to software, digital files, and AI systems (Art. 4(1)). Compensation now covers defects attributable to manufacturers, component makers, importers, non-EU suppliers, modifiers, or platform operators (Art. 7–8). Injured parties must still prove defect, damage, and causation (Art. 10(1)), though presumptions and disclosure obligations ease this burden. Defects are defined by consumer expectations but also by post-market learning (Art. 7(2)(b)) and interaction with connected systems (Art. 7(2)(c)). Courts may order disclosure from producers (Art. 9), subject to trade secrets, though critics highlight delays, costs, and information overload (Ben-Shahar and Schneider, 2010; Kahneman, 2012). Article 10 introduces rebuttable presumptions of defect or causation, codifying doctrines such as *res ipsa loquitur* (Martorano, 1966).

Despite these developments, structural weaknesses persist: the outdated concept of "defect," exclusion of compensation for the defective product itself, vague notions such as "technical complexity," and reliance on disclosure that risks inconsistency and high costs. Ultimately, both the Parliament's 2020 proposal and the 2024 reform fall short of adapting liability law to the opacity and autonomy of AI. The former faltered due to causal indeterminacy; the latter modernised producer liability but preserved fragmentation, limiting the framework's effectiveness in addressing the risks of technological innovation (Di Gregorio, 2024).

### 2.2 Between Technological Neutrality and Legal Fragmentation: Rethinking AI Liability

The Proposal for a Directive on Liability and Artificial Intelligence (COM(2022) 496 final) was conceived to complete the EU framework for damages caused by AI, especially high-risk systems, but stalled in the legislative process. As an autonomous text complementing the Product Liability Directive, it addressed negligent civil liability, extending some provisions to non-high-risk systems. Based on technological neutrality and the AI Act's risk-based categories (Regulation (EU) 2024/1689) (Wagner, 2023), it recognised the inadequacy of national rules given AI's opacity, but rejected strict liability in favour of fault-based procedures, perpetuating disparities. High-risk AI was defined via Annex III or additional criteria, yet interpretative uncertainty persisted (Faccioli, 2024).

The Directive imposed disclosure obligations on providers or deployers, creating a presumption of fault but not causation, criticised for excessive costs, delays, and obstruction. Article 4 further presumed causation between fault and malfunction, mandatory for high-risk AI and discretionary otherwise, reversing the traditional relation between fault and causation and complicating human–machine contexts such as autonomous vehicle accidents (Bertolini, 2025). Fault, redefined as breach of technical standards, risked conflicting with national doctrines such as medical liability. Thus, the text clashed with entrenched traditions, failed to resolve causal opacity, and reinforced fragmentation through overreliance on technological neutrality, definitional ambiguities, evidentiary burdens, and poor coordination with national laws.

Its failure illustrates the tension between horizontal and sectoral regulation. Attempts at general rules, intended to secure the “Brussels Effect” (Resta, 2022), collided with legal diversity. Categories like “high-risk” proved too indeterminate, undermining certainty. A more sector-specific method is needed, regulating professional fields and acknowledging AI’s heterogeneity.

Despite a decade of debate, results remain limited. Product liability, intended as a safety net, is weakened by litigation barriers and the outdated notion of “defect.” The European Parliament’s strict liability proposal sought to internalise risks but collapsed under definitional uncertainty and causation issues. Legislators abandoned it, favouring the producer liability reform, which preserved structural weaknesses, and procedural rules modelled on German law that interfere with doctrines of causation and fault (Scognamiglio, 2023).

The Draft ultimately failed because excessive generality and pursuit of neutrality generated cascading problems: uncertainty in classifying “high-risk” AI, risks of fragmentation, burdensome disclosure, and tensions with national civil liability. Horizontal rules for all AI proved excessive, altering the substantive balance of causation and fault. Future regulation must address professional sectors directly, with tailored liability regimes.

