INBOTS
Inclusive Robotics for a better Society

INBOTS WHITE PAPER

ON

INTERACTIVE ROBOTICS REGULATORY FRAMEWORK & RISK MANAGEMENT FRAMEWORK

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Table of Contents

Versioning and Contribution History

Version	Date	Modified by	Modification reason
v.01			
v.02			
v.03			

1. Executive Summary

This White Paper offers a first identification and assessment of national and EU regulations applicable to Interactive Robotics, as far as regulatory and risk management frameworks are concerned.

The first section discusses the definition and theoretical functions of liability, toghether with the rationales behind its ascription, and identifies the applicable legal framework in case of damages caused by robotics applications, after clarifying why the latter qualify as "products".

In the second section, the functions of safety regulations and product certification in the EU are discussed, together with the role and the legal value of standards. An analysis of the legal framework and of relavant technical standards is provided, and some preliminary considerations on the possibility of addressing ethical concerns trhough standardization are sketched.

The third session identifies and discusses the applicable legal framework on liability, focussing on the products' liability directive and its national implementations, as well as European initiatives and revisions in the field.

In the Final White Paper, the current analysis will be finetuned and expanded, while review and assessment of the current legal and ethical framework will be monitored, as to allow update and revision when necessary.

In particular, further research will be conducted as to identify possible development of ethical standards at the European, national and international level, and to understand whether a standardization methodology and approach is admissible for interactive robotics, and upon which conditions. In order to do so, the Final White Paper will critically compare the utilitaristic and the neo-kantian approach to the development of ethical principles, and question the possibility of encoding ethical principles in the robotics applications. The current analysis of the liability framework will also be complemented by an inquiry of the legal landscape relevant for the development of an insurance market covering damages caused by robotics applications.

The framework so identified – in the field of ethics, safety regulation, standardization, ethics, liability and insurance – will then be assessed, as to test its adequacy to meet the challenges brought about by interactive robotics. Possible reforms will be suggested, to favour the development of the EU Robotic Industry, ensuring safety and quality design, consumer protection, responsible research and innovation, and protection of fundamental rights.

The White Peper is the result of desk-research, as well as constant interaction with different parts of the robotics community – academics, policy-makers, engineers, stakeholders, end-users –, established within the various activities perfomed by WP5 partners both within the INBOTS Project's (the INBOTS Conference, the ERF) and in different and coordinated actions and projects (such as the European Centre of Excellence on the Regulation of Robotics and Artificial Intelligence "EURA", hosted by SSSA, and the Expert Group on Liability and New Technologies created by the European Commission), fueling and validating the ongoing studies. Indeed, said activities served to inform the robotics community about the most advanced debate occurring at EU policy-making level, establishing and favouring a dialogue between such experts and the robotics community, enabling roboticists to expose an informed point of view and debate some of the fundamental findings of the group of legal experts. Overall, the WP5 activies allowed a cross-fertilization of the current legal, engineering, policy-making and business perspective, in

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order to have a better identification of the problems brought about by new technologies and of the strategies to be adopted for their solutions, which are reflected in the present deliverable.

2. Introduction

1. The theoretical functions of liability

In legal terms, being **liable means to be responsible or answerable for, to be legally obligated**. It concerns both civil, administrative and criminal law and can arise from various sources of legal obligations, such as torts, crimes, taxes, fines, or contracts.

a. The distinction between civil, criminal and administrative liability

Criminal liability rules react to the commission of a crime. In these cases, it is usually the State that prosecutes the defendant before a magistrate, having to demonstrate – beyond reasonable doubt – that the defendant's conduct meets both the mental and the physical element required for offence to be punished under criminal law. The penalties provided for criminal offences are fines and imprisonment, as well as other non-custodial punishments.

Administrative liability is a type of financial responsibility provided for by the legal systems, which is posed by agents of the public administration (employees and public officials but also other subjects who perform tasks for the P.A.) for damage to the tax authorities.

Civil liability rules determine who is supposed to bear the negative economic consequences arising from an accident[1], and under which conditions. Typically, the party is held liable, and thence bound to compensate, who is deemed to have caused the accident. Liability is established after a trail, where the claimant has to prove specific elements, grounding the liability affirmed: under English civil law, for example, to hold a person liable for negligence, the claimant needs to prove that the defendant had a duty, that s/he breached it, and that such breach caused damages recoverable under law.[2]

b. *Ex ante* deterrence, *ex post* compensation and punishment

The idea underlying civil liability is that of **avoiding socially undesirable deviations from intended and expected conducts, and of repairing the damages deriving thereof, when they occur**.

Thus, at least in theory, liability rules pursue three distinct functions, namely ***ex ante* deterrence** – whereby agents will avoid the sanctioned behaviour, knowing that they will not get away with it without having to pay for the damage caused –, ***ex post* compensation of the victim** – forcing the internalization of the negative consequences arising from the illicit behaviour, as to make good for the loss suffered from the infringement of the right – and ***ex post* punishment of the illicit**

[1] Similarly, liability means «the law determining when the victim of an accident is entitled to recover losses from the injurer»: Polinsky, A. Mitchell, and Steven Shavell. Handbook of law and economics. (Elsevier, 2007).

[2] Walter Van Gerven, Jeremy Lever, and Pierre Larouche, *Tort Law* (Oxford: Hart Publishing, 2000). As leading cases on the tort of negligence and on compensatory damages arising therefrom, see *Donoghue v Stevenson* [1932] AC 532, 580; *Nettleship v Weston* [1971] 2 QB 691; *Smith v Leech Brain & Co* [1962] 2 QB 405; *The Wagon Mound No.2* [1967] 1 AC 617 Privy Council.

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behaviour, through the imposition of compensatory duties, functioning as sanctions.

Despite civil liability rules perform all three functions described above, **the role concretely performed may vary**, depending on a series of circumstances. Firstly, it depends on the **specific theoretical account** adopted to explain civil liability, as well as to mould its functioning.

According to the first, and more ancient theory, liability shall be attributed according to the principle of **retributive justice**, namely, that **the blameworthy deserves to suffer, because of the socially reprehensible character of his/her conduct**. This theory has been superseded as the general explanation of liability rules, starting from the separation of criminal law and civil (tort) law as two different disciplines and forms of claims. However, some considerations still hold true, and could be used, for example, to explain the recovery of punitive damages in common law jurisdictions, where the defendant is condemned to pay a sum which exceeds the harm suffered, due to the particular recklessness of his/her conduct[3].

The **corrective justice** theory understands tort law as embodying a system of first- and second-order duties. First-order duties prohibit conducts that are deemed illicit (e.g. because they are immoral, or extremely dangerous), while second-order duties set obligations to make good for the wrong caused by the breach of first-order duties[4]. Differently from the retribution-oriented version of liability, for a loss to be wrongful and worthy of compensation, it does not need to derive from a morally blameworthy conduct: the **main focus lays on the reparation of the victim's right**, caused by the wrongdoer's breach of a relevant first-order duty[5]

In **law and economics (L&E) theories**, liability rules are mostly interpreted and justified as instrumental for obtaining **efficient behaviours and, thus, for increasing the overall social benefit**; they allow dangerous, yet socially desirable, conducts, while shifting the cost of the accidents to the party who is deemed responsible for causing it. According to said theories, paying damages is almost equal to buying the right to obtain the benefits associated with the wrong, and the choice on whether to protect a specific entitlement through liability rules, instead of property rules or inalienability rules, shall depend on efficiency-based reasons, such as the opportunity to allow changes in the original allocation of the entitlements, and in the difficulties connected with leaving their valuation to the market.[6]

Clarifying the theoretical underpinnings of liability rules is fundamental: as it will be further explained below, **different theories of liability justify different mechanisms for apportioning and attributing liability, as well as the recoverability of the damages suffered**.

[3] *Rookes v. Barnard* (1965) 81 LQR 116.
[4] *The Stanford Encyclopedia of Philosophy*, s.v. "Theories of the Common Law of Torts."
[5] Ibid.
[6] Guido Calabresi and Douglas A. Melamed, "Property Rules, Liability Rules, and Inalienability: One View of the Cathedral," *Harvard Law Review* 85, 6 (1972).

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i. Ex ante deterrence in product liability: concurrence of liability rules and product regulation

Since liability rules force to internalize the cost of the damage one is likely to cause, they may be shaped as to induce desirable behaviours, by making the tort inefficient from the perspective of the wrongdoer.[7]

In the case of **product liability,** the producer is **indirectly burdened with a duty to manufacture and commercialize safe products**, since the latter, – if correctly used – would cause no or minimal harm, keeping his/her liability to a minimum.

However, liability rules are not the only source of legal obligations on this matter. Indeed, **complex and detailed legal frameworks are set to introduce first-order duties ensuring product safety, both as a general obligation, and through the provision of narrow-tailored rules, setting specific technical requirements that the products have to meet in order to be lawfully released onto the market**. The way in which those fields of law interact, and how they complement one another, will be further investigated throughout the report (§§4, 3).

2. The rationales for the ascription of liability

As anticipated (§1.b), the **different rationales** underlying the attribution of liability for damages caused (or the administrative and criminal offences committed) shape the construction of specific liability rules, e.g. by determining different **imputation criteria**, as well other relevant criteria related to the types and extent of recoverable damages (e.g. causation/remoteness, subjective element, liability caps, limitation periods etc.).

a. Liability based on the reprehensibility of the conduct

The decision to attribute liability on one specific subject could rest on the fact that the latter caused the damage through a blameworthy conduct. Many tort law systems – such as the Italian one[8] – have a general rule **prescribing liability on the basis of fault**: this criterion serves to punish a blameworthy behaviour by imposing to the wrongdoer a duty to make good for the damage caused.

At the same time, fault-based liability pursues a different and complementary rationale: it creates economic disincentives, as the imposition of the obligation to compensate also deterring harmful behaviour.

In this sense, liability based on the reprehensibility of the conduct is moved by all the different goals defined above ***ex ante* deterrence, *ex post* compensation and sanction**.

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[7] In this sense, liability rules shall be constructed as to avoid forms of efficient breach. The case for the legitimacy of efficient breaches has famously been formulated by Goetz, Charles J., and Robert E. Scott. "Liquidated damages, penalties and the just compensation principle: Some notes on an enforcement model and a theory of efficient breach." *Columbia Law Review* 77.4 (1977): 554-594, and Birmingham, Robert L. "Breach of contract, damage measures, and economic efficiency." *Rutgers L. Rev.* 24 (1969): 273, «repudiation of obligations should be encouraged where the promisor is able to profit from his default after placing his promisee in as good a position as he would have occupied had performance been rendered»; *contra*: Fried, *Contract as a Promise: A Theory of Contractual Obligation* (Oxford: Oxford University Press, 1981).; Coleman, *The Practice of Principle: In Defence of a Pragmatist Approach to Legal Theory* (Oxford: Oxford University Press, 2003).

[8] Art. 2043 Italian civil code: «*Risarcimento per fatto illecito.* Qualunque fatto doloso o colposo, che cagiona ad altri un danno ingiusto, obbliga colui che ha commesso il fatto a risarcire il danno».

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b. Liability based on the position held towards a specific cause of danger

Other times, the defendant is liable in tort despite having done nothing blameworthy, **because of the particular position s/he held towards the source of damage**. In this sense, someone may be held legally responsible because s/he holds a duty to watch over some entity – such as the keeper, owner or user of a dangerous thing, the keeper or user of an animal –, or is the person who benefits from having or using such things, or running a specific activity[9].

This rationale can be associated to **a strict or semi-strict liability**, depending on whether or not the defendant may exclude his liability – i.e. by demonstrating that s/he took all the necessary measures to prevent the harm from occurring, or by demonstrating that the latter was caused by force major or an act of God –.

c. Liability based on the ability to manage and internalize risk

The other rationale for ascribing liability is that of identifying the **person who is best positioned to manage and internalize the risks associated with a given activity, preventing their occurrence and minimizing their consequences, as well as to compensate the victim once an accident occurs**. This ground for ascribing liability is particularly common in L&E literature.

One specific approach adopting this rationale is the so called **Risk Management Approach** (henceforth RMA), which is grounded on the idea that liability should not be attributed on the basis of considerations of fault – defined as the deviation from a desired conduct – typical of most tort law systems, but rather on the party who is best positioned to (i) minimize risks and (ii) acquire insurance.[10]

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[9] Examples from Italian civil code: artt. Article 2047. «Injury caused by person lacking capacity: If an injury is caused by a person incapable of understanding or intending, compensation is due from those who were charged with the custody of such person, unless they prove that the act could not have been prevented. If the person injured is unable to secure compensation from the person charged with the custody of the person lacking capacity, the court, considering the financial conditions of the parties, can order the person who caused the injury to pay equitable compensation» art. 2048 « Liability of parents, guardians, teachers, and masters of apprentices: The father and mother, or the guardian, are liable for the damage occasioned by the unlawful act of their minor emancipated children, or of persons subject to their guardianship who reside with them. The same applies to a parent by affiliation. Teachers and others who teach an art, trade, or profession are liable for the damage occasioned by the unlawful act of their pupils or apprentices while they are under their supervision. The persons mentioned in the preceding paragraphs are only relieved of liability if they prove that they were unable to prevent the act»; art. 2049 «Liability or masters or employers: Masters and employers are liable for the damage caused by an unlawful act of their servants and employees in the exercise of the functions to which they are assigned»; Article 2050. «Liability arising from exercise of dangerous activities: Whoever causes injury to another in the performance of an activity dangerous by its nature or by reason of the instrumentalities employed, is liable for damages, unless he proves that he has taken all suitable measures to avoid the injury»; art. 2051 «Damage caused by things in custody: Everyone is liable for injuries caused by things in his custody, unless he proves that the injuries were the result of a fortuitous event»

[10] Erica Palmerini and Andrea Bertolini, "Liability and Risk Management in Robotics," in Digital Revolution: Challenges for Contract Law in Practice, ed. Reiner Schulze and Dirk Staudenmayer (Baden-Baden: Nomos, 2016); Andrea Bertolini, "Insurance and Risk Management for Robotic Devices: Identifying the Problems," Global Jurist, no. 2 (2016). For an application of the RMA in case of industrial robotics and autonomous vehicles, see Tjerk Timan et al., Study on Safety of Non-Embedded Software. Service, Data Access, and Legal Issues of Advanced Robots, Autonomous, Connected, and Ai-Based Vehicles and Systems: Final Study Report Regarding Cad/Ccam and Industrial Robots. (Brussel: European Commission, 2019).; the same

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One fundamental consideration underpinning the RMA is that liability rules are not always efficient in ensuring adequate incentives towards a desirable conduct, be it a safety investment – such as in the case of producers' liability (§1.a) – or a diligent conduct – such as the driver's in the case of road circulation –, and that end is best attained through the adoption of detailed *ex ante* regulation, such as product-safety rules (on this matter, see also §3).

