

### Guide to the Machinery Regulation 2023/1230



White paper Status: November 2023

#### Disclaimer

Our white paper has been compiled with great care. It contains information about the current Pilz interpretation of the new EU Machinery Regulation. All details are provided in accordance with the current state of knowledge and interpretation and to the best of our knowledge and belief. While every effort has been made to ensure the information provided is accurate, we cannot accept liability for the accuracy and entirety of the information provided, except in the case of gross negligence. In particular, it should be noted that statements do not have the legal quality of assurances or assured properties. We are grateful for any feedback on the contents.

#### Copyright

All rights to this publication are reserved by Pilz GmbH & Co. KG. We reserve the right to make technical changes. Copies may be made for the user's internal purposes. The names of the products, goods and technologies used are trademarks of the respective companies.

Pilz GmbH & Co. KG Felix-Wankel-Straße 2 73760 Ostfildern, Germany

© 2023 by Pilz GmbH & Co. KG, Ostfildern 1st edition

#### At a glance

The new **EU Machinery Regulation 2023/1230** replaces the existing Machinery Directive 2006/42/EC, which has been in force since 29 December 2009. It was published in the EU Official Journal on 29 June 2023 and entered into force 20 days later, without being transposed into national law. Application of the new plant and machinery requirements in accordance with the EU Machinery Regulation becomes mandatory on **20 January 2027**.

The Machinery Directive 2006/42/EC is one of the most important pieces of legislation for harmonising the essential safety requirements for machinery within the European Union. It describes standardised health and safety requirements for interaction between human and machine. The Directive promotes the free movement of machinery within the single market and guarantees a high level of protection for EU workers and consumers.

The EU Commission gives the following reasons for revising the existing Machinery Directive: "Experience with the application of Directive 2006/42/EC has shown inadequacies and inconsistencies in the product coverage and conformity assessment procedures. It is therefore necessary to improve, simplify and adapt the provisions set out in that Directive to the needs of the market and provide clear rules in relation to the framework within which products within the scope of this Regulation may be made available on the market."

In summary, it can be said that: The EU Commission has further developed the Machinery Directive 2006/42/EC to become the EU Machinery Regulation (MR) 2023/1230, in order to improve safety levels further, take account of security aspects and stay abreast of new technological developments. If you compare the automation and engineering of today with the requirements and technologies of fourteen years ago, it is clear that this revision is more than sensible. Because digitisation and networking, as well as the new related issues of Industrial Security and Artificial Intelligence, are significantly changing factory halls and the plant and machinery within them.

Manufacturers and operators have 42 months to familiarise themselves with the new EU Machinery Regulation. This guide will explain the changes in the new Machinery Regulation, as compared with the Machinery Directive.

#### Author



**Matthias Wimmer** has worked in the field of safety technology and its associated regulations for more than 25 years – at national, European and international level. He is a long-standing member of international standards committees, including ISO 13849 "Safety of machinery – Safety-related parts of control systems", and has experience of working for a notified body. Matthias Wimmer is certified to CMSE, CEFS, CESA (TÜV Nord) and CSE (TÜV Saarland).

His main areas of activity at Pilz are:

- Interpretation of the standards and preparation for internal and external applications
- Planning and fulfilment of complex customer projects related to functional safety and implementation of European specifications
- Training on functional safety and European engineering directives

#### 75 years of Pilz: Values. Create. Future.

As a global supplier of products, systems and services for automation technology, in 2023 Pilz can look back on a 75-year success story: Founded in 1948, today the Pilz Group employs around 2,500 staff in 42 subsidiaries and branches. This pioneer of safe automation, with its headquarters in Ostfildern, creates safety worldwide for human, machine and environment with its complete automation solutions.

The portfolio of the technology leader includes sensor, control and drive technology, as well as systems for industrial communication, diagnostics and visualisation. An international range of services with consultancy, engineering and training completes the offer. The safety and security solutions are used in many industries beyond mechanical engineering, such as intralogistics, railway technology or the robotics sector, for example.