In the end, the EU legislator preserved an outdated system: product liability still excludes compensation for the defective product itself and remains tied to the elusive concept of defect. The procedural innovations add little clarity, leaving courts ill-equipped to address AI opacity. Abandoning reform entrenched fragmentation and path dependency, ensuring persistent uncertainty and insufficient victim protection (Lasmar Almada, 2024).

### **3. Algorithmic Non-Discrimination and Vulnerable Persons**

According to the World Health Organization, about 15 per cent of the world's population has some form of vulnerability (disabled and elderly people) that limits the freedom to enjoy public relations, to live in an urban environment and to exercise the fundamental rights.

Article 3 of the UN Convention officially introduces disability into the sphere of human rights, with the aim of to eliminating obstacles to the enjoyment of fundamental rights (Art. 5) (Marra, 2011), of removing discrimination while promoting inclusion also through the digitalization of services.

Furthermore, at the European level, the general prohibition of discrimination is contained in Article 19 TFEU, which is a fundamental document of the European Union's anti-discrimination framework and empowers the institutions to carry out acts to encourage member states' policies to prevent inequality.

The protection of the rights of persons with disabilities against discriminatory acts is then enshrined in the Charter of Fundamental Rights of the European Union, which, in Article 21, prohibits discrimination also based on 'disability' and provides in Article 26 for the 'inclusion' of persons with disabilities in the social and employment fabric, promoting their self-determination. In the broader international framework, the rights of disabled people have acquired a position among the fundamental rights with the proclamation, in the 2006 UN Convention on the Rights of Persons with Disabilities (UNCRPD). At the same time the Strategy on the Rights of Persons with Disabilities 2021-2030 aimed at improving social inclusion, the realization of wellbeing, and the recognition of the full exercise of the rights of persons with disabilities, in a perspective also accepted in the recent directives on the accessibility of products, services and websites and by the Court of Justice.

The use of new technologies, including AI systems and Internet of Things plays a fundamental role in ensuring the inclusion of fragile groups in the social context and in the urban social economic empowerment, especially in the field of transport (Al Mureden-Calabresi, 2021; Turci, 2024), healthcare, education (Di Gregorio, 2020, p. 19; Di Gregorio, 2023, p. 55).

Legal systems, including the Italian one, have identified solutions to the issues posed by ageing, fostering the wellbeing and autonomy of the elderly promoting access to public goods and services on an equal footing with other citizens, adapting goods and services for the city also to people's disability conditions using the technology

and AI system (e.g. by using robot assistants, by optimising access routes to health services through AI). The protection of vulnerable people rights by legal system constitutes also the criterion for evaluating the effectiveness of the measures adopted and based on new technologies.

At the same time, developments in technology are accompanied by new risks for the individual rights (P. Perlingieri, 2020; C. Perlingieri – Martone, 2023) making it necessary to devise strategies for compliance with the rules in force and with the drafting, where necessary, of new rules capable of exploiting the opportunities offered by scientific development, but at the same time able of limiting the risks generated by the production and marketing of instruments and Apparatuses, including the phenomenon of algorithmic discrimination, which can significantly affect vulnerable people in Smart Cities.

In this teleological context are important interventions of the European legislator, In particular, Directive 2016/2102/EU on the accessibility of public bodies' websites and mobile applications (Web Accessibility Directive, WAD), which obliges all public and private bodies in the EU to make their websites and mobile applications accessible, transposed within the Italian legal system by Legislative Decree no. 106/2018 and Directive 2019/882/EU on the requirements of accessibility of products and services in the internal market of the European Union (European Accessibility Act), which was enacted to ensure full web accessibility to the websites of PAs and private companies, so that the content can also be used by people with disabilities, implemented by d. lgs. 27.5.2022, no. 82 and intended to harmonise the internal legislation of the Member States,

With a special focus on the elderly population, the Italian legislature implemented the principles of digital accessibility with Law No. 33/2023, which establishes the criteria for the promotion of active ageing and social inclusion, including digital literacy interventions for the elderly, which are fundamental for access to the services offered to fragile people in the social context and in the Smart Cities.