3. Robots as products & the applicable legal framework

When discussing issues of liability, it is often claimed that robots constitute peculiar entities, which do not fall squarely into the existing legal framework, and that new legal paradigms are thus needed for regulating the harmful consequences caused by them.[11] More specifically, it has been claimed that some robotics and artificial intelligence applications are so technologically advanced, that they invite "a systemic change to laws or legal institutions in order to preserve or rebalance established values";[12] that, being their actions so much outside humans' control, we should deem them responsible for the wrong caused, instead of blaming the producer, the owner or the user behind them.[13]

Theoretically, two different approaches may be used to justify legal reform. Pursuant to an **ontological perspective**, we may need new rules when the object of regulation is so different from what we have been regulating, so far that a distinct legal qualification, is due thus leading to the application of different rules. In this sense, it is possible to argue that the new features displayed by advanced robotics are such that they shall be deemed subjects, instead of mere objects. On the contrary, a **functionalist approach** assesses legal rules according to their adequacy in performing the functions attributed to them, and the overall consequences of their application.[14] Thus, on a functional basis, one may argue that existing rules lead to undesirable consequences either in terms of excessive harm being caused or not enough technology being developed and distributed into the market.[15]

Indeed, the case for holding robots directly liable is often based both on both functional and ontological considerations, but no clarity is made on the perspective adopted, despite the latter bears radically different theoretical and practical consequences. If the robot is to be deemed a subject – not an object – then not only it would

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approach is used to assess civil liability of drones in Andrea Bertolini, Artificial Intelligence and Civil Law; Liability Rules for Drones (Brussel: European Parliament, 2018).

[11] Ryan Calo, "Robotics and the Lessons of Cyberlaw," *California Law Review* 103, (2015).:513-563; Christophe Leroux et al., *Suggestion for a Green Paper on Legal Issues in Robotics. Contribution to Deliverable D.3.2.1 on Els Issues in Robotics* (2012), http://www.eurobotics-project.eu/cms/upload/PDF/euRobotics_Deliverable_D.3.2.1_ELS_IssuesInRobotics.pdf; ibid.; Luciano Floridi and J.W. Sanders, "On the Morality of Artificial Agents," *Minds and Machine* 14 (2004).: 349-379

[12] Calo., 513-563.; Leroux et al; ibid.; Floridi and Sanders.

[13] Ler Leroux et al., "Suggestion for a green paper on legal issues in robotics. Contribution to Deliverable D3. 2.1 on ELS issues in robotics." (2012).

[14] Andrea Bertolini, "Robots as Products: The Case for a Realistic Analysis of Robotic Applications and Liability Rules," *Law Innovation and Technology* 5, no. 2 (2013); Andrea Bertolini, "Robots and Liability - Justifying a Change in Perspective," in *Rethinking Responsibility in Science and Technology*, ed. Fiorella Battaglia, Julian Nida-Rümelin, and Nikil Mukerji (Pisa: Pisa University Press, 2014).; Palmerini and Bertolini, in *Digital Revolution: Challenges for Contract Law in Practice*.

[15] On the distinction between the two perspectives and the need to address them separately, Bertolini, "Robots as Products: The Case for a Realistic Analysis of Robotic Applications and Liability Rules." Bertolini, "Robots and Liability - Justifying a Change in Perspective," in *Rethinking Responsibility in Science and Technology*. In similar terms, also Fabio Fossa, "Artificial Moral Agents: Moral Mentors or Sensible Tools?," *Ethics and Information Technology* 20, no. 2 (June 01 2018), http://dx.doi.org/10.1007/s10676-018-9451-y.

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be liable for the damage caused, but it would be entitled with rights and obligations, going far beyond the mere duty to compensate (i.e. traditional "personal" rights). On the contrary, if the only reason for considering it a person is that of segregating selected assets and shielding single human beings from the legal and economic consequences of its operations, and eventually providing a diversified taxation scheme, then the overall legal and ethical implications radically differ, and the two stances shall not be confused.[16]

That being said, ontological and legal consideration **shall be kept separate**.

As it will be demonstrated in the following pages, neither the functional nor the ontological assumptions are sufficiently justified, as to ground the exceptionalist claim and the proposed reform of liability rules associated with it. On the one hand, **it is disputable whether holding robots directly accountable for the damages caused is preferable, everything considered, to holding the humans behind them liable.**[17] **On the other hand, the ontological claim according to which new robots' essential qualities make them subjects, rather than mere objects, is far from being proved**.

Since the robots' liability claim is often grounded in the idea that we shall avoid the so called "responsibility gap",[18] two assertions in particular need to be evaluated, namely: i) whether the peculiar features displayed by advanced robotics, such as their asserted autonomy and ability to modify themselves, make them moral and legal agents, and ii) whether it is true that – absent legal reforms – humans would be called to respond for damages upon which they had no or very limited control.

a. Why robots cannot be considered as a «moral agent»

One entity can be deemed a subject, instead of an object, only when it can qualify as a moral agent.[19]

Indeed, it is often said that robots – especially advanced robots and artificial intelligences applications, which are able to act without the constant monitoring and control of a human agent, interacting with the environment, often in an unpredictable fashion – are «autonomous». It is indeed this feature that is used to justify the afore-mentioned change of prospective, grounding the claim for a new «robot's personal liability»[20].

However, **stating that robots are «autonomous» is highly ambiguous, as only some kinds of autonomy amount to the concept of moral agency, that justifies the ontological ascription of liability**.

For an entity to be deemed a moral agent, it shall display what is usually referred to as **«strong autonomy», i.e. the ability to decide freely and coordinate one's action towards a chosen end**. Yet, **current robots**, conceived to complete a specific task identified

[16] See WP2.
[17] For social and ethical considerations on this point: Joanna J Bryson and Philip P. Kime, "Just an Artifact : Why Machines Are Perceived as Moral Agents," in *Proceedings of the Twenty-Second International Joint Conference on Artificial Intelligence: Barcelona, Catalonia, Spain, 16–22 July 2011*, ed. Toby Walsh (Menlo Park, CA, USA AAAI Press, 2011).
[18] Andreas Matthias, "The Responsibility Gap: Ascribing Responsibility for the Actions of Learning Automata," *Ethics and Information Technology* 6 (2004).
[19] For a philosophical account of this matter, see:
[20] Floridi and Sanders.

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by their user, **do not show such form of autonomy**, and it is even disputed whether a similar condition could ever be achieved and, if so, it should be actively pursued at all.[21]

On the contrary, most robots display what is called «weak autonomy», namely the condition under which the robot's behaviour are not determined by the intervention of an external agent, who merely identifies the goal to be achieved.

So long as the machine performs the tasks it was originally designed for, it acts, by definition, under the producer's or programmer's control. The complexity of its functioning makes it particularly difficult to identify whom, among the different subjects involved, is to blame for the damage occurred; however, this does not alter the fact that **such applications act heteronomously, thus do not display moral agency**.[22]

This hold true even for those technologies based on the so called «ability to learn», such as neural based systems and genetic algorithms. The ability of the robot to learn and modify itself does not make it an individual, since it is still not free of exerting that degree of self-determination featured by a truly autonomous and independent being.[23]

Neither the lack of control from the programmer is such that the latter cannot be deemed the moral agent behind the robot's actions, since **said "responsibility gap"[24] is more apparent than real**. Indeed, the peculiar unpredictability of the robots' behaviour merely requires the training and associated evolution of the robots to be included in the development phase, so that they are put onto the market only when they have achieved sufficient skills as to ensure safe interactions and functioning.

These considerations clearly explain why **there is no ontological argument imposing a shift in the current legal framework**. That being said, it is nevertheless possible that **functional arguments may still justify the adoption of different liability rules, identifying robots as bearers of (specific) rights and duties, on the basis of constitutional principles and policy considerations,** i.e. to ease compensation of the victims.

However, unless **robots display** ability to earn **autonomous assets**, **we will always need to identify someone else to cover the negative occurrence deriving from their activity: again, the human behind them**.[25]

b. Why robots cannot be considered as "animals"

Since the humans behind the robots' functioning cannot predict and control all the behaviors of the robots, especially of those displaying the highest possible form of heteronomous autonomy, **it has been suggested that we should held the user responsible in his stead,**

[21] Mathias Gutman, Benjamin Rathgeber, and Tareq Syed, "Action and Autonomy: A Hidden Dilemma in Artificial Autonomous Systems," in *Robo- and Informationethics. Some Fundamentals*, ed. Michael Decker and Mathias Gutman (Lit Verlag, 2012). Bertolini, "Robots as Products: The Case for a Realistic Analysis of Robotic Applications and Liability Rules."
[22] Gutman, Rathgeber, and Syed, in *Robo- and Informationethics. Some Fundamentals*. Bertolini, "Robots as Products: The Case for a Realistic Analysis of Robotic Applications and Liability Rules."
[23] Bertolini, "Robots as Products: The Case for a Realistic Analysis of Robotic Applications and Liability Rules.", 159.
[24] Gutman, Rathgeber, and Syed, in *Robo- and Informationethics. Some Fundamentals*.

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according to the owner's – or keeper's – vicarious liability set for in case of damages caused by domestic animals, which is grounded on the fact that animals behave in an intrinsically unpredictable, and thus dangerous, manner, but, not being granted any property right, they cannot compensate the harm caused; therefore, it is the person who gains personal advantage from the animal that is required to bear the cost of having or using it. However, **such claim is once again not sustainable from an ontological perspective, since animals and robots are profoundly different from robots**.

The unpredictability of the robots' behaviour may be due to the way it responds to the changing environment, or to the ability it learns or the functional structure it assumes due to this interaction with the environment and the evolution deriving therefrom. However, while an animal's actions are always unpredictable, erratic behaviour, those of a robot are not. Indeed, if a given outcome was to be foreseen, it would be possible to prevent it, either by designing the product differently, or by not granting to the robot the degree of freedom from which the danger derives. **As long as the machines executes the program designed by the human, even if through inputs derived from the environment, its behaviour may be deemed predictable for the purpose of the application of product liability standards**. On the contrary, the unpredictability of the animal's actions derives from its nature or erratic behaviour, and thus cannot be associated with the former.[26]

c. Why robots shall be considered as product and who shall be held responsible for them

Since **robots** are not autonomous – in a strong sense –, and having excluded that they could be considered as animals, they **shall be deemed as objects**, and more precisely as **products**: "**artefacts crafted by human design and labour, for the purpose of serving identifiable human needs**" [27]. From a legal point of view, this means when they cause a damage, **product liability rules apply**. Given that such framework is based on a wide concept of control – in the sense that the theory of liability which underlies those rules rests on the idea that the producer shall be responsible because, and as long as, s/he is in full control of the features and actions of the products – it has been suggested that product liability rules are not adequate for the purpose of regulating the consequences deriving from a damaged caused by them, as they would widen the aforementioned responsibility gap.

However, and as already explained, the supposed lack of control is more apparent than real, since even features connected to the robots' advanced ability to learn are such that unpredictable circumstances and evolutions can be secured within the training phase, and – should an application be deemed totally unpredictable – developers should not release it onto the market at all.

Once again, this does not entail that existing liability rules should not be changed at all, to accommodate advanced technological applications. As already highlighted, **under a functionalist perspective, social and policy considerations may suggest the adoption of a favourable liability scheme, which could incentivize the development of**

[26] Bertolini, "Robots as Products: The Case for a Realistic Analysis of Robotic Applications and Liability Rules."
[27] Ibid.; Bryson and Kime, in *Proceedings of the Twenty-Second International Joint Conference on Artificial Intelligence: Barcelona, Catalonia, Spain, 16–22 July 2011*.

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applications which are particularly valuable for society, such as prosthesis or devices intended to help the otherwise disabled in their everyday tasks.[28]

4. Ensuring product safety

a. The rationale behind product safety regulation

Product liability rules aim at balancing opposite interests: inducing the development of safe products and distributing them in the market for profit. This explains why not all damages are to be compensated through liability rules at all times. If the negative outcome corresponds to a level of risk, which is deemed desirable for society, then the damage shall stay with the victim, or be indemnified through alternative mechanisms – e.g. no-fault based compensation schemes, mandatory insurance – not directly burdening the producer or programmer of the machine, since being the given activity overall beneficial to society it needs to be encouraged rather than opposed.[29] The producer's possibility to exclude his/her liability under the PLD by relying on the so called "development risk defence" is one – possibly criticizable – way of balancing up the conflicting interests at stake (§1.a)

As we will see in the following analysis, the actual nature of EU product liability rules is extremely complex. The general provision holding producers (and retailers, when the former are not identifiable) liable for the damages caused by the products they put into circulation responds to a "pro-consumer" perspective, since the semi-strict liability standard adopted is primarily aimed at compensating the victim for the harm suffered, and is only secondarily directed to influence a determinate duty of care.