#### Contents

1. EC Machinery Directive becomes EU Machinery Regulation
1.1. When does the EU Machinery Regulation come into force?
1.2. What is the difference between a directive and a regulation?
1.3. Is there a transition period?
2. What's changing, what's important and what needs to be done9
2.1. Changed structure
2.2. Structure of the new EU Machinery Directive 2023/1230 in comparison with the Machinery
Directive 2006/42/EC 9
2.3. Definition: "What is a machine?"
2.4. Higher risk machinery 11
2.5. Conformity assessment procedures and routes to conformity in accordance with the EU
Machinery Regulation
2.6. Digital instructions for use
2.7. Industrial Security
2.8. Self-evolving machinery
2.9. Safety-related software
2.10. Principles of safety integration – New feature
2.11. Mobile machinery – New feature
2.12. Harmonised standards
2.13. Substantial modification
2.14. Authorised representative
2.15. Obligations of distributors/importers
2.16. Conclusion
3 How can Pilz beln you? 20
4. Contact form22
5. Contents of EU Machinery Regulation 2023/1230

### 1. EC Machinery Directive becomes EU Machinery Regulation

#### 1.1. When does the EU Machinery Regulation come into force?

The new EU Machinery Regulation was adopted with a vote in the European Parliament on 18 April 2023. The regulation became legally valid when it was **published in the <u>EU Official</u>** Journal on **29 June 2023**. Its official title is "<u>Regulation (EU) 2023/1230</u> 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". Shortly afterwards, on 4 July 2023, there was a <u>correction</u> to the dates of the regulation. According to the corrected date, application of the EU Machinery Regulation will become **mandatory on 20 January 2027 (key date regulation)**.

# 1.2. What is the difference between a directive and a regulation?

Normally, once adopted or renewed, EU directives must first be incorporated by EU member states into their national legislation. A regulation is a legally binding instrument, which all EU countries must implement in full. In other words, once published, regulations apply unamended and immediately in each EU member state.



#### 1.3. Is there a transition period?

The EU Machinery Regulation has a transition period of 42 months until its application is mandatory. This period began when the regulation entered into force, 20 days after it was published in the EU Official Journal. The transition period ends on 20 January 2027 (key date regulation).

There will be no coexistence period with choice of provision, either before or after this cut-off date. With the transition period, there is sufficient opportunity for manufacturers to adapt to the new rules, and must then convert over on the exact day. For example, from the 20 January 2027, declarations of conformity must be issued in accordance with the new EU Machinery Regulation.

A special situation occurs with products that were declared in accordance with the Machinery Directive before the key date of 20 January 2027, but then lie in stock for some time and are only incorporated into an actual application some time later. In this case it is not necessary to ask the product manufacturer for a new declaration of conformity, as the product has already been placed on the market. The situation may be somewhat less clear when products are in stock beyond the key date at the original manufacturer, have not been delivered, and therefore have not been "placed on the market". In this case, the replacement of the regulations is applicable from the specified key date.



Figure 1: Milestones in the EU Machinery Regulation 2023/1230

It should be noted that **individual articles** of the EU Machinery Regulation 2023/1230 apply before the key date of 20 January 2027:

- Article 6(7), articles 48 and 52: make it easier to expand the list of machinery with increased potential risk. However, that does not represent a change to the existing procedure. In this respect, the implementation date from 19 July 2023 is unproblematic.
  - Article 52: The transitional provisions defined here are important! Existing EC typeexaminations in accordance with the Machinery Directive 2006/42/EC shall remain valid until they expire, even if this should be after 20 January 2027.
- Article 50(1): Laying down the rules on penalties applicable to infringements of the EU Machinery Regulation from 14 October 2023
- Articles 26 to 42: Notification of conformity assessment bodies from 14 January 2024
- Article 6(2-6) and (11); article 47 and 53(3) from 20 July 2024: This enables the list of hazardous machinery in Annex I to be changed/expanded without revising the regulation completely. In practice this means that where the use of harmonised standards or the involvement of a notified body is mandatory for a machine's conformity assessment, the list of those machines can be amended more easily.
- Article 53: specifies a regular review of the EU Machinery Regulation. Initially in July 2028 and every four years thereafter, the EU Commission must evaluate and review the regulation. This may give rise to some amendments to the regulation. So a type of four-year maintenance cycle for the regulation is prescribed for the future.



Figure 2: Safety for human and machine

# 2. What's changing, what's important and what needs to be done

#### 2.1. Changed structure

From a purely editorial perspective, the order of the articles and appendices has changed. For example, particularly hazardous machinery can be found in Annex I, rather than Annex IV as previously. The essential health and safety requirements have moved to Annex III.