Ultimately, the European and national frameworks on non-discrimination and digital inclusion show that the regulation of artificial intelligence cannot be confined to safeguarding technological innovation but must also ensure the effective protection of vulnerable persons, by preventing algorithmic exclusion and fostering a model of technological development genuinely oriented towards the respect of fundamental rights.

#### **4. AI and Healthcare**

The increasing use of next-generation digital medical devices is promoting the automation of healthcare processes and promises to make crucial phases autonomous: from workflow management and departmental coordination to diagnostics, therapy administration, and patient monitoring. This transformation is driven by the significant benefits these technologies seem to guarantee, offering tangible improvements in both the quality and quantity of services.

However, while the potential of robotics and artificial intelligence (AI) is clear, assessing the risks associated with their use is far more complex, particularly regarding the identification of parties who may be held legally liable in the event of damage (De Berardinis, 2020). The rapid diffusion of AI in healthcare raises legal issues linked to evident contraindications affecting fundamental rights such as health, liberty, dignity, and self-determination. Consequently, the law faces a challenge requiring profoundly innovative interventions to fill current gaps.

The introduction of AI – particularly machine learning systems – surpasses the limits of individual medical experience by enriching it with knowledge derived from vast clinical datasets. This computational power allows for the interpretation of increasingly heterogeneous clinical information. Within this context, the healthcare professional operates in a complex network of people, structures, and tools that cannot be entirely mastered, meaning the allocation of damage is moving away from the classical scheme based on the predictability of one's own actions (Amore and Rossero, 2023).

The main issues in classifying liability can be summarised in two areas:

The attribution of liability is complicated by the presence and interaction of multiple actors, including producers of hardware or neural networks and the providers of the healthcare service itself through structures involving several professionals (Prifti, Stamhuis and Heine, 2022).

On the objective side, the so-called black-box effect results in the impossibility of observing the training, self-learning, and correction stages that lead to a decision. This undermines the traditional scientific method, as only the output can be inferred from static connection weights. Post-hoc explanation techniques can only provide an approximate reconstruction.

The black-box effect is an intrinsic feature of AI systems. The European Data Protection Supervisor has examined it in terms of explainable AI (XAI)—the ability of AI systems to provide clear explanations of their decisions. Striving for maximum explainability should, theoretically, allow for the development of more suitable liability criteria, moving away from pure strict liability, which would otherwise impose a *probatio diabolica* on both clinicians and injured patients.

Reducing reliance on strict liability also helps contain the risk of defensive medicine, which could discourage the adoption of AI. The EU's AI Act aims to promote the development and use of AI systems, hence the need for transparent tools. However, while explainability might be a workable solution for non-generative AI, reconstructing the decision-making processes of generative AI currently appears impossible, leaving many questions on liability standards open.

The EU Regulation aims to ensure AI systems on the market are safe and respect the Union's fundamental rights and values. It confirms a risk-based approach, introducing differentiated obligations depending on the level of risk posed (Marsico, 2024). Regulatorily, the aim is to adapt constitutional principles to AI applications, outlining a human-centric and trustworthy AI inspired by ethical purposes.

Nevertheless, the problem of allocating liability remains central when an AI system causes harm. The difficulties are exacerbated by technological peculiarities like the black-box effect. After initially considering a dedicated instrument (the withdrawn 2022 Proposal for a Directive on AI Liability), the EU legislator has so far left the matter to the general framework and to national legislation. In practice, patients can rely both on EU law protections—particularly product liability—and on ordinary civil remedies against physicians or healthcare institutions under the medical liability rules of each Member State.

## **5. Autonomous Horizons: Charting the Regulatory Course for AI in Aviation and Maritime Transport**

The integration of Artificial Intelligence (AI) and Machine Learning (ML) promises transformative safety, efficiency, and autonomy in transport, but also raises complex legal and regulatory challenges. Aviation and maritime sectors lead this shift, with regulators such as the European Union Aviation Safety Agency (EASA, the EU body responsible for civil aviation safety) and the International Maritime Organization (IMO, the UN agency overseeing global shipping regulation) seeking frameworks that balance innovation with safety. This section examines sectoral issues, EASA's AI Roadmap, IMO's work on Maritime Autonomous Surface Ships (MASS), the impact of the forthcoming EU AI Act, and unresolved liability questions.