On the contrary, that of ensuring safe products is the main goal of a different legal framework, which is complementary to product liability rules, namely product safety regulation.

The European product safety framework is complex and comprises both generally applicable rules as well as norms set up for specific types of products. General rules are defined in the General Product Safety Directive[30], (henceforth, GPSD, analysed more in depth in §4), and require firms to: i) ensure that items placed on the marker are safe – meaning that "under normal or reasonably foreseeable conditions […] do not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons"[31]–; ii) inform consumers of any risks associated with the products supplied; and iii) take corrective action when that products prove to be unsafe.

Under product safety regulation, a product is presumed to be safe it meets all statutory safety requirements under European or national law, or – being they absent – if conforms national standards, Commission recommendations, codes of practice, best practice in the sector concerned, state of the art and technology, reasonable consumer safety expectations.

[28] Bertolini, "Robots as Products: The Case for a Realistic Analysis of Robotic Applications and Liability Rules."
[29] Bertolini, Andrea. "Robots and liability: justifying a change in perspective." *Rethinking responsibility in science and technology*. Pisa University Press, 2014. 143-166.
[30] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (GPSD).
[31] Art. 2(b), GPSD.

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However, compliance with technical standards and certification of products does not exclude liability in case damage occurs. Product liability works as a safety net, as it aims at ensuring compensation when damages arise, regardless of the compliance with *ex ante* safety regulation.

b. Inadequacy of traditional product safety approach to robotics

While traditional product safety rules still need to be respected by technologically advanced devices, they may prove inadequate for regulating robotics and artificial intelligence applications. Indeed, traditional safety mostly refers to the absence of risks, intended as the absence of features which are likely to cause harm to the user of the products, or to by-standers, or to their property. On the contrary, R&AI applications also **give rise to different and broader types of ethical and societal concerns, as they affect people's privacy, dignity, security, autonomy and safety – both physical and psychological –, raising serious legal and ethical questions**.

Human-machine interaction must be safe not only from a physical point of view but also social and relational perspective. For example, personal robotics shall be constructed as to increase human health and wellbeing – by assisting an increasingly-aging populating, offering rehabilitation-related-services to patients in clinics etc. –, and could potentially expand such beneficial impact by adopting a robot-as-service approach, which could adjust to the users' specific and personalized needs.

When such kind of applications are involved, **it is necessary to consider not only the immediate service offered to the individual user, but also to current social challenges in a broad perspective, thus having an all-compassing notion of health and wellbeing in mind**, which is not only based physical wellbeing, or clinical conditions, but also takes into consideration the general condition of the patient and his role and position in society[32]. If not correctly regulated, the use of robotics and AI applications might have negative side-effects, such as the isolation of the users and impoverishment of human relationships, which cannot be substituted those with machines. In this sense, it is fundamental for policy-makers and legislator to identify parameters and tools which could help the robotic community to recognize and address those challenges, ultimately allowing the roll-out of technological applications that meet the legitimate needs of the society (i.e. taking care of the elderly, helping patients during rehabilitation etc.), without giving way to forms of deceptions and dehumanization, which equally represent a danger for the overall society.[33]

However, no legal or ethical requirement in this regard has yet been adopted (but for the Final Ethical Guidelines developed by the High Level Expert Group, §5.b).

Likewise, **the innovative nature of such devices, together with the long-term and partially unpredictable effects of their use, make it difficult** for researchers and businesses **to identify, evaluate and mitigate the risks they may give rise to**. Legislators and policy makers have **insufficient data for defining the conditions of lawfulness of these devices, for regulating the overall process –** from idea-development, to testing, certification and post-market surveillance – **as well as for critically assessing the effectiveness and efficiency of the adopted legislation**.

[32] Koszegi, Sabine Theresia. "High-Level Expert Group on Artificial Intelligence." (2019): 3-3.
[33] Bertolini, Andrea. "Human-Robot Interaction and Deception." *Osservatorio del diritto civile e commerciale* 7.2 (2018): 645-659.

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This means that **product safety regulation – broadly intended – shall be reshaped as to better meet the new challenges brought about by technological innovation**.

Since testing is fundamental in order to have a correct assessment of known/unknown risks, and limit the "responsibility gap" discussed above, it is important that product safety regulation is complemented and integrated by a legal framework allowing the most advanced, efficient and effective ways of testing. For interactive robotics, real-life testing shall complement simulation in order to evaluate safety and performance in machine learning-interactive and connected technology.[34]

5. The role of regulation in robotics

a. The function of robotics regulation

Regulating robotics and artificial intelligence constitutes one of the biggest challenges that Europe faces. Lack, delay or inadequacy of regulation may indeed allow technologies which are not respectful of and driven by the European core values and principles. At the same time, they may have a chilling effect, thus hindering, instead of fostering technological innovation.

How liability is attributed and apportioned among the different players involved, and how such subjects are able to insure for such costs, is a matter of seminal importance. **Not only does it determine the incentives to the very development and diffusion of new technologies, but it also influences the adoption of specific devices and technical solutions**. Liability rules, together with insurance regulation, impact the development and diffusion of new technologies, by favouring some over others.

b. The European approach to robotics and artificial intelligence

EU Institutions have long recognized the opportunities offered by robotics and AI, as well as the challenges connected to it, and accordingly moved towards the elaboration of a clear and coherent European approach and investment in this technology, as part of its **Digital Single Market** policy.[35]

On the 25th of April 2008, the Commission put forward a **European approach to artificial intelligence and robotics**,[36] dealing with technological, ethical, legal and socio-economic aspects to boost EU's research and industrial capacity and to put AI at the service of European citizens and economy. Said "European approach to AI" aims at boosting the European technological and industrial capacity and AI uptake across the economy, while anticipating and addressing socio-economic changes, and ensuring an appropriate ethical and legal framework, based on the Union's values, and in line with the Charter of Fundamental Rights of the EU.

It rests on three pillars:

1. **Being ahead of technological developments and encouraging uptake by the public and private sectors,** connecting and strengthening AI research centres across Europe; supporting the development of an "AI-on-demand platform" that will provide

[34] Timan et al. "*Study on Safety of Non-Embedded Software",* European Commission, 2019.
[35] Further info on this topic can be found at: https://ec.europa.eu/digital-single-market/en
[36] *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, 2018). Available at: https://ec.europa.eu/digital-single-market/en/news/communication-artificial-intelligence-europe [accessed 7th June 2018].

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access to relevant AI resources in the EU for all users; and supporting the development of AI applications in key sectors. Policy and investment recommendations on how to strengthen Europe's competitiveness will be released in June 2019 by High Level Expert Group on Artificial Intelligence (AI HLEG), specifically established by the European Commission itself.

2. **Prepare for socio-economic changes brought about by AI,** by supporting business-education partnerships to attract and keep more AI talent in Europe; setting up dedicated training and retraining schemes for professionals; foreseeing changes in the labour market and skills mismatch; supporting digital skills and competences in science, technology, engineering, mathematics (STEM), entrepreneurship and creativity; encouraging member States to modernize their education and training systems.
3. **Ensure an appropriate ethical and legal framework,** in particular related to liability, fairness of decision-making, trust and transparency in the use of data[37] and in the functioning of AI-based applications.

Indeed, the final **Ethics Guidelines for Trustworthy Artificial Intelligence on 8 April 2019 by the High-Level Group on Artificial Intelligence**[38] put building Trust in Human-Centric Artificial Intelligence as a prerequisite to ensure a human-centric approach to AI. According to the AI HLEG, ensuring that European values are at the heart of creating the right environment of trust for the successful development and use of AI requires respect of the following principles: i) human agency and oversight; ii) technical robustness and safety; iii) privacy and data governance; iv) transparency, diversity, non-discrimination and fairness; v) societal and environmental well-being; vi) accountability. Aiming to operationalize these requirements, the Guidelines present an assessment list that offers guidance on each requirement's practical implementation, and that will be assessed by stakeholders in the following piloting phase.

3. Safety and certification

1. The functions of safety regulations and product certification in the EU

2. Product safety regulation: origin and current state of art

European safety regulation is thus intended to define the level of safety that is demanded of every specific product.

However, before focussing on specific pieces of legislation (§4), it is fundamental to clarify how the overall framework of product safety regulation was developed and is currently structured, in particular due to the intertwine between products' essential safety requirements set out by EU directives and regulations, technical standards, and certification procedures.

Indeed, compliance with product safety regulation in Europe is based on a **complex system of product certification**, having a twofold aim: ensuring high levels of product quality and

[37] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119, 4.5.2016, p. 1–88.

[38] Intelligence.

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safety, thus strengthening the users' confidence and protection, and easing free movement of goods across Member States (MSs) by setting uniform rules and procedures.[39]

To this end, since the so called «**New Approach**» adopted in 1985, **legislative harmonization is limited to the essential safety requirements, that products placed on the EU market must meet, while the relevant technical specifications are laid down by technical standards, developed at the European, international and national level**. "European" standards are harmonized technical standard (hEN), developed by private subjects for the application of EU harmonization, upon request from the Commission[40], for which a legal presumption of conformity applies. Indeed, **products manufactured in compliance with hEN benefit from a presumption of conformity with the corresponding essential requirements of the applicable legislation**, and, in some cases, the manufacturer may benefit from a simplified conformity assessment procedure (e.g. the manufacturer's declaration of conformity). However, the application of harmonized or other standards remains voluntary, and the manufacturer can always apply alternative technical solutions, but, in this case, s/he will have to demonstrate that the latter answer the needs of the essential requirements, often through a process involving a conformity assessment body.

In 2008, the New Approach was further integrated by **New Legislative Framework Approach** – constituted by Regulation on accreditation and market surveillance[41], another Regulation on technical rules[42], and a Decision on marketing of products[43] - with the aim of improving market surveillance rules, boosting confidence in product assessment and establishing a common legal framework for industrial products.

a. The functions of certification

Certification is the procedure products meant to be traded onto the EU market needs to undergo, to assess whether they meet the minimum safety requirements set out by relevant legislation, and obtain the «conformity mark», certifying said compliance.[44]

However, as already highlighted, the fact that a product was "certified" (or self-certified, when appropriate) under current legislation does not *per se* exclude that a specific products turns out to be defective, or that its use may lead to defects and accidents, possibly causing the producer to be held liable pursuant to – for instance – the PLD.

[39] For an extensive overview of this topic, see: Timan et al.
[40] The Machinery Directive (henceforth, MD) applicable to most robotic devices is a fundamental case in point.
[41] Regulation (EC) 765/2008 setting out the requirements for accreditation and the market surveillance of products
[42] Regulation (EC) 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another EU country.
[43] Decision 768/2008 on a common framework for the marketing of products, which includes reference provisions to be incorporated whenever product legislation is revised. In effect, it is a template for future product harmonisation legislation. Presumption of conformity in Decision 768/2008: Products which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements covered by those standards or parts thereof, set out in … [reference to the relevant part of the legislation].
[44] Timan et al.

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3. The role and the legal value of standards

a. Legal and *de facto* relevance of standards

In general, **standards are adopted by international (e.g. ISO) and EU organizations, and in some cases even national authorities**;[45] a specific type of standards – harmonized standards (hEN) – are developed by a recognized European Standards Organisation – CEN, CENELEC, or ETSI – following a request from the European Commission, and manufacturers, other economic operators, or conformity assessment bodies are supposed to use them as to demonstrate that products, services, or processes comply with relevant EU legislation.[46]

Both harmonized and non-harmonized standards, however, are not binding regulations: compliance is required with directives and other legislation, not with technical norms, and standards are merely used as a way of meeting the requirements set thereof, as they identify the best practice or state of the art in a given area, or with respect to a given application.

Nonetheless, manufacturers are still free to satisfy legislative prescriptions in alternative ways, radically disregarding eventually existing standards. Despite the voluntary application, the ECJ stated in the **James Elliott ruling that hENs are part of EU law, thus falling its own jurisdiction** under Article 267 of the Treaty on the Functioning of the European Union (henceforth, TFEU)[47]. The actual relevance of the case – whether it merely involves interpretative questions or opens up at the possibility for the ECJ to review said standards – remains for the moment being unsolved.

Indeed, since standards are deemed acknowledged rules of technology, describing what it takes for a product to be safe, **judges often assume that a product has been manufactured with "due care" or "due diligence", if it complies with the relevant standards, also when solving issues related to product conformity and defect-based liability**. Still, since standards, even harmonized one, are not mandatory, **non-compliance does not necessarily mean the product is defective**, but sellers and manufacturers merely need to resort to other tools to demonstrate that the product fulfils the customary requirements. If this cannot be done, then the buyer would assert his/her rights, including the removal of the fault, delivery of a fault-free product, or compensation for any damages arising from the absence of warranted characteristics.[48] Likewise, the mere fact that mass-produced product have been certified, and have been manufactured by relaying on technical standards, does not exclude that a specific product may be found to be defective under the PLD framework.

b. Relation between national and European standards

Since, as stated before, standards are not binding legal acts, traditional rules, such as *lex posterior derogat priori*, *lex superior derogat inferiori* and most of all *lex specialis derogat generali* cannot solve hypotheses in which different standards, produced at various level (international, European or national) address the same dangers, technologies or product classes.

