

The new Machinery Regulation

The new Machinery Regulation entered into force on 19 July 2023 and must be applied in full from 14 January 2027. By then, the requirements of the Regulation must already have been implemented by the economic operators. The new requirements include in particular the coverage of new risks related to software & AI.

Scope of application

The Regulation addresses all economic operators¹ who place machinery, partly completed machinery or related products on the market in the EU. Complete machinery also includes assemblies which still miss the uploading of software, such as control or safety software. The term safety component now also includes software that fulfils safety functions, as well as safety components with fully or partially self-evolving behaviour using machine learning. This means that, for the first time, stand-alone software is also subject to the requirements of machinery legislation.

New machinery classifications

Due to technological developments in recent years, the Regulation sets out new classification rules for machinery. Risks arising from new technologies such as AI must be taken into account in design and construction. Machinery that operates in a networked environment must be protected against cyberattacks and tampering. Particularly high-risk class-A machinery includes, among other things, safety software with self-learning elements using machine learning. A notified body must mandatorily be involved in the conformity assessment of class-A machinery, while class-B machinery, which is largely identical to the high-risk machinery specified in Annex IV of the Machinery Directive, can also be assessed by means of

internal production control if all health and safety requirements are covered by harmonised standards.

Digital instructions for use

The Machinery Regulation for the first time allows the digital provision of instructions for use in the B2B sector, in which case it must be indicated on the machinery, packaging or an accompanying document how to access the instructions. It must also be possible to download and save them. A hardcopy is only to be made available at the customer's request. Stricter requirements apply in the relationship with consumers to whom safety information must be provided as a hardcopy.

Let's talk about machinery safety and security!

We would be pleased to advise you on the implementation of the new requirements under machinery law. Get in touch with us now without obligation!

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¹ These are manufacturers, authorised representatives, importers and distributors.