



POLICY BRIEF

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MACHINERY REGULATION (MR)

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Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC PE/6/2023/REV/1 OJ L 165, 29.6.2023

<p>BACKGROUND OF THE LEGISLATIVE ACT</p>	<p>The machinery regulation (MR) lays down a baseline set of health and safety requirements for the design and construction of ‘<i>machinery, related product, and partly completed machinery</i>’¹. Machinery is intended as a diversity of things but the main element is that there is ‘<i>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.</i>’² The EU institutions approved this regulation as an update of the previous machinery directive (MD)³ because of several factors explained in the recitals. The first reason is the importance of the machinery sector as part of the engineering industry⁴. The second one is that the previous directive showed ‘<i>inconsistencies</i>’ in the product value chain and its product conformity assessment procedures⁵. The third underlying reason is the fast pace of technological evolution, with the emergence of AI systems that act as safety components in the interaction with machinery. The MD and MR are regulatory legislations that are part of a specific branch of EU law which is known as conformity or safety legislation. All the different pieces of legislation (MR included) have one final objective: to guarantee that the product or services are marketed or put into service in the European (Digital) Single Market by obtaining the CE marking, which certifies the conformity of the product or service with the EU standards for health and safety. The common trait of these legislations, MR included, is that the manufacturer will have to comply with a set of requirements. The number of such requirements is directly proportional to the level of risk that the product or service entails. According to the level of risk, the manufacturer will select the necessary conformity procedure which might require a third impartial check from an auditing/certification entity that has been agreed by the Member States (MS) and the EU Commission. These bodies in the MR are called notified bodies, and their task is to carry out conformity assessment on behalf of (MS’s) notifying authorities. The MR’s full implementation by MS will be on 14 January 2027.</p>
<p>HIGHLIGHTS</p>	<ul style="list-style-type: none"> • The MR has a well-defined scope⁶ and applies to: <i>i)</i> interchangeable equipment <i>ii)</i> safety components; <i>iii)</i> lifting accessories; <i>iv)</i> chains, ropes

¹ Article 1 MR.

² Remember that Article 3(1) MR also contains variants on this same concept.

³ Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery and amending Directive 95/16/EC (recast) OJ L 157, 9.6.2006, p. 24–86.

⁴ Recital 2 MR.

⁵ Recital 3 MR.

⁶ Article 2 MR.



	<p>and webbing; <i>v</i>) removable mechanical transmission devices. The exclusions of products are listed in the other paragraphs of Article 2 MR, such as weapons (d), and aeronautical products (f).</p> <ul style="list-style-type: none"> • In Article 3 MR, the definition of safety component includes software. In the MR safety function means that the product/component eliminates or grossly reduces a risk. However, the safety component is marketed separately from the main machinery product or component. Specifically, Annex II indicates that software as a safety component can have a full or partial self-evolving behavior using machine learning approaches. • Not only the manufacturers but all the actors involved in a machinery or related product's value chain have duties and obligations (Articles 10 – 19 MR). For instance, the importers' obligation to <i>'place only compliant machinery or related product on the market'</i>⁷ • Annexes deal with the following issues: how machinery or related products are related to a specific conformity procedure within the text (Annex I); an indicative list of safety components (Annex II); the essential health and safety requirements relating to the design and construction of machinery or related products (Annex III); iv) technical documentation accompanying the machinery object (Annex IV); the EU declaration of conformity and declaration of incorporation requirements (V); specific conformity procedures (Annexes VI, VII, VIII, IX).
IMPACT	<p>Potentially relevant scenarios</p> <p>The MR concerns the BRIEF project as biorobotics products can use machinery or machinery-related products, such as lifting accessories for co-bots. The sets of procedures and duties for manufacturers now start from the design of these objects and the essential requirements for health and safety are more detailed than before. Therefore, they need to be studied and to do that one needs to learn the content of Annex III of the regulation.</p>
	<p>Interdependencies in other policy areas</p> <p>The most direct interdependencies are with</p> <ul style="list-style-type: none"> • the Regulation on standardization EU/1025/2012⁸ because it will apply whenever harmonized standards are mentioned. This regulation's fundamental rule is that the EU Commission may need to establish a standard to harmonize further the Single Market, hence the name harmonized standard. Therefore, the EU Commission can delegate the European main standardization bodies (ETSI, CEN, CENELEC) to create the requested standard. The standard is then published in the official journal of the EU and each MS needs to implement it into national law to make it binding. Every time that the MR refers to harmonized standards, it means that the EU Commission might or might not have

⁷ Article 13(1) MR.

⁸ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council Text with EEA relevance OJ L 316, 14.11.2012, p. 12–33.



	<p>already approved them. In any case, these standards are binding for manufacturers which will need to be in conformity with them.</p> <ul style="list-style-type: none">• the AI Act in its annex II, it mentions the MD which will be repealed by the MR as part of the harmonization legislation bound to fall in the high-risk AI systems' compliance rules. Annex II complements Article 6 of the AI Act when it identifies the AI systems that are considered high-risk. From the combined reading of the AI act with the MR, when software is used as a safety component and is certified by a third-party body, under the MR, it will also be considered a high-risk AI system that will need to comply with all the duties outlined in the AI Act for this kind of algorithms•
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