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[45] Source: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en
[46] Timan et al. "*Study on Safety of Non-Embedded Software",* European Commission, 2019.
[47] C-613/14, James Elliott Construction Limited v Irish Asphalt Limited, Judgment of the Court (Third Chamber) of 27 October 2016, ECLI:EU:C:2016:821.
[48] See Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees.

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In such a hypothesis, any standard can be prevalent on others, if it is enshrined in a body of law or explicitly mentioned in a binding contract.

Standard-conflict problems are, anyway, **prevented by other rules and practices**. For example, agreements that bind European standardization organizations (ESOs), such as CEN, and International ones (such as ISO), require ESOs to first assess whether international organizations have already issued standards on the issue at stake. If an international standard indeed exists, ESOs can either adopt it thoroughly, or further develop the international standard.

Moreover, WTO member States are required not to issue standards contrasting international ones.

Briefly, and limited what is sketched above, **international standards enjoy primacy over European standards, which in turn enjoy primacy over national ones**. If the three levels coincide, this can be easily seen by the standard names: for example, UNI EN ISO 9001 standard is issued consistently at national (namely, Italian), European and international level.

4. Analysis of the legal framework

a. Relevant directives

Given the variety of technological applications falling within the notion of (interactive) robotics, it is quite difficult to identify the applicable legal framework, particualrly in the field of product safety and certification.

Indeed, the majority of the product safety legislation is either related to a specific type of product or application (e.g. medical products), or is meant to regulate – and its application is thus triggered by – trasversal features or characteristic (e.g. functining upon the use of energy).

Indeed, **the applicable legislation is necessarily identified through a case-by-case approach, taking into account both the technical features of the robots, the use they are destined for, the environment they will be installed or be used in, as well as the impact they will have on direct and indirect users.**

Since this report adopts a general perspective, however, in the following pages we will present a **description of some directives and regulation which are** – or could be expected to be – **relevant for a broad class of robotics applications,** which can be qualified as falling within the scope of application of the former.

First and formost, robots may be considered «**machinery**» – namely «an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application» –, or «**partly completed machinery**» – «an assembly which is almost machinery but which cannot in itself perform a specific application» –, thus being regulated by the **Machinery Directive** (henceforth, MD).[49]

Additionally, some devices – such as exoskeletons – may also be considered as «**personal protective equipment**» (henceforth, PPE) – i.e. «equipment designed and manufactured to

[49] Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC, in OJ L 157, of June 9th, 2006.

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be worn or held by a person for protection against one or more risks to that person's health or safety» –, which fall within the scope of the **Personal Protective Equipment Directive, or the Regulation repealing it** (henceforth, respectively, PPED and PPER).[50]

Some devices may also be classified as «**medical devices**», i.e. as an «instrument, apparatus, appliance, material or other article […] intended by the manufacturer to be used for human beings for the purpose of: — diagnosis, prevention, monitoring, treatment or alleviation of disease, — diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, — investigation, replacement or modification of the anatomy or of a physiological process […]»[51]. Should that be the case, the **Medical Device Directive and Regulation would apply** (MDD, MDR)[52].

As already recalled, **whenever more specific rules do not apply, robots still qualify as "product"**, and thus the **General Product Safety Directive** – which is meant to have general applications – comes into play.

Likewise, other legislation having transversal relevance– such as the Law Voltage Directive or the Data Protection Regulation – will be analysed, on the ground that specific robot may displays the characteristic triggering their application.

i. The Machinery Directive framework

The MD envisages different procedures, depending both on the type and function of the machinery involved, and its compliance with harmonized standards.

Pursuant to art. 12, MD, if robots do not fall within the list of "dangerous" devices set out by Annex IV, MD, the manufacturer may certify it through the assessment of conformity with internal checks provided for in (Annex VIII). If, on the contrary, it falls within said category – as it is likely to be – a further distinction applies. If the manufacturer complied with hEN standards covering all the relevant essential health and safety requirements, s/he may choose among (a) the procedure for assessment of conformity with internal checks on the manufacture of machinery (Annex VIII); (b) the EC type-examination procedure (Annex IX), plus the internal checks on the manufacture of machinery (Annex VIII, point 3); (c) the full quality assurance procedure (Annex X). If such compliance with harmonized standards is lacking, the manufacturer is allowed to choose among two of the more burdening procedures, described above under the letters (b) and (c).

Pursuant to Art. 13, MD, «partly completed machinery» do not need to be certified, but it is sufficient that «(a) the relevant technical documentation described in Annex VII, part B is prepared; (b) assembly instructions described in Annex VI are prepared; (c) a declaration of incorporation described in Annex II, part 1, Section B has been drawn up».

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[50] Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC, in OJ L 81, of March 31st, 2016. Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment, OJ L 399, of December 30th, 1989.

[51] Art. 1 MDD.

[52] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12.7.1993, p. 1–43. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance), OJ L 117, 5.5.2017, p. 1–175.

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ii. The Medical Devices Directive and Regulation

Under art. 9, MDD and Annex IX, medical devices are divided into four classes, according to several criteria, such as duration of treatment and invasiveness, which consequently affect the certification procedure to follow, pursuant to art. 11 MDD.

Four classes – again Class I, IIa, IIb, and III – are described at art. 51, MDR, in combination with Annex VIII, MDR, which provides twenty-two classifying rules. Rule I, Annex VIII, MDR, states again that non-invasive devices belong to Class I, while Rule 9, Annex VIII, MDR, follows almost verbatim Rule 9, Annex IX, MDD. On this point, legal and regulatory framework has remained substantially unchanged after MDR entry into effect.

TABLE IRRF&RMF 1 MEDICAL DEVICES CLASSES

Category	Certification procedure under the MDD	Certification procedure under the MDR
Class III	(a) the full quality assurance set out in Annex II; or (b) the EC type-examination set out in Annex III, coupled with eith (i) the EC verification set out in Annex IV; or (ii) the production quality assurance set out in Annex V	conformity assessment based on a quality management system and on assessment of technical documentation a conformity assessment as specified in Annex IX, or, alternatively, the conformity assessment based on type-examination the manufacturer specified in Annex X, coupled with the conformity assessment based on product conformity verification.
Category IIa	either: (a) Annex II full quality assurance (but the examination of the design of the product does not apply; or (b) f Annex III EC type-examination, coupled with: (i) Annex IV EC verification; or (ii) Annex V production quality assurance; or (iii) Annex VI product quality assurance.	conformity assessment specified in Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device for each category of devices. Alternatively, the manufacturer may choose to draw up the technical documentation set out in Annexes II and III coupled with a conformity assessment as specified in Section 10 or Section 18 of Annex XI. The assessment of the technical documentation shall apply for at least one representative device for each category of devices.
Category IIb	subjected to EC type-examination (see Article 8 (2)) and to one of the tw	Conformity assessment as specified in Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device per generic device group.
Class I	Annex VII, having a EC declaration of conformity being made before the device are put on the market.	manufacturers shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III.

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Around 15% of harmonized standards related to the MDD or MDR framework is relevant when interactive robots are at stake.

iii. The Personal Protective Equipment Directive and Regulation

The PPED classifies PPE into three categories, according to the complexity of their design.[53]. The PPER explicitly mentions the three risk categories at Annex I, according to a pattern similar to PPED.

TABLE IRRF&RMF 2 PERSONAL PROTECTIVE EQUIPMENT DIRECTIVE CATEGORIES

Category	Definition	Certification procedure under the PPED	Certification procedure under the PPER
Category I – «simple design»	Defined in the exhaustive list at article 8 (3) PPED	the manufacturer declares conformity by means of an EC declaration of conformity only	internal production control (module A) set out in Annex IV
Category II – neither «simple» nor «complex» design	Not defined by Article 8 (3) and (4) (a) PPED	subject to an EC type-examination by a notified body and an EC declaration of conformity is then produced	EU type-examination (module B) set out in Annex V, followed by conformity to type based on internal production control (module C) set out in Annex VI
Category III – «complex design».	Defined by the exhaustive list at Article 8 (4) (a) PPED	subjected to EC type-examination (see Article 8 (2)) and to one of the two quality assurance procedures as described at Article 11A and 11B (respectively 'EC' quality control system for the final product and System for ensuring EC quality of production by means of monitoring, both of which involve a notified body.) An EC declaration of conformity is then produced.	EU type-examination (module B) set out in Annex V, and either of the following: (i) conformity to type based on internal production control plus supervised product checks at random intervals (module C2) set out in Annex VII; (ii) conformity to type based on quality assurance of the production process (module D) set out in Annex VIII.

Less than 10% of harmonised standards related to personal protective equipment are relevant for interactive robots.

[53] European Commission, *Ppe Guidelines Guide to Application of the Ppe Directive 89/686/Eec* (2017). 21 ff.

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iv. Low Voltage Directive

The LVD[54] entitles a presumption of conformity on the basis both of harmonized standards, and – even though to a different extent – of international and national standards[55], while essential safety objectives are indeed clarified in Annex I, LVD. The said directive can be deemed relevant for at least some devices and systems, since it applies to equipment which functions with an operating voltage between 50 V and 1000 V (if they require alternating current) or between 75 and 1500 V (if they require direct current)[56].

LVD provides only one conformity assessment procedure, namely the internal production control (module A)[57], and no intervention of notified bodies is ever required. The manufacturer is therefore required to prepare technical documentation, including reference to harmonized and non-harmonized standards, then to draw up an EU declaration of conformity and to affix the CE marking accordingly.

Since interactive robots can vary extremely among one another, it is not possible to assess generally which LVD-related standards are relevant for such a device category.

v. Electromagnetic Compatibility Directive.

Virtually all robots involve electricity, therefore they must undergo the requirements provided by the Electromagnetic Compatibility Directive (EMD)[58]. Thus, the directive applies to any "apparatus"; i.e. any finished appliance or combination thereof made available on the market as a single functional unit, intended for the end-user and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance, or "fixed installation", namely a particular combination of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently at a predefined location.

Under the EMD equipment which is in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential requirements set out in Annex I covered by those standards or parts thereof.

Approximately 10% of the total amount of harmonised standards related to Electromagnetic Compatibility is relevant for interactive robots (§4.b).

The EMD envisages two different conformity assessment procedures on the compliance of apparatus[59] with the essential requirements set out in Annex I.

Pursuant to Art. 14, EMD the manufacturer is allowed to choose among (a) an internal production control set out in Annex II or (b) an EU-type examination that is followed by Conformity to type based on internal production control set out in Annex III.

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[54] Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits Text with EEA relevance, in OJ L 96, 29.3.2014.
[55] Arts. 12, 13, and 14, LVD.
[56] Art. 1, LVD.
[57] Annex III, LVD.
[58] Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast) Text with EEA relevance. See OJ L 96, 29.3.2014.
[59] Under the directive,

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Also, the manufacturer may choose to restrict the application of the EU type examination that is followed by Conformity to type based on internal production control to some aspects of the essential requirements, provided that for the other aspects of the essential requirements an internal production control is applied.

The EMD do not establish conformity assessment procedures for fixed installations, but pursuant to art. 19, EMD, an apparatus «which has been made available on the market and which may be incorporated into a fixed installation shall be subject to all relevant provisions for apparatus set out in this Directive».

However, if the apparatus which is intended for incorporation into a particular fixed installation and is otherwise not made available on the market, the requirements of Articles 6 to 12 and Articles 14 to 18 shall not be compulsory in the case but the accompanying documentation shall identify the fixed installation, its electromagnetic compatibility characteristics, the precautions taken in order not to compromise the conformity of that installation, the information referred to in Article 7(5) and (6) and Article 9(3) and the good engineering practices referred to in point 2 of Annex I shall be documented for as long as the fixed installation is in operation.

vi. Hazardous substances in Electrical and Electronic Equipment

It should be noted that the Directive (EU) 2017/2102 of the European Parliament and of the Council of 15 November 2017 amend the Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE) thus a relevant array of EU law concerning mainly mercury, lead, cadmium, hexavalent chromium and phthalates is now recast in RoHS 2 Directive[60].

Pursuant to Art. 16, EEED, «Materials, components and EEE on which tests and measurements demonstrating compliance with the requirements of Article 4 have been performed, or which have been assessed, in accordance with harmonised standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to comply with the requirements of this Directive».

The EEED do not envisage a conformity assessment procedure on the compliance of electrical and electronic equipment with the requirements of Article 4, but pursuant to art. 7, EEE, refers to the internal production control procedure in line with module A of Annex II to Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.

However, pursuant to art. 7 and art. 13, EEED, if «other applicable Union legislation requires the application of a conformity assessment procedure which is at least as stringent», compliance with the requirements of Article 4 may be verified within that conformity assessment procedure and a «single technical documentation may be drawn up».

Materials, components and EEE on which tests and measurements demonstrating compliance with the requirements of Article 4 have been performed, or which have been assessed, in accordance with harmonised standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to comply with the requirements of this Directive.

[60] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment Text with EEA relevance. See OJ L 174, 1.7.2011

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The only harmonised standard related to RoHS 2 Directive is relevant for interactive robot (§4.b).

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b. Relevant standards

A list and short description of the standards relevant for interactive robotics, together with the legal documents mentioning them, is provided below.