Aviation, already a pioneer in automation, now faces AI-driven autonomy. EASA's AI Roadmap establishes a risk-based "AI trustworthiness" framework aligned with the European Commission's *Ethics and Guidelines on Trustworthy AI* (EASA & Daedalean, 2024). It outlines a phased approach from lower-level assistance to higher autonomy. Key pillars include "Learning Assurance" (ensuring AI learns safely), "AI Explainability" (making AI decisions understandable), and "AI Safety Risk Mitigation" (identifying and reducing risks).

A persistent challenge is AI's "black box" nature (Turci, 2025), meaning that its internal decision-making processes are often opaque. This complicates accident investigations and liability attribution (Prakash, 2021). EASA therefore stresses explainability so that operators can understand AI outputs, which is vital for both safety and accountability.

In maritime transport, the IMO's Joint MSC-LEG-FAL Working Group on MASS is preparing a goal-based framework and a non-binding MASS Code (IMO, 2023). A central issue concerns the role of the ship's "master". Although ultimate responsibility remains with a human, the master may control the vessel remotely from a Remote Operations Centre (ROC) that raises jurisdictional questions under the United Nations Convention on the Law of the Sea (UNCLOS) when ROCs are located outside the vessel's flag State (Ringbom, 2019). Additional challenges stem from the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers (STCW), which sets minimum global competence requirements for ship crews, alongside unresolved issues about how to define "remote operators" and how to mitigate interoperability and cybersecurity risks (IMO, 2023).

The EU AI Act (Burden & Stenberg, 2023), expected in 2025, will broadly affect mobility. Its risk classification system deems AI safety components in Annex II products as high-risk, requiring CE marking (the EU's product safety certification) and registration, but exempts aviation, motor, and agricultural vehicles that are already regulated under other regimes. This creates fragmentation: for example, an AI collision-avoidance system may be considered high-risk in industrial machinery but exempt in trucks.

Annex III also designates certain stand-alone uses of AI as high-risk, including traffic management and pollution control. Thus, AI embedded in a car's steering may be exempt, but AI managing city traffic lights could be high-risk. Manufacturers operating in both markets must therefore comply with high-risk obligations. Users of such systems (Art. 29) must also ensure oversight, data quality, and GDPR-compliant Data Protection Impact Assessments (DPIAs). Regulatory sandboxes (Arts. 53–55) provide controlled environments for testing innovative AI applications, even allowing the use of personal data beyond its original purpose when required for public safety or environmental goals.

Despite evolving frameworks, liability for AI-driven damage remains unsettled in Europe. The reformed Product Liability Directive (EU) 2024/2853 attempts to address issues posed by evolving systems (Art. 7(2)(b)–(c)) (Di Gregorio, 2024). New provisions on disclosure (Art. 9) and presumptions (Art. 10) aim to ease litigation but may instead create costly and complex proceedings (Faccioli, 2024). The withdrawn AI Liability Directive (COM(2022) 496 final) had sought to address opacity through disclosure obligations and causality presumptions, but failed due to complexity and lack of alignment across Member States. The result is continuing legal uncertainty, fragmented national approaches, and risks that victims may not be compensated. In the United States, cases involving Tesla and Uber highlight how liability may be shared between manufacturers, operators, and infrastructure providers (Prakash, 2021). Maritime law adds the specific issue of the “remote master”: if an ROC in another country controls a MASS, questions arise about which jurisdiction and liability rules apply, and current conventions such as the Civil Liability Convention (CLC) and the Convention on Limitation of Liability for Maritime Claims (LLMC) cannot resolve these conflicts (Dremluuga & bin Mohd Rusli, 2020).