# 2.2. Structure of the new EU Machinery Directive 2023/1230 in comparison with the Machinery Directive 2006/42/EC

Machinery Directive 2006/42/EC	EU Machinery Regulation 2023/1230
Article 1	Article 2
Article 2	Article 3
Article 3	Article 9
Article 4(1) and (2)	Article 8
Article 4(3) and (4)	-
Article 5	Articles 10 and 11
Article 6	Article 4
Article 7	Article 20(1)
Article 8(1)	Articles 6(1) and 7(1)
Article 8(2)	-
Article 9	-
Article 10	Article 44(3)
Article 11	Articles 43, 44 and 45
Article 12	Article 25
Article 13	Article 11
Article 14 (and Annex XI)	Articles 26 to 42
Article 15	Article 5
Article 16	Articles 23 and 24
Article 17	Article 46
Article 18	Article 49
Article 19	-
Article 20	-
Article 21 a	Article 47
Article 22	Article 48
Article 23	Article 50
Article 24	-
Article 25	Article 51

Article 26	-
Article 27	-
Article 28	Article 54(1)
Article 29	Article 54(2) and (3)
Annex I – General principles and	Annex III – Part A (Definitions)
section 1.1.1 (Definitions)	and Part B (General principles)
Annex I sections 1.1.2-1.1.8	Annex III section 1
Annex I section 2	Annex III section 2
Annex I section 3	Annex III section 3
Annex I section 4	Annex III section 4
Annex I section 5	Annex III section 5
Annex I section 6	Annex III section 6
Annex II Parts A and B	Annex V Parts A and B
Annex III	-
Annex IV	Annex I
Annex V	Annex II
Annex VI	Annex XI
Annex VII Parts A and B	Annex IV Parts A and B
Annex VIII in conjunction with Article 12(3a)	Annex VI
Annex VII (number 3) in conjunction with Article 12(3b)	Annex VIII
Annex IX	Annex VII
Annex X	Annex IX
Annex XI	Article 30
Article 1	Article 2
Article 2	Article 3
Article 3	Article 9
Article 4(1) and (2)	Article 8

Table 1: Annex XII – Correlation table

#### 2.3. Definition: "What is a machine?"

The EU Machinery Regulation defines the term "machine" and the familiar special cases (now "related products") – such as interchangeable equipment, safety components, lifting accessories, chains, ropes, and webbing, as well as removable mechanical transmission devices – in the familiar way. The term "assembly of machinery" has also been largely retained – but additionally mentions the term software. A machine missing the software intended for a specific application also falls under this definition.



Figure 2: EU Machinery Regulation for the protection of human and machine

#### 2.4. Higher risk machinery

Higher risk machinery is now divided into two categories:

- Annex I Part A lists machinery with behaviour that can be modified by self-learning mechanisms, for example.
- Annex I Part B contains other categories of machinery, which were previously listed in Annex IV.

#### The EU Machinery Regulation lists these six machine categories under Annex I Part A:

- 1. Removable mechanical transmission devices including their guards
- 2. Guards for removable mechanical transmission devices
- 3. Vehicle servicing lifts
- 4. Portable cartridge-operated fixing and other impact machinery
- 5. Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions
- 6. Machinery that has embedded systems with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions that have not been placed independently on the market, in respect only of those systems

With these machine types, machine manufacturers alone can no longer declare conformity in conjunction with a harmonised standard, as was previously possible in the Machinery Directive. In future, a **notified body** must be involved. This is necessary in part due to the reference to artificial intelligence (described in the text as "using machine learning approaches"). This type of machinery always requires the involvement of a notified body. It can either certify the machine itself through an EU type-examination or certify the underlying quality assurance system prior to the actual production of the machine.

However, for **machine categories listed in Part B**, the machine manufacturer themself can still declare conformity with the Machinery Regulation in combination with a harmonised standard, with the aid of internal production control.

# 2.5. Conformity assessment procedures and routes to conformity in accordance with the EU Machinery Regulation

Various options are considered as conformity assessment procedures. The modular system familiar from other directives is now also used in the Machinery Regulation. The following modules are defined in the regulation's annexes:

Modules	Type of check	Notified body required?
Module A, Annex VI	<ul> <li>Internal production control</li> </ul>	<ul> <li>Self-certification</li> </ul>
Module B, Annex VII	EU type-examination	$\checkmark$
Module C, Annex VIII	<ul> <li>Internal production control when produced in series</li> </ul>	<ul> <li>Conformity check with the sample tested in accordance with Module B</li> </ul>
Module H, Annex IX	Full quality assurance	$\checkmark$
Module G, Annex X	<ul> <li>Unit verification</li> </ul>	$\checkmark$
From the manufacturer's perspective, Modules A and C are comparable, as are Modules B		

and G. The difference is in production as a single unit or in series.

- The following specific conformity assessment procedures are considered, based on the classification of a machine in accordance with Article 25 of the Regulation:
  - On machinery in accordance with Annex I Part A, one of the three following procedures can be used, at the choice of the manufacturer:
    - The EU type-examination (Module B), followed by production control (Module C), which ensures that the example produced conforms with the sample tested,

or

- Conformity assessment of the example produced, based on the certified quality assurance system (Module H)

or

- Conformity assessment based on unit verification of the example produced (Module G).