TABLE IRRF&RMF 3 RELEVANT STANDARDS FOR INTERACTIVE ROBOTICS

Document identifier	Title	Abstract	Committee reference	Publication date	Category	Legal connection
EN ISO 10218-1	Robots and robotic devices - Safety requirements for industrial robots - Part 1: Robots (ISO 10218-1:2011)	ISO 10218-1:2011 specifies requirements and guidelines for the inherent safe design, protective measures and information for use of industrial robots. It describes basic hazards associated with robots and provides requirements to eliminate, or adequately reduce, the risks associated with these hazards. ISO 10218-1:2011 does not address the robot as a complete machine. noise emission is generally not considered a significant hazard of the robot alone, and consequently noise is excluded from the scope of ISO 10218-1:2011. ISO 10218-1:2011 does not apply to non-industrial robots, although the safety principles established in ISO 10218 can be utilized for these other robots.	CEN/TC 310 Advanced manufacturing technologies	2011-07-00	Safety	Machinery-Directive (Type C)
EN ISO 10218-2	Robots and robotic devices - Safety requirements for industrial robots - Part 2: Robot systems and integration (ISO 10218-2:2011)	ISO 10218-2:2011 specifies safety requirements for the integration of industrial robots and industrial robot systems as defined in ISO 10218-1, and industrial robot cell(s). The integration includes the following: the design, manufacturing, installation, operation, maintenance and decommissioning of the industrial robot system or cell; necessary information for the design, manufacturing, installation, operation, maintenance and decommissioning of the industrial robot system or cell; component devices of the industrial robot system or cell. ISO 10218-2:2011 describes the basic hazards and hazardous situations identified with these systems and provides requirements	CEN/TC 310 Advanced manufacturing technologies	2011-07-00	Safety	Machinery-Directive (Type C)

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		to eliminate or adequately reduce the risks associated with these hazards. ISO 10218-2:2011 also specifies requirements for the industrial robot system as part of an integrated manufacturing system. ISO 10218-2:2011 does not deal specifically with hazards associated with processes (e.g. laser radiation, ejected chips, welding smoke). Other standards can be applicable to these process hazards.				
EN ISO 13482	Robots and robotic devices - Safety requirements for personal care robots (ISO 13482:2014)	ISO 13482:2014 specifies requirements and guidelines for the inherently safe design, protective measures, and information for use of personal care robots, in particular the following three types of personal care robots: mobile servant robot, physical assistant robot, person carrier robot. These robots typically perform tasks to improve the quality of life of intended users, irrespective of age or capability. ISO 13482:2014 describes hazards associated with the use of these robots, and provides requirements to eliminate, or reduce, the risks associated with these hazards to an acceptable level. ISO 13482:2014 covers human-robot physical contact applications. ISO 13482:2014 presents significant hazards and describes how to deal with them for each personal care robot type. ISO 13482:2014 covers robotic devices used in personal care applications, which are treated as personal care robots. ISO 13482:2014 is limited to earthbound robots. ISO 13482:2014 does not apply to: robots travelling faster than 20 km/h, robot toys, water-borne robots and flying robots, industrial robots (see ISO 10218), robots as medical devices, military or public force application robots. The scope of ISO 13482:2014 is limited primarily to human care related hazards but, where appropriate, it includes	CEN/TC 310 Advanced manufacturing technologies	2014-02-00	Safety	Machinery-Directive (Type C)

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		domestic animals or property (defined as safety-related objects), when the personal care robot is properly installed and maintained and used for its intended purpose or under conditions which can reasonably be foreseen.				
EN 614-2+A1	Safety of machinery - Ergonomic design principles - Part 2: Interactions between the design of machinery and work tasks	This European Standard establishes the ergonomics principles and procedures to be followed during the design process of machinery and operator work tasks. These European Standard deals specifically with task design in the context of machinery design, but the principles and methods may also be applied to job design. This European Standard is directed to designers and manufacturers of machinery and other work equipment. It will also be helpful to those who are concerned with the use of machinery and work equipment, e.g. to managers, organizers, operators and supervisors. In this European Standard the designer refers to the person or group of persons responsible for the design.	CEN/TC 122 Ergonomics	2008-09-00	Safety	Machinery-Directive (Type B)
EN 842+A1	Safety of machinery - Visual danger signals - General requirements, design and testing	This European Standard describes criteria for the perception of visual danger signals in the area that people are intended to perceive and to react to such a signal. It specifies the safety and ergonomic requirements and the corresponding physical measurements and subjective visual check. It also provides guidance for the design of the signals to be clearly perceived and differentiated as described in 5.3 of EN 292-2:1991. This European Standard does not apply to danger indicators: Presented in either written or pictorial form; Transmitted by data display units. This European Standard does not apply to special regulations	CEN/TC 122 Ergonomics	2008-09-00	Safety	Machinery-Directive (Type B)

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		such as those for public disaster and public transport.				
EN 894-1+A1	Safety of machinery - Ergonomics requirements for the design of displays and control actuators - Part 1: General principles for human interactions with displays and control actuators	This European Standard applies to the design of displays and control actuators on machinery. It specifies general principles for human interaction with displays and control actuators, to minimize operator errors and to ensure an efficient interaction between the operator and the equipment. It is particularly important to observe these principles when an operator error may lead to injury or damage to health.	CEN/TC 122 Ergonomics	2008-10-00	Safety	Machinery-Directive (Type B)
EN 894-2+A1	Safety of machinery - Ergonomics requirements for the design of displays and control actuators - Part 2: Displays	This European Standard gives guidance on the selection, design and location of displays to avoid potential ergonomic hazards associated with their use. It specifies ergonomics requirements and covers visual, audible and tactile displays. It applies to displays used in machinery (e. g. devices and installations, control panels, operating and monitoring consoles) for occupational and private use. Specific ergonomics requirements for visual display terminals (VDTs) used for office tasks are given in the standard EN ISO 9241.	CEN/TC 122 Ergonomics	2008-10-00	Safety	Machinery-Directive (Type B)
EN 894-3+A1	Safety of machinery -	This European Standard gives guidance on the selection, design and location of control actuators so that they are	CEN/TC 122 Ergonomics	2008-10-00	Safety	Machinery-Directive

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	Ergonomics requirements for the design of displays and control actuators - Part 3: Control actuators	adapted to the requirements of the operators, are suitable for the control task in question and take account of the circumstances of their use. It applies to manual control actuators used in equipment for occupational and private use. It is particularly important to observe the recommendations in this European Standard where operating a control actuator may lead to injury or damage to health, either directly or as a result of a human error.				(Type B)
EN 894-4	Safety of machinery - Ergonomics requirements for the design of displays and control actuators - Part 4: Location and arrangement of displays and control actuators	This European Standard contains ergonomic requirements for the location and arrangement of displays and control actuators in order to avoid hazards associated with their use. This European Standard applies to displays and control actuators for machinery and other interactive equipment (e. g. devices and installations, instrument panels, control and monitoring consoles). This European Standard is not applicable to the location and arrangement of displays and control actuators which are manufactured before the date of its publication as EN.	CEN/TC 122 Ergonomics	2010-06-00	Safety	Machinery-Directive (Type B)
EN 1005-1+A1	Safety of machinery - Human physical performance - Part 1: Terms and definitions	This European Standard provides terms and definitions on concepts and parameters used for EN 1005-21, prEN 1005-3, EN 1005-4 and EN 1005-5. Basic concepts and general ergonomic principles for the design of machinery are dealt with in EN 292-1, EN 292-2 and EN 614-1. This document is not applicable to specify the machinery which is manufactured before the date of publication of this document by CEN.	CEN/TC 122 Ergonomics	2008-10-00	Safety	Machinery-Directive (Type B)

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EN 1005-2+A1	Safety of machinery - Human physical performance - Part 2: Manual handling of machinery and component parts of machinery	This European Standard specifies ergonomic recommendations for the design of machinery involving manual handling of machinery and component parts of machinery, including tools linked to the machine, in professional and domestic applications. This European Standard applies to the manual handling of machinery, component parts of machinery and objects processed by the machine (input/output) of 3 kg or more, for carrying less than 2 m. Objects of less than 3 kg are dealt with in prEN 1005-51). The standard provides data for ergonomic design and risk assessment concerning lifting, lowering and carrying in relation to the assembly/erection, transport and commissioning (assembly, installation, adjustment), operation, fault finding, maintenance, setting, teaching or process changeover and decommissioning, disposal and dismantling of machinery. This standard provides current data on the general population and certain sub-populations (clarified in annex A). This part of the standard does not cover the holding of objects (without walking), pushing or pulling of objects, hand-held machines, or handling while seated. This document is not applicable to specify the machinery which are manufactured before the date of publication of this document by CEN.	CEN/TC 122 Ergonomics	2008-10-00	Safety	Machinery-Directive (Type B)
EN 1005-3+A1	Safety of machinery - Human physical performance - Part 3: Recommended force limits for	This European Standard presents guidance to the manufacturer of machinery or its component parts and the writer of C-standards in controlling health risks due to machine-related muscular force exertion. This standard specifies recommended force limits for actions during machinery operation including construction, transport and commissioning (assembly, installation,	CEN/TC 122 Ergonomics	2008-10-00	Safety	Machinery-Directive (Type B)

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	machinery operation	adjustment), use (operation, cleaning, fault finding, maintenance, setting, teaching or process changeover) decommissioning, disposal and dismantling. The standard applies primarily to machines which are manufactured after the date of issue of the standard. This standard applies on one hand to machinery for professional use operated by the adult working population, who are healthy workers with ordinary physical capacity, and on the other hand to machinery for domestic use operated by the whole population including youth and old people. The recommendations are derived from research on European population. This document is not applicable to specify the machinery which are manufactured before the date of publication of this document by CEN.				
EN 1005-4+A1	Safety of machinery - Human physical performance - Part 4: Evaluation of working postures and movements in relation to machinery	This European Standard presents guidance when designing machinery or its component parts in assessing and affecting health risks due only to machine-related postures and movements, i.e. during assembly, installation, operation, adjustment, maintenance, cleaning, repair, transport, and dismantlement. This European Standard specifies requirements for postures and movements without any or with only minimal external force exertion. The requirements are intended to reduce the health risks for nearly all healthy adults. This European Standard is not applicable to the machinery, which is manufactured before the date of publication of this European Standard by CEN.	CEN/TC 122 Ergonomics	2008-10-00	Safety	Machinery-Directive (Type B)

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EN ISO 12100	Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)	ISO 12100:2010 specifies basic terminology, principles and a methodology for achieving safety in the design of machinery. It specifies principles of risk assessment and risk reduction to help designers in achieving this objective. These principles are based on knowledge and experience of the design, use, incidents, accidents and risks associated with machinery. Procedures are described for identifying hazards and estimating and evaluating risks during relevant phases of the machine life cycle, and for the elimination of hazards or sufficient risk reduction. Guidance is given on the documentation and verification of the risk assessment and risk reduction process. ISO 12100:2010 is also intended to be used as a basis for the preparation of type-B or type-C safety standards. It does not deal with risk and/or damage to domestic animals, property or the environment.	CEN/TC 114 Safety of machinery	2010-11-00	Safety	Machinery-Directive (Type A)
EN ISO 13849-1	Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design (ISO 13849-1:2015)	ISO 13849-1:2015 provides safety requirements and guidance on the principles for the design and integration of safety-related parts of control systems (SRP/CS), including the design of software. For these parts of SRP/CS, it specifies characteristics that include the performance level required for carrying out safety functions. It applies to SRP/CS for high demand and continuous mode, regardless of the type of technology and energy used (electrical, hydraulic, pneumatic, mechanical, etc.), for all kinds of machinery. It does not specify the safety functions or performance levels that are to be used in a particular case. This part of ISO 13849 provides specific requirements for SRP/CS using programmable electronic system(s). It does not give specific requirements for the design of products which	CEN/TC 114 Safety of machinery	2015-12-00	Safety	Machinery-Directive (Type B)

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		are parts of SRP/CS. Nevertheless, the principles given, such as categories or performance levels, can be used.				
EN ISO 13849-2	Safety of machinery - Safety-related parts of control systems - Part 2: Validation (ISO 13849-2:2012)	ISO 13849-2:2012 specifies the procedures and conditions to be followed for the validation by analysis and testing of the specified safety functions, the category achieved, and the performance level achieved by the safety-related parts of a control system (SRP/CS) designed in accordance with ISO 13849-1.	CEN/TC 114 Safety of machinery	2012-10-00	Safety	Machinery-Directive (Type B)
EN ISO 13850	Safety of machinery - Emergency stop function - Principles for design (ISO 13850:2015)	ISO 13850:2015 Standard specifies functional requirements and design principles for the emergency stop function on machinery, independent of the type of energy used. It does not deal with functions such as reversal or limitation of motion, deflection of emissions (e.g. radiation, fluids), shielding, braking or disconnecting, which can be part of the emergency stop function. The requirements for this International Standard apply to all machines, with exception to machines where an emergency stop would not reduce the risk; hand-held or hand-operated machines.	CEN/TC 114 Safety of machinery	2015-11-00	Safety	Machinery-Directive (Type B)
EN ISO 13855	Safety of machinery - Positioning of safeguards with respect to the approach speeds of parts of the human body (ISO 13855:2010)	ISO 13855:2010 establishes the positioning of safeguards with respect to the approach speeds of parts of the human body. It specifies parameters based on values for approach speeds of parts of the human body and provides a methodology to determine the minimum distances to a hazard zone from the detection zone or from actuating devices of safeguards. The values for approach speeds (walking speed and upper limb movement) in ISO 13855:2010 are time tested and proven in practical experience. ISO 13855:2010 gives guidance for typical approaches. Other types of	CEN/TC 114 Safety of machinery	2010-05-00	Safety	Machinery-Directive (Type B)