AI in transport offers major benefits but also novel risks. EASA and IMO are proactively shaping sectoral frameworks, while the AI Act will set horizontal standards for non-exempt systems (Turci, 2025). Yet liability gaps persist. Only sustained collaboration between regulators, industry, legal experts, and insurers can secure safe, efficient, and accountable autonomous transport.

## **6. Conclusion**

The analysis demonstrates that the European Union has progressively developed a dense, multi-layered regulatory architecture for Artificial Intelligence, rooted in the twin objectives of safeguarding fundamental rights and fostering innovation. While the AI Act represents a milestone in consolidating a risk-based approach, significant challenges remain in the field of civil liability, where the unresolved issues of causation, fault, and compensation persist. The technological neutrality is a guiding principle that has ensured continuity with established regimes, yet it has also revealed its limitations in addressing the opacity and autonomy of AI systems.

Sectoral perspectives, particularly in healthcare, financial services, and transport, highlight that horizontal rules are insufficient to capture the specificities of complex domains where algorithmic decision-making intersects with human vulnerability and systemic risks. Likewise, the debate on non-discrimination underscores the need for inclusive technological governance to ensure that innovation does not exacerbate pre-existing inequalities.

The future trajectory of European regulation will therefore depend on its ability to balance horizontal coherence with sector-specific precision. A sustainable model of governance should integrate robust principles at Union level with tailored instruments capable of responding to the peculiarities of each field of application. Only through this dual strategy AI can evolve into a tool that promotes human dignity, equality, and social solidarity, transforming potential sources of conflict into drivers of responsible innovation and collective progress.

**Author contributions:** This paper is the result of joint research and reflection by the Authors. For the purposes of this paper, however, paragraphs 1 and 3 are attributed to Valentina Di Gregorio; paragraphs 2, 5, and the conclusions are attributed to Matteo Turci, and paragraph 4 is attributed to Monica Gigola.

**Ethics statement:** No ethical clearance was required for this research.

**AI statement:** AI tools have been used to check the compliance of the paper to style guidelines.

## **References**

- Al Mureden, E. – Calabresi, G. (2021) *Driverless cars. Intelligenza artificiale e futuro della mobilità*, Bologna.
- Amore, N. – Rossero, E. (2023) *Robotica e intelligenza artificiale nell'attività medica. Organizzazione, autonomia, responsabilità*, Giappichelli, Torino.
- Barcellona, E. (2009) *Le tutele dell'acquirente nella vendita di beni di consumo tra responsabilità garanzia ed esatto adempimento*, *Contratto e Impresa*, Vol. 2009, pp. 171 ff.
- Ben-Shahar, O. – Schneider, C.E. (2010) *The failure of mandated discourse*, *University of Pennsylvania Law Review*, Vol. 159, pp. 687 ff.