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		approach, for example running, jumping or falling, are not considered in ISO 13855:2010. Safeguards considered in ISO 13855:2010 include: electro-sensitive protective equipment, including light curtains and light grids (AOPDs), and laser scanners (AOPDDRs) and two-dimensional vision systems; pressure-sensitive protective equipment, especially pressure-sensitive mats; two-hand control devices; interlocking guards without guard locking.				
EN ISO 13856-2	Safety of machinery - Pressure-sensitive protective devices - Part 2: General principles for design and testing of pressure-sensitive edges and pressure-sensitive bars (ISO 13856-2:2013)	ISO 13856-2:2012 establishes general principles and specifies requirements for the design and testing of pressure-sensitive edges and pressure-sensitive bars used as safeguards and not as actuating devices for normal operation. ISO 13856-2:2012 is applicable to pressure-sensitive edges and pressure-sensitive bars, with or without an external reset facility, used to detect persons or body parts that can be exposed to hazards such as those caused by the moving parts of machines. It is not applicable to determining the suitability of a pressure-sensitive edge or pressure-sensitive bar for a particular safeguarding application, selection of an appropriate performance level for safety-related parts of control systems (SRP/CSs) other than to give minimum values, dimensioning or configuring of the effective sensing area of pressure-sensitive edges or pressure-sensitive bars in relation to any particular application or to stopping devices according to IEC 60204-1 used only for normal operation, including emergency stopping of machinery.	CEN/TC 114 Safety of machinery	2013-04-00	Safety	Machinery-Directive (Type B)

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EN ISO 13856-3	Safety of machinery - Pressure-sensitive protective devices - Part 3: General principles for design and testing of pressure-sensitive bumpers, plates, wires and similar devices (ISO 13856-3:2013)	ISO 13856-3:2013 establishes general principles and specifies requirements for the design and testing of those pressure-sensitive protective devices, with or without an external reset facility, that are not specified in either ISO 13856-1 or ISO 13856-2, and the majority of which are produced for specific applications and are not available as "off-the-shelf" items. ISO 13856-3:2013 also gives specific requirements for the following pressure-sensitive protective devices: pressure-sensitive bumpers; pressure-sensitive plates; pressure-sensitive wires (trip wires). It deals with the design of a pressure-sensitive device with regard to safety and reliability rather than its suitability for particular applications. It is not applicable to specifying the dimensions of pressure-sensitive protective devices in relation to any particular application or stopping devices according to IEC 60204-1 used for the normal operation, including emergency stopping of machinery. While requirements are given for the immunity of the device to electromagnetic disturbances, these are not intended to cover all aspects of electromagnetic compatibility (EMC).	CEN/TC 114 Safety of machinery	2013-07-00	Safety	Machinery-Directive (Type B)
EN ISO 13857	Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs (ISO 13857:2008)	ISO 13857:2007 establishes values for safety distances in both industrial and non-industrial environments to prevent machinery hazard zones being reached. The safety distances are appropriate for protective structures. It also gives information about distances to impede free access by the lower limbs. It covers people of 14 years and older (the 5th percentile stature of 14-year olds is approximately 1 400 mm). In addition, for upper limbs only, it provides information for children older than 3 years (5th percentile stature of 3-year olds is approximately 900 mm) where reaching through	CEN/TC 114 Safety of machinery	2008-03-00	Safety	Machinery-Directive (Type B)

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		openings needs to be addressed.				
EN ISO 14159	Safety of machinery - Hygiene requirements for the design of machinery (ISO 14159:2002)	This International Standard specifies hygiene requirements of machines and provides information for the intended use to be provided by the manufacturer. It applies to all types of machines and associated equipment used in applications where hygiene risks to the consumer of the product can occur. This International Standard does not cover requirements relative to the uncontrolled egress of microbiological agents from the machine.	CEN/TC 114 Safety of machinery	2008-04-00	Safety	Machinery-Directive (Type B)
EN 349+A1	Safety of machinery - Minimum gaps to avoid crushing of parts of the human body	The object of this European Standard is to enable the user (e. g. standard makers, designers of machinery) to avoid hazards from crushing zones. It specifies minimum gaps relative to parts of the human body and is applicable when adequate safety can be achieved by this method. This European Standard is applicable to risks from crushing hazards only and is not applicable to other possible hazards, e. g. impact, shearing, drawing-in.	CEN/TC 114 Safety of machinery	2008-06-00	Safety	Machinery-Directive (Type B)
EN 60204-11	Safety of machinery - Electrical equipment of machines - Part 11: Requirements for HV equipment for voltages above 1000 V a.c. or 1500 V	Applies to the electrical and electronic equipment and systems of machines, including a group of machines working together in a coordinated manner, but excluding higher level system aspects (i.e. communications between systems).	CLC/TC 44X Safety of machinery - Electrotechnical aspects	2000-11-00	Safety	Machinery-Directive (Type C)

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	d.c. and not exceeding 36 kV (IEC 60204-11:2000, EN 60204-11/AC:2010)					
EN 60335-1	Household and similar electrical appliances - Safety - Part 1: General requirements (IEC 60335-1:2010, modified)	IEC 60335-1:2010 deals with the safety of electrical appliances for household and similar purposes, their rated voltage being not more than 250 V for single-phase appliances and 480 V for other appliances. Battery-operated appliances and other d.c. supplied appliances are within the scope of this standard. Appliances not intended for normal household use, but which nevertheless may be a source of danger to the public, such as appliances intended to be used by laymen in shops, in light industry and on farms, are within the scope of this standard. Examples of such appliances are catering equipment, cleaning appliances for commercial use, and appliances for hairdressers. The principal changes in this edition as compared with the fourth edition are as follows: - updated the text of the standard to align with the most recent editions of the dated normative references; - modified the functional safety requirements using programmable electronic circuits including software validation requirements; - updated Clause 29 to cover insulation requirements subjected to high frequency voltages as in switch mode power supply circuits; - updated Subclause 30.2 to further align the pre-selection option with the end-product test option; - deleted some notes and converted many other notes	CLC/TC 61 Safety of household and similar electrical appliances	2012-01-00	Safety	Machinery-Directive (Type C)

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		to normative text; - clarified requirements for class III constructions. The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 12 months or later than 36 months from the date of publication. The contents of the corrigenda of July 2010 and April 2011 have been included in this copy.				
EN 61310-1	Safety of machinery - Indication, marking and actuation - Part 1: Requirements for visual, acoustic and tactile signals (IEC 61310-1:2007)	Specifies requirements for visual, acoustic and tactile methods of indicating safety-related information, at the human-machine interface and to exposed persons. It specifies a system of colours, safety signs, markings and other warnings, intended for use in the indication of hazardous situations and health hazards and for meeting certain emergencies. It also specifies ways of coding visual, acoustic and tactile signals for indicators and actuators to facilitate the safe use and monitoring of the machinery. It includes the following significant technical changes with respect to the previous edition: Adapted to the basic standards IEC 60073, IEC 60417, ISO 3864-1, ISO 7000 and ISO 7010.	CLC/TC 44X Safety of machinery - Electrotechnical aspects	2008-02-00	Safety	Machinery-Directive (Type B)
EN 61310-2	Safety of machinery - Indication, marking and	It gives general rules on marking for identification of machinery, for safe use related to mechanical and electrical hazards, and for the avoidance of hazards arising from incorrect connections. Includes the	CLC/TC 44X Safety of machinery - Electrotechnical	2008-01-00	Safety	Machinery-Directive (Type B)

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	actuation - Part 2: Requirements for marking (IEC 61310-2:2007)	following significant technical changes with respect to the previous edition: Annex A: additional safety signs included and updated.	aspects			
EN 61310-3	Safety of machinery - Indication, marking and actuation - Part 3: Requirements for the location and operation of actuators (IEC 61310-3:2007)	Specifies safety-related requirements for actuators, operated by the hand or by other parts of the human body, at the human-machine interface. It gives general requirements for the standard direction of movement for actuators; the arrangement of an actuator in relation to other actuators; the correlation between an action and its final effects. It includes the following significant technical changes with respect to the previous edition: Table 1, Table 2 and Table A.1 have been revised editorially.	CLC/TC 44X Safety of machinery - Electrotechnical aspects	2008-02-00	Safety	Machinery-Directive (Type B)
EN 61496-1	Safety of machinery - Electro-sensitive protective equipment - Part 1: General requirements and tests (IEC 61496-1:2012)	IEC 61496-1:2012 specifies general requirements for the design, construction and testing of non-contact electro-sensitive protective equipment (ESPE) designed specifically to detect persons as part of a safety related system. Special attention is directed to functional and design requirements that ensure an appropriate safety-related performance is achieved. An ESPE may include optional safety-related functions, the requirements for which are given in Annex A. This third edition cancels and replaces the second edition published in 2004 and its amendment 1 (2007). The main changes with respect to the previous edition are as follows: The design, test and verification requirements have been updated to make them consistent with the latest standards for functional safety and EMC. The contents of the corrigendum of April 2015 have been included in this copy.	CLC/TC 44X Safety of machinery - Electrotechnical aspects	2013-11-00	Safety	Machinery-Directive (Type B)

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EN 62061	Safety of machinery - Functional safety of safety-related electrical, electronic and programmable electronic control systems (IEC 62061:2005/A2:2015)	Specifies requirements and makes recommendations for the design, integration and validation of safety-related electrical, electronic and programmable electronic control systems (SRECS) for machines. It is applicable to control systems used, either singly or in combination, to carry out safety-related control functions on machines that are not portable by hand while working, including a group of machines working together in a coordinated manner.	CLC/TC 44X Safety of machinery - Electrotechnical aspects	2015-08-00	Safety	Machinery-Directive (Type B)
EN 614-1+A1	Safety of machinery - Ergonomic design principles - Part 1: Terminology and general principles	This European Standard establishes the ergonomic principles to be followed during the process of design of machinery. This European Standard applies to the interactions between operators and machinery when installing, operating, adjusting, maintaining, cleaning, dismantling, repairing or transporting equipment, and outlines the principles to be followed in taking the health, safety and well-being of the operator into account. This European Standard provides a framework within which the range of more specific ergonomics standards and other related standards relevant to machinery design should be applied. The ergonomic principles given in this European Standard apply to all ranges of human abilities and characteristics to ensure safety, health and well-being and overall system performance. Information will need to be interpreted to suit the intended use.	CEN/TC 122 Ergonomics	2009-02-00	General	Machinery-Directive (Type B)
EN ISO 13732-1	Ergonomics of the thermal environment - Methods for the	ISO 15536-1:2006 provides temperature threshold values for burns that occur when human skin is in contact with a hot solid surface. It also describes methods for the assessment of the risks of burning,	CEN/TC 122 Ergonomics	2008-09-00	Ergonomics	Machinery-Directive (Type B)

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	assessment of human responses to contact with surfaces - Part 1: Hot surfaces (ISO 13732-1:2006)	when humans could or might touch hot surfaces with their unprotected skin. In addition, ISO 13732-1:2006 gives guidance for cases where it is necessary to specify temperature limit values for hot surfaces but does not set surface temperature limit values. ISO 13732-1:2006 deals with contact periods of 0,5 s and longer. It is applicable to contact when the surface temperature is essentially maintained during the contact. It is not applicable if a large area of the skin (approximately 10 % or more of the skin of the whole body) can be in contact with the hot surface. Neither does it apply to skin contact of more than 10 % of the head or contact which could result in burns of vital areas of the face. ISO 13732-1:2006 is applicable to the hot surfaces of all kind of objects: equipment, products, buildings, natural objects, etc. It is applicable to hot surfaces of products that may be touched by healthy adults, children, elderly people and also by people with physical disabilities. For the purposes of simplification, it mentions only products; nevertheless, it applies to all other objects as well. It is applicable to products used in any environment, e.g. in the workplace, in the home. It does not provide data for the protection against discomfort or pain.				
EN ISO 11204	Acoustics - Noise emitted by machinery and equipment - Determination of emission sound pressure levels at a workstation and at other	ISO 11204:2010 specifies a method for determining the emission sound pressure levels of machinery or equipment, at a workstation and at other specified positions nearby, in any environment which meets certain qualification requirements. A workstation is occupied by an operator and may be located in open space, in the room where the source under test operates, in a cab fixed to the source under test, or in an enclosure remote from the source under test. One or	CEN/TC 211 Acoustics	2010-05-00	Acoustic	Machinery-Directive (Type B)

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	specified positions applying accurate environmental corrections (ISO 11204:2010)	more specified positions may be located in the vicinity of a workstation, or in the vicinity of an attended or unattended machine.				
EN ISO 11205	Acoustics - Noise emitted by machinery and equipment - Engineering method for the determination of emission sound pressure levels in situ at the workstation and at other specified positions using sound intensity (ISO 11205:2003)	ISO 11205:2003 specifies an engineering method (grade 2 accuracy) to determine the emission sound pressure level of machines in situ, at the workstation or at other specified positions, using sound intensity. It is an alternative to ISO 11201, ISO 11202 and ISO 11204 for in situ measurements. It is applicable to all kinds of test environments provided that the requirements on background noise and field indicators are fulfilled. ISO 11205:2003 is applicable to equipment emitting stationary broadband noise. The noise can differ between operational cycles and can be with or without discrete frequency or narrow band components.	CEN/TC 211 Acoustics	2009-08-00	Acoustic	Machinery-Directive (Type B)
EN ISO 11688-1	Acoustics - Recommended practice for the design of low-noise machinery and equipment - Part 1: Planning (ISO/TR 11688-1:1995)	Serves as an aid to understanding the basic concepts of noise control in machinery and equipment. The recommended practice presented is intended to assist the designer at any design stage to control the noise of the final product. Makes references to numerous technical publications dealing with acoustical problems.	CEN/TC 211 Acoustics	2009-08-00	Acoustic	Machinery-Directive (Type B)

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5. Ethical aligned design

a. Addressing ethics through standardization (methodological concerns and criticism)

Several attempts to justify, create and apply standards of ethics and ethical reasoning have been developed in the history of philosophy. Although there are controversial debates about the concrete normative content of ethical standards and their justification through today, standardization is generally possible in ethics. One can differentiate descriptive and normative forms of standardization. Whereas descriptive standardization relates to a wider disciplinary range including sociology, political sciences or psychology, normative ethics is a unique philosophical way of critically standardizing both moral reasoning and moral values. This draft version is about the first task: the conceptualization and methodology of standardizing moral reasoning.

i. First Step: Three Formal Concepts of Standardizing Ethics

In order to better understand the unique ethical forms of standardization, in the first step it is important to terminologically differentiate between the words 1. "ethics", 2. "moral" and 3. "ethos"/"codex"/"code of ethics". Etymologically all three terms trace back to the ancient Greek term *ἔθος*.[61] Morals (2.) describes the contingent concrete values and habits that shape human behaviour in social life. Those values and habits can strongly differ between certain groups of persons.[62] One example is table manners. In European societies, most people learn to stick to certain rules while eating with forks, knifes and spoons. Slurping and noisy drinking is often evaluated as a form of poor behaviour – at least in certain social contexts like public events or business dinners. Technical tools play a genuine role in moral behaviour. The ways in which we sit on a chair in front of a table are morally regimented as well as the ways in which we are supposed to use our cutlery and dishes. For instance, in Asia it is not seen as unusual to sit on the floor while eating. The tools also differ. Asian people are trained to eat with chopsticks since their early childhood.

As this example shows, simple forms of standardizing morals relate in a weak sense to the sociocultural background of socialization. In contrast to ethics (1.), standardization is pragmatic and involves implicit knowledge. Often, we follow moral rules without making them explicit. We interact in different styles. Communication is traversed by moral norms such as nearly every aspect of human habits and behaviour. The phenomenon of culture shock illustrates how contingent moral habits can clash and cause challenges in finding new orientation in foreign cultures. On a simple level this can be observed when those accustomed to Western table utensils try to eat Sushi in the traditional Japanese way. For someone who is not skilled in using chopsticks, it is a technical challenge to grasp Sushi, dip it into the soy sauce and eat it without spilling. Technical practice is closely related to cultural practice and therefore to moral values. On the other hand, the Sushi example also illustrates processes of globalisation and cultural transfer. Today many Asian restaurants can be found all over the world. Both aspects – the contingent and diverse cultural socialization and the amalgamation of value-systems due to

[61] Dieter Birnbacher, *Analytische Einführung in Die Ethik. 2. Auflage.* (Berlin, New York: Walter de Gruyter, (2007).: 1-3); Otfried Höffe, *Ethik. Eine Einführung* (München: C.H. Beck, (2013).:9-11); Annemarie Pieper, *Einführung in Die Ethik*, 7 ed. (Tübingen: Francke, (2017).:21-26).
[62] Birnbacher., 7-56; William K. Frankena, *Ethik. Eine Analytische Einführung.* (Wiesbaden: Springer, 2017)., S. 6-11; Pieper., pp. 22-35.

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globalisation – have an impact on the question of how to standardize moral norms while using robots.

As soon as we start to think explicitly and rationally about our moral habits, we do ethics. Ethics (1.) is the science of morals (2.). The terms are not synonyms, even if in ordinary language we use them interchangeably. In contrast to morals, ethics includes dialogical argumentation, counterarguments and has a high theoretical demand. Insofar, the standardization of ethics is challenged by theoretical demands that are linked to overarching reasons and universal moral laws. Those laws should be created on the basis of explicit knowledge and are intended to be true for every human being – not only for certain groups of persons. Two forms of ethics can be differentiated: (1.a.) descriptive ethics, where the object of investigation (morals (2.)) is described in explicit and therefore standardized phrases; and (1.b.) normative ethics, where the object of investigation is critically evaluated.[63] Often the term morality is used as a synonym of normative ethics. However, ethics is much more than only describing how people behave. The rational justification of moral values and habits, but also the critical evaluation of concrete unmoral actions, is one of the unique key areas of philosophical ethics.

Another third term is ethos, codex or code of ethics (3.). Examples are the *Hippocratic Oath* and Isaac Asimov's *Robot Laws*[64]. Per definition an ethos is a strict form of normative standardisation because it summarizes at (least certain) moral values and habits in an explicitly written form.[65] In the case of the Hippocratic Oath it receives the form of an ethos of vocation – it applies to the concrete profession of medical practitioners.[66] Another example is the FEANI *Ethics and Conduct of Professional Engineers*[67]. A code of ethics does not need to totally regulate the whole range of possible moral behaviour. It fulfils its function when at least some rules are expressed in standardized linguistic phrases that can be passed on to new generations. What differentiates this from ethics (1.) is that an ethos might be the result of tradition and maybe ethical reasoning as well, but this is not required. A code of ethics can also be the naïve and uncritical summary of habitual heritage. In the first step it turned out that three meanings need to be differentiated in order to receive an initial formal understanding of how to standardize ethics. The following are weak and strong ways of standardizing:[68]

1. "ethics": science of morals, relating to rational reasoning, justification and theoretical approaches on the basis of explicit knowledge

1.a. descriptive ethics: standardizing (formally strong) the object of observation (= morals (2.)) by putting it into normalized linguistic formulations, describing how people behave and making implicit habits explicit

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[63] Birnbacher., S. 1-63; Frankena., S. 4-5; Pieper., S. 15-50

[64] John Jordan, *Roboter* (Wiesbaden: Berlin University Press, 2017)., S. 51-54; Gunter Laßmann, *Asimovs Robotergesetze. Was Leisten Sie Wirklich?* (Hannover: Heise, 2017)., Chap. 2, Abs. 4, Kap. 2.2 und 2.3; Isaac Asimov, *I, Robot* (Voyager Classics, 2013).sim, Runaround

[65] Ludger Honnefelder, "Sittlichkeit / Ethos," in *Handbuch Ethik.*, ed. Hüwell M, Hübenthal Ch, and Werner M (Stuttgart/Weimar: Metzler, 2006)., S. 509-510; Dietmar Mieth, "Erfahrung," in *Handbuch Ethik.* , ed. Hüwell M, Hübenthal Ch, and Werner M (Stuttgart/Weimar: Metzler, 2006)., S. 345-346; Pieper., S. 21-26

[66] Giovanni Maio, *Mittelpunkt Mensch: Ethik in Der Medizin. Ein Lehrbuch* (Stuttgart: Schattauer, 2012)., S. 94-101; Urban Wiesing, "Der Hippokratische Eid," in *Thik in Der Medizin. Ein Studienbuch*, ed. Urban Wiesing (Stuttgart: Reclam, 2008).

[67] See: https://www.feani.org/sites/default/files/PDF_Documents/Position_papers/Position_Paper_Code_of_Conduct_Ethics_approved_GA_2006.pdf

[68] See also: Michael Funk, *Roboter- Und Drohnenethik. Eine Methodische Einführung.* (Wiesbaden: Springer, 2019)., chapter 11.

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1.b. normative ethics: standardizing (formally strong) the object of observation (= morals (2.)) by critically reflecting its content and methodically creating universal ethical rules, evaluating how people behave, and arguing how they *should* behave and why

2. "morals": standardizing (formally weak) contingent moral values and habits by tradition, education and socialization, primarily based on implicit knowledge, including technical practice

3. "ethos"/"codex"/"code of ethics": standardizing (formally strong) moral rules – therefore making them explicit – by putting them into a normalized linguistic form, it´s close to but also more than morals since a code of ethics relates to a linguistic standardization on the basis of explicit knowledge, and it´s neither descriptive ethics nor normative ethics, but maybe – not necessarily –the output of normative ethical assessment.

ii. Second Step: Between the Deontological Approach and Utilitarianism – How to Justify Ethical Rules?

In a second step it is important to methodologically differentiate between form and content. What has been elaborated so far was an etymological conceptual analysis of ethics (1.), morals (2.) and code of ethics (3.). It belongs primarily to the form of standardizing ethics. Another question is, how the concrete content, concrete moral values and habits are justified, how they should look in detail, and how they can be applied in real life. This section is about the first substantive aspect: how can moral values be ethically justified?

In the case of morals (2.) the standardization is pretty weak and subjective on the basis of implicit (moral) knowledge. From the very individual point of view, a concrete person could believe that her/his persuasions are morally correct and should be true all over the world. Ethics (1.) in contrast, relates to explicit reasoning and the sphere of objective rational arguments. The formal demand of theoretical laws leads to an epistemologically strong form of standardization. In the formal sense, ethical rules are close to legal laws. But in terms of content the methods of justification for an ethical rule strongly differ from those of legal laws. Many approaches exist. Two of the most famous and influential methodologies of ethical reasoning can be found in the deontological approach (I.) and in utilitarism (II.).

The deontological tradition is often linked to Immanuel Kant, but it is not limited to Kantian philosophers only. Here a general starting point of ethical reasoning is primarily located in the motivation of an action. Consequently, the good will received the status of a key term. Because of the initial reasoning before an action is performed, the regulation operates top-down: from abstract duties to concrete performances in real life. Therefore, a main principle is formulated with the demand that it be universally valid. Every maxim – the subjective norm of action – is fundamentally deduced from the categorical imperative. Standardization in deontological ethics means the application of a universally true abstract principle (which is the categorical imperative) to the reasons of actions (top-down approach, 1.b. I.). Kant himself created several formulations. One common English translation reads like this:

"Act only according to that maxim whereby you can, at the same time, will that it should become a universal law."[69]

[69] Immanuel Kant, *Grounding for the Metaphysics of Morals* (Hackett [Akademie Ausgabe of Kant's works. Fourth volume. 4:421], 1993 [1785])., p. 30; see also Immanuel Kant, *Kritik Der Praktischen Vernunft. Grundlegung Zur Metaphysik Der Sitten. Band Vii Werkausgabe. Herausgegeben Von Wilhelm Weischedel.* (Frankfurt a.M.: Suhrkamp, 1974)., S. 51, *GMS BA 52.*

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Whereas the Kantian tradition has a strong influence in continental Europe, another approach to normative ethics is more prominent in the Anglo-American world: utilitarism. Due to a central focus on general duties and the motivation of an action, Kantian ethics belong to the category of deontological approaches.[70] *Utilitarian* ethics in contrast are characterized by a certain attention to the consequences of actions. That´s why utilitaristic approaches belong to the category of consequentialism. Insofar the abstract general principle of maximizing utility is applied, utilitaristic ethics proceed – just like the Kantian approach – top down. The crucial theoretical criterion is therefore the maximizing of wellbeing, benefit or happiness for a maximum of people.[71] On the other hand, the strict consideration of consequences for the ethical evaluation of an action put a high methodical priority on bottom-up procedures. The general principle and abstract reasoning top down become secondary. Pragmatism, empirical issues and the evaluation of the concrete factual action receive a primary bottom-up status – proceeding from the empirical anticipation of consequences of an action to the ethical norm that guides the moral action (1.a.II.). In conclusion it can be summarized that the deontological approach (1.a.I.) belongs to the formally and methodically strong top-down standardization, whereas utilitarism (1.a.II.) remains formally and methodically strong, but its normalization of values follows a bottom-up methodology:[72]

1. "ethics": formally strong & methodically strong standardization

1.a. descriptive ethics

1.b. normative ethics

1.a.I. Deontological approach: standardization by applying a universally true abstract principle to the reasons of actions (top-down standardization)

1.a.II. Utilitarism: standardization by applying utility to the pragmatic consequences of actions (bottom-up standardization)

2. "morals": formally weak & methodically weak standardization

3. "ethos"/"codex"/"code of ethics": formally strong & methodically weak standardization

4. Liability and Insurance

1. Applicable legal framework (Identification and discussion)

The legal framework regulating liability for damages caused by robotic application is constituted by the harmonized European legislation on product liability, as well its national implementation.

a. The Product Liability Directive

The Product Liability Directive[73] sets the conditions under which the producer is liable for damages caused by defects in his/her products. Pursuant to the directive, products are defined

[70] Birnbacher., pp. 113-154; Frankena., pp. 13-33; Pieper., pp. 190-193, pp. 226-229.
[71] Birnbacher., pp. 173-240; Frankena., pp. 35-55; Otfried Höffe, "Einleitung," in *Einführung in Die Utilitaristische Ethik. 5. Auflage.*, ed. Höffe (Tübingen/Basel: A. Francke, 2013).
[72] See also: Funk., Chapter 4, Chapter 6, Chapter 11
[73] 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. OJ L 210, 7.8.1985, p. 29–33.

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as «all movables, with the exception of primary agricultural products and game, even though incorporated into another movable or into an immovable»[74], while producers are defined as «the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer»[75].

According to the directive, producers, or the subject identified by art. 3 (the importer of a product within the European Union, and the seller of the product – in case the producer cannot be identified), are responsible for the damages caused from the use of the product, so long as the product is defective, and there is a causal nexus between the defect and the damage which compensation is sought for.

A product is deemed **defective** when it **«does not offer the safety that a person is entitled to expect, considering all circumstances», such as the presentation of the product, its reasonably expected use, and the time in which it was put into circulation**.

Three types of defect may occur: a **manufacturing defect** occurs when a single specimen in a mass production deviates from the intended design; an «**information defect**» arises when the warnings about the potential dangers arising from the use of the device are not adequately communicated or signalled; and, lastly, a «**design defect**» occurs when the product's design is defective, since it does not offer the necessary level of safety, or is unreasonably dangerous.