- Bertolini, A. (2020) Artificial Intelligence and Civil Liability, Brussels, Policy Department for Citizens' Rights and Constitutional Affairs, pp. 61–72.
- Bertolini, A. (2025), *Intelligenza artificiale e responsabilità civile. Problema, sistema, funzioni*, Il Mulino, Bologna.
- Bertolini, A. – Riccaboni, M. (2020) Grounding the case for a European approach to the regulation of automated driving: The technology-selection effect of liability rules, *European Journal of Law and Economics*, Vol. 2020, pp. 240 ff.
- Bradford, A. (2020) *The Bruxelles Effect: How the European Union Rules the World*, Oxford University Press, Oxford.
- Burden, H. – Stenberg, S. (2023) Implications of the AI Act in relation to mobility, *Transportation Research Procedia*, Vol. 72, pp. 1832–1839.
- Castronovo, C. (1981) General Private Law and Secondary Rights. Civil liability and banking enterprise, *Jus*, Vol. 1981, p. 158 f.
- Commission Staff Working Document (2018) Evaluation of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, SWD(2018) 157 final, Brussels.
- De Berardinis, V. (2020) L'impiego delle nuove tecnologie in medicina, in Alpa, G. (ed.) *Diritto e intelligenza artificiale*, Pacini, Pisa, pp. 489 ff.
- Di Gregorio, V. (2020) Principio di non discriminazione e diritti delle persone con disabilità: dal modello sociale alla Web Accessibility Directive, in *Accessibilità Web e tecnologia assistiva. Strumenti di inclusione digitale*, p. 19 ss.
- Di Gregorio, V. (2022) *Intelligenza artificiale e responsabilità civile: quale paradigma per le nuove tecnologie?*, *Danno e responsabilità*, Vol. 51.
- Di Gregorio, V. (2023) Il principio di non discriminazione delle persone con disabilità, in Ivaldi, P. – Schiano di Pepe, L. (eds.), *Uguaglianza e giustizia. Itinerario di una ricerca dottorale*, Genoa, p. 55 ff.
- Di Gregorio, V. (2024) *Intelligenza artificiale e robotica: profili di responsabilità civile in materia di tutela dei soggetti fragili*, in Dameri, P. – Bruzzone, M. (eds.), *Smart City. Prospettive di ricerca*, Genoa, p. 105 ss.
- Dremluiga, R. – bin Mohd Rusli, M.H. (2020) The Development of the Legal Framework for Autonomous Shipping: Lessons Learned from a Regulation for a Driverless Car, *Journal of Politics and Law*, Vol. 13(3), pp. 295–301.
- EASA – Daedalean (2024) *Concepts of Design Assurance for Neural Networks (CODANN) II with appendix B*, January 2024.
- European Commission (2018) *Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions. Artificial Intelligence for Europe*, Brussels.
- European Commission (2020) *European Data Strategy* [online], available at: [https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/european-data-strategy\\_en](https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/european-data-strategy_en)
- European Parliament (2020) Report with recommendations to the Commission on a civil liability regime for artificial intelligence (2020/2014(INL)), Plenary sitting.
- European Parliament Legislative Train (2025) *Artificial Intelligence Liability Directive* [online], available at: <https://www.europarl.europa.eu/legislative-train/theme-a-europe-fit-for-the-digital-age/file-ai-liability-directive>
- Expert Group on Liability and New Technologies (2019) *Report on Liability for Artificial Intelligence and other emerging digital technologies*, European Commission, Brussels.
- Faccioli, M. (2024) *La responsabilità civile per danni cagionati da sistemi di intelligenza artificiale nel prisma dell'onere della prova*, *Rivista critica del diritto privato*, Vol. 2024, pp. 952 ff., 962 ff.
- Finocchiaro, G. (2024) *Diritto dell'intelligenza artificiale*, Zanichelli, Bologna.
- Gabrielli, E. – Ruffolo, U. (2019) *Artificial intelligence and liability*, *Giurisprudenza italiana*.
- IMO (2023) Report of the MSC-LEG-FAL Joint Working Group on Maritime Autonomous Surface Ships (MASS) on its second session, MSC 107/5/1, 2 May 2023.
- Kahneman, D. (2012) *Thinking, Fast and Slow*, Penguin, London.
- Krutzinna, G. – Floridi, L. (2019) *Ethical Medical Data Donation: A Pressing Issue*, in Krutzinna, G. – Floridi, L. (eds.) *The Ethics of Medical Data Donation*, Springer, Cham.
- Lawson, A. (2012) *Securing rights to reasonable accommodation under the convention on the rights of persons with disabilities: a role for disability studies?* in *Tutela della persona e Disability Studies*, Atti del Convegno Catanzaro, 6.12.2012, Reggio Calabria, 2012, p. 30.
- Lasmar Almada, M.A. (2024) *Delegating the Law of Artificial Intelligence. A Procedural Account of Technology-Neutral Regulation*, European University Institute, Fiesole.
- Legrand, P. (1977) The impossibility of “legal transplants”, *Maastricht Journal of European and Comparative Law*, Vol. 4, pp. 111 ff.
- Marra, A. (2011) voce *Barriere architettoniche*, in *Enc. dir., Annali*, IV, Milano, p. 196.
- Marsico, G.M. (2024) *L'approccio basato sul rischio*, in Cassano, G. – Tripodi, E.M. (eds.) *Il regolamento europeo sull'intelligenza artificiale. Commento al Reg. (UE) n. 1689/2024*, Maggioli, Santarcangelo di Romagna, pp. 377 ff.
- Martorano, F. (1966) *On the manufacturer's liability for placing harmful products on the market (concerning a ruling by the Supreme Court of Cassation)*, *Foro Italiano*, Vol. V, pp. 13–32.
- Nitzberg, M. – Zysman, J. (2022) *Algorithms, Data, and Platforms: The Diverse Challenges of Governing AI*, *Journal of European Public Policy*, Vol. 1753.
- Pajno, A., Donati, F. – Perrucci, A. (2022) *Intelligenza artificiale e diritto: una rivoluzione?*, *Proprietà intellettuale, società e finanza*, Vol. 3, Il Mulino.