Despite the claimant is not required to identify the specific cause of the defect, proving the its defective nature be in itself burdensome, as it may involve technical skills and data which the victim is likely not to possess. This happens especially when **design-defects** are involved, since assessing that the product should have been designed different entails acquiring the expert opinion of a technician. Of course, the more **technologically complex** is the product, the harder it will be for the victim to prove the presence of a defect (again, especially in its design).

Despite often defined as holding the producer strictly liable, **the PLD actually sets a system of semi-strict liability**. Indeed, art. 7 allows **manufacturers to escape liability by demonstrating that:**

a. s/he did not put the product into circulation;

b. it is probable that the defect did not exist at the time when the product was put into circulation, or that it came into being afterward;

c. the product was neither manufactured for sale or any form of distribution for economic purpose, not manufactured or distributed in the course of his business;

d. the defect is due to compliance with mandatory regulations;

e. the state of scientific and technical knowledge at the time the product was put into circulation was not such as to enable the existence of the defect to be discovered;

f. in case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instruction given by the manufacturer of the products;

[74] Art. 2 PLD.
[75] Art. 3 PLD.

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The liability of the producer can also be reduced due to the victim's contributory negligence.

Since the PLD sets a regime of maximum harmonization for product liability claims, MSs may create or keep different liability rules, as far as they belong to a different system of contractual or non-contractual liability, such as fault or warranty for latent defects.

i. The national implementation of the Product Liability Directive

MSs have implemented the PLD with significant difference, both in its scope of application, and in exercising the discretionality left to them in the implementation of the directive.

Germany, for example, has enacted both the Gesetz über die Haftung für fehlerhafte Produkte (Produkthaftungsgesetz, henceforth ProdHaftG)[76] as general legislative framework, and other special liability statues for specific technologies, such as the Gesetz zur Regelung der Gentechnik, or the Atomgesetz[77], while France only has one single legislation, which apply to all the technology constituting "products" under the PLD[78].

With respect to the latter issue, the ProdHaftG provides for certain monetary limits on compensation: in case of death and bodily injury, a maximum amount of € 85million is recoverable, regardless of whether the award is set to compensate several damages caused by a single defective product, or a series of products of identical terms[79]. On the contrary, French law compensates any kind of damages, but for those explicitly excluded by the directive, and no maximum limit on the award is set.

b. Eu initiatives and revisions

The PLD has been subject to extensive assessment and evaluation by the European Commission. The latter has published a series of reports, and a Staff Working document summarizing the results of the latter[80]. Also, it appointed an **Expert Group working in two formations, one dealing with the directive itself, the other with new technologies, to evaluate the applicability of the PLD to traditional products and new technologies and developing «guiding principles for possible adaptations of applicable laws related to new technologies»**.

The PLD was found adequate to face the challenges posed by existing products, but the evaluation process leads to highlight some issues, also in light of the application of the PLD across all MSs, which concern both technologically advanced products and more traditional ones.

Before considering those issues which the studies have fund problematic, it is worth highlighting that the assessment itself is not free of criticalities. Indeed, it affirms the out-of-court-settlement for claims regarding defective products, but reached such conclusion through a Computer Assisted Telephone Interview CATI survey and confirmed by some interviewees, namely IT representatives, legal experts, and large producers, showing no data on the actual

[76] Gesetz über die Haftung für fehlerhafte Produkte vom 15. Dezember 1989 BGBl. I S. 2198.
[77] Gesetz über die friedliche Verwendung der Kernenergie vom 23. Dezember 1959 BGBl. I S. 814.
[78] Loi n. 98-389 of May 19, 1998, modifying the French civil code.
[79] §10 ProdHaftG.
[80] *Commission Staff Working Document. 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* (Brussels: European Commission, 2018).

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numbers of cases settled, and resorting to possibly biased surveyed groups, being those who benefit from the limited number of claims brought about under the current framework.[81]

Finally, it shall be stressed how other bodies of regulation – such as the directive on sales of consumers' goods[82] (henceforth, SCGD) legislation –, that structurally offer a remedy for the user without the need to resort to in-court litigation, are at times erroneously overlapped with the PLD. Indeed, the cited report highlights that «even if the Product Liability Directive and the contractual liability legislation have different but complementary scopes, often clients do not know the difference between the Product Liability Directive and the guarantee».

Moving on the problems highlighted in the study, three points arise.

Firstly, **it is still unclear whether software could be included in the notion of product, thus being subject to the PLD regime**. This uncertainty represents a major problem, as technologically advanced products often display both software and hardware elements, which are tightly connected in their functioning.

Secondly, and as anticipated before, **the ascertainment of the causal nexus between the defect and the damage substantially burdens the claimant, preventing litigation or its success**. In cases of advanced robotics, determining that the product is defective, and that the harm is the consequence of a defect in the functioning of the device requires extensive data about the design and functioning of the product, presupposing relevant technical expertise, which might not be easily acquired by the victim.

Thirdly, defences, such as the **development risk defence** (art. 7, let. E, PLD) **might allow manufacturers to escape liability, leaving the burden of the economic consequences of the accident on the victim.** However, as indicated by recitals n° 1 and 2, PLD respectively, said rules are intended to ensure « […] a differing degree of protection of the consumer against damage caused by a defective product to his health or property», and «liability without fault on the part of the producer is the sole means of adequately solving the problem»

If the main aim of the directive is that of ensuring victim's compensation, the circumstance that the agent may not be reprehended for the standard of behaviour S/he conformed to appears secondary. Pursuant to the **RMA approach** (§2.c), **the risk of unexpected and unforeseeable outcomes is better borne by the party who derives economic benefits from the activity overall, rather than the occasional harmed party,** since s/he is best positioned to insure against such events, having enough data to assess the statistical possibility of their occurrence, thus ensuring compensation, while at the same time managing such costs by spreading them onto all users of the same product.

5. Key Findings

The White Paper addressed three main issues: (i) the definition of liability and its functions, and the identification of the applicable framework in case of damages caused by robots; (ii) the definition of safety regulation and its function, with particular reference to certification and standardization; (iii) the development of ethical standards. The following section summaries the main findings of the current research.

[81] Timan et al.
[82] Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees.

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(i) The definition of liability and its functions and the identification of the applicable framework in case of damages caused by robots.

Civil liability determines who bears the negative economic consequences arising from an accident, and under which conditions, deterring socially undesirable deviations from intended and expected conducts, compensating damages deriving thereof and punishing the illicit behaviour.

Theoretical and policy approaches shape liability rules, making one or more functions prevail and leading to different apportionment/attribution of liability and damages' recoverability. Under retributive justice theories, the blameworthy is punished because of the socially reprehensibility of their conduct; considerations of corrective justice focus on the reparation of the victim's right, caused by the breach of a relevant first-order duty, regardless of its blameworthiness; Law&Economics theories use liability rules for maximizing economic efficiency, allowing dangerous yet socially desirable conducts, while shifting the cost of the accidents to the party who is deemed responsible for causing it.

Many tort law systems have a general fault-based liability rule, imposing a duty to make good for the damage caused, also creating economic disincentives against harmful behaviours. Sometimes the defendant is held strictly or semi-strictly liable because of the particular position s/he held towards the source of damage, or because s/he is best positioned to manage and internalize the risks associated with a given activity, preventing their occurrence and minimizing their consequences, as well as to compensate the victim. The Risk Management Approach (RMA) claims that liability should not be attributed on the basis of fault, but rather on the party who is best positioned to (i) minimize risks and (ii) acquire insurance, while the desirable conduct is best attained through the adoption of detailed *ex ante* regulation.

The claim that robots' actions are so much outside humans' control, that they are to be deemed "subject of law", directly responsible for the wrong caused is not justified from an ontological perspective: to be held morally and legally liable, an entity shall qualify as a strong autonomous agent. Current robots only enjoy a "weak autonomy": they are developed to perform specific heteronomously-identified tasks, and lack the consciousness required to have intentional mental states necessary to decide freely and coordinate their action towards a chosen end, as well as to understand the moral significance of their actions. Thus, robots still qualify as "products" and, whenever they cause a damage, product liability rules apply. Indeed, the lack of control which is sometimes used to question the adequacy of said framework is more apparent than real: even in case of machine-learning technologies, unpredictable circumstances and evolutions can be secured within the training phase, while totally unpredictable applications should not be released onto the market at all.

However, under a functional perspective, social and policy considerations may suggest different liability schemes, to incentivize the development of socially valuable applications.

The product liability directive (PLD) – as well as its national implementations – has been subject to extensive assessment and evaluation and was found adequate to face the challenges posed by existing products. However, the assessment itself is not free of criticalities, both in the methodology through which it was conducted and in the overall judgement achieved. Indeed, the PLD offers insufficient protection to the victim, due to the difficulties in ascertaining and apportioning liability, as well as in proving the defect of the product and the causal nexus between the defect and the damage, and to the various grounds upon which the manufacturer may escape liability, such as the development risk defence. Pursuant to the RMA, the risk of unexpected and unforeseeable outcomes shall be borne by the party who derives economic

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benefits from the activity, since s/he is best positioned to insure against such events, having enough data to assess the statistical possibility of their occurrence, thus ensuring compensation, while at the same time managing such costs by spreading them onto all users of the same product.

(ii) The definition of safety regulation and its function, with particular reference to certification and standardization European.

Safety regulation defines the level of safety that is demanded of every specific product. A product is presumed to be safe if it meets all statutory safety requirements under European or national law, or – in their absence – if it conforms to national standards, Commission's recommendations, codes of practice, state of the art and reasonable consumer safety expectations. According to the «New Approach», legislative harmonization is limited to the essential safety requirements, while technical specifications are laid down by standards developed at the European, international and national level. "Harmonized" standard (hEN) are developed by private subjects upon request from the Commission, and grant the product a legal presumption of conformity, allowing simplified conformity assessment procedures. Conformity with standards is voluntary: the manufacturer may apply alternative solutions but will have to demonstrate that they satisfy the essential requirements, thorugh third party conformity assessment.

Given the variety of interactive robotics, the applicable safety legislation shall be identified on a case-by-case approach, taking into account the technical features of the robots, the use they are destined for, the environment they will be installed or be used in, as well as the impact they will have on direct and indirect users. Robots normaly qualify as machinery, or partly completed machinery, thus being regulated by the Machinery Directive. Some devices, such as exoskeletons, may also be considered as «personal protective equipment», which fall within the scope of the Personal Protective Equipment Directive and the Regulation repealing it, while others may also be classified as «medical devices», so that the Medical Device Directive and Regulation would apply. When more specific rules do not apply, robots still qualify as "product", and thus the General Product Safety Directive comes into play. Likewise, other legislations having transversal relevance – such as the Law Voltage Directive and the Electromagnetic Compatibility Directive, – may apply, depending on the specific features displayed by the robot.

The report offers a detailed analysis of the certification procedure requested by the different legal frameworks, and of the relevant standards.

Traditional product safety rules may prove insufficient for regulating robotics and AI applications, which give rise to different and broader types of ethical and societal concerns, as they affect people's privacy, dignity, security, autonomy and safety, both physical and psychological. Likewise, the innovative nature of such devices, together with the long-term and partially unpredictable effects of their use, make it difficult for researchers and businesses to identify, evaluate and mitigate the risks they may give rise to.

Indeed, regulating robotics and artificial intelligence constitutes one of the biggest challenges that Europe faces. Lack, delay or inadequacy of regulation may allow technologies which are not respectful of and driven by the European core values and principles, or have a chilling effect, thus hindering, instead of fostering technological innovation. Within the Digital Single Market, the Commission put forward a European approach to artificial intelligence and robotics, which aims at boosting the European technological and industrial capacity and AI uptake across the economy, while anticipating and addressing socio-economic changes, and ensuring an appropriate ethical and legal framework, based on the Union's values, and in line with the

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Charter of Fundamental Rights of the EU. The final Ethics Guidelines for Trustworthy Artificial Intelligence put building Trust in Human-Centric Artificial Intelligence as a prerequisite to ensure a human-centric approach to AI, based on) human agency and oversight; ii) technical robustness and safety; iii) privacy and data governance; iv) transparency, diversity, non-discrimination and fairness; v) societal and environmental well-being; vi) accountability.

(iii) The development of ethical standards

Although there are controversial debates about the concrete normative content of ethical standards and their justification through today, standardization is generally possible in ethics. The report focuses on the conceptualization and methodology of standardizing moral reasoning, and differentiate among different three ways of standardizing: ethics, morals and codes of ethics. "Ethics" constitutes the science of morals, relating to rational reasoning, justification and theoretical approaches on the basis of explicit knowledge; descriptive ethics standardizes in a formally strong way the object of observation, i.e morals, by putting it into normalized linguistic formulations, describing how people behave and making implicit habits explicit; normative ethics, on the contrary performs similar standardization of morals, but critically reflects its content and methodically creates universal ethical rules, evaluating how people behave, and arguing how they *should* behave and why. "Morals" standardizes in a formally weak way contingent moral values and habits by tradition, education and socialization, primarily based on implicit knowledge, including technical practice. "Ethos"/"codex"/"code of ethics", constitutes a formally strong standardization of moral rules – therefore making them explicit – by putting them into a normalized linguistic form.

The report then considers how moral values can be ethically justified, distinguishing between the deontological (I.) and utilitaristic (II.) approach. The first one belongs to the formally and methodically strong top-down standardization, whereas the second remains formally and methodically strong, but its normalization of values follows a bottom-up methodology.

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