- Palmerini, E. – Bertolini, A. (2016) Liability and risk management in robotics, in Schulze, R. – Staudenmayer, D. (eds.) *Digital Revolution: Challenges for Contract Law in Practice*, Nomos, Baden-Baden, p. 254 f.
- Perlingieri, C. – Martone (a cura di) (2023) *Nuove tecnologie e cultura del diritto civile*, Esi.
- Perlingieri, P. (2020) Sul trattamento algoritmico dei dati, in *Tecnologie e diritto*, p. 181 ff.
- Podsiadla, A. (2013) What Robotics Can Learn from the Contemporary Problems of Information Technology Sector. *Privacy by Design as a Product Safety Standard - Compliance and Enforcement*, Stanford Law School, Stanford (CA).
- Poletti, G. (2022) Gli intermediari dei dati, *European Journal of Privacy Law & Technologies*, Vol. 46.
- Prakash, S.K. (2021) Artificial Intelligence and Autonomous Vehicles with Case Laws, *Indian Journal of Law and Legal Research*, Vol. 2(2), pp. 1–17.
- Prifti, K., Stamhuis, E. – Heine, K. (2022) Digging into the Accountability Gap: Operator’s Civil Liability in Healthcare AI-systems, in Custers, B. – Fosch-Villaronga, E. (eds.) *Law and Artificial Intelligence. Regulating AI and Applying AI in Legal Practice*, TMC Asser Press, Leiden, pp. 279 ff.
- Resta, G. (2022) What is “European” in the Proposed EU Regulation on Artificial Intelligence, *Diritto dell’impresa e dell’informazione*, Vol. 2, pp. 342 ff.
- Ringbom, H. (2019) *Regulating Autonomous Ships—Concepts, Challenges and Precedents*, *Ocean Development & International Law*, Vol. 50(2), pp. 1–29.
- Scognamiglio, C. (2023) Civil liability and artificial intelligence: which solutions for which problems?, *Rivista critica del diritto privato*, Vol. 2023, pp. 1082 ff.
- Stanzione, P. (2024) Open Banking, Open Finance and the Protection of Personal Data, in Falace, M. – Morera, S. (eds.) *Dall’Open Banking all’Open Finance. Profili di diritto dell’economia*, Giappichelli, Turin, pp. 65 ff.
- Turci, M. (2024) Le nuove tecnologie al servizio del cittadino: Smart city e diritti fondamentali, in Dameri, P. – Bruzzone, M. (eds.), *Smart City. Prospettive di ricerca*, Genoa, p. 143 ff.
- Turci, M. (2025) Beyond Human Factor: AI-Induced Risks in Shipping Insurance, Conference presentation “AI e Assicurazioni nel Ramo Trasporti: Regolamentazione, Rischi e Opportunità nell’Era Digitale”, 27 May 2025, Genoa (Italy).
- Wagner, G. (2023) Liability rules for the digital age. Aiming for the Brussels Effect [online], available at: [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=4320285](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4320285)
- Wagner, G. (2024) Next Generation EU product liability - For digital and other products, *Journal of European Tort Law*, Vol. 15, pp. 196 ff.