- If the specific machine is listed in Annex I Part B, the following should be applied: Where harmonised European standards with reference to the Machinery Regulation are available and have been applied, Module A can also be applied under the sole responsibility of the manufacturer, in addition to the options listed above. However, if there are no harmonised standards available or they are not enough to cover all aspects of the machine, or if the manufacturer wishes to knowingly deviate from these standards, the same rules apply as for machinery from Annex I, Part A. Specifically, the involvement of a notified body is required.
- ▶ There remain all the other categories of machinery, which are not regarded as machinery with increased risk. As before, they can be placed on the market under the manufacturer's sole responsibility in accordance with Module A.
- New in Article 10 is the explicit mention of the ongoing obligations for manufacturers. The article specifically requires manufacturers to take measures (recall where appropriate), if machinery could potentially not meet the requirements of the Machinery Regulation, but are nonetheless already on the market. That should actually be a matter of course however, explicitly naming this obligation with this level of clarity in the Machinery Regulation and not just in a product safety directive is something new.

#### 2.6. Digital instructions for use

The option to supply the instructions for use in digital form, long-awaited in practice and favourable to environmental protection, has now found its way into the text of the regulation:

- Instructions must be available in a digital, printable format.
- On request, printed instructions must continue to be provided. The legislator stipulates that a free version should be available within one month of the machine being purchased.
- For "non-professional users", safety information must be provided in paper format.

A mandatory marking requirement on the machinery and accompanying documents, indicating how to access the digital instructions, has also been introduced.

A new obligation has also been imposed on the manufacturer: They must have the instructions available digitally for **at least ten years** after the machine is delivered. It would be possible to lose track of this if the product itself has reached the end of its sales phase.

A **digital EU declaration of conformity** has also been permitted. Partly completed machinery may also be delivered with digital assembly instructions and a digital declaration of incorporation.

#### 2.7. Industrial Security

The EU Machinery Regulation also takes up the new subject of "security". Article 20 refers to the <u>EU Regulation (EU) 2019/881</u>. This regulation is one potential way of meeting the requirement of the EU Machinery Regulation. We can assume that in future there will also be appropriate harmonised standards for this requirement.

Within the essential health and safety requirements for the design and construction of machinery or related products in Annex III under point 1.1.9, protection against software corruption is required on the machine, particularly when connecting "devices" (connections to other data sources, e.g. programming devices or network interfaces). In the style of an essential health and safety requirement, the connection of devices is regarded as a potential risk with regard to the modification of machine-integrated software, and the requirement is made that the safety functions of the machine must not be compromised as a result.

In future manufacturers must designate parts of their software that are relevant to conformity and provide protection against accidental as well as deliberate modification. What's more, in future, each machine must collect evidence of a legitimate or illegitimate intervention in the software, actually record it in other words.

In conclusion it can be said that industrial security is a mandatory element for the safety of machinery, and no longer open to the interpretation of those placing the machine on the market. Manufacturers will need to draw up appropriate industrial security concepts. In this respect, industrial security is one of the main themes of the Machinery Regulation. Manufacturers of networked machinery should prepare well in this regard, because they will also face demands from other areas of legislation (e.g. Cyber Resilience Act, Radio Equipment Directive).



Figure 3: Concepts must be drawn up for the growing significance of industrial security.

#### 2.8. Self-evolving machinery

Also new is the term "**self-evolving machinery**". This is nothing other than another way of saying the term "artificial intelligence". Firstly, this subject influences the question as to whether a notified body needs to be engaged. Secondly, the subject belongs in a risk assessment in any case, because modified software could entail new or even higher risks! In an extreme case, consideration must be given as to whether self-learning software can potentially result in a new machine. An extremely interesting subject, not just for the manufacturer, but also for the notified bodies. Bases for assessment must first be established.

#### 2.9. Safety-related software

Not completely new – but now addressed more clearly – is the subject of **safety-related software**. If this type of software is placed on the market as a standalone product, it is viewed as a safety component and is therefore subject to the rules of the Machinery Regulation. In the vast majority of current cases, function libraries for programmable controllers are tested and certified together with the respective hardware, for example. However, if such blocks are offered separately by a third party, for example, they must be provided with a declaration of conformity and a CE mark.

#### 2.10. Principles of safety integration – New feature

Machinery must be designed and constructed in such a way that it is possible for the user, where applicable, to test the safety functions. Where appropriate, machinery must be equipped with a **description of the procedures enabling it to be tested, adjusted, maintained and used**. This point enables the operator to test the safety-related functions in accordance with the manufacturer's specifications in future. They are already obliged to do so. However, until now they had to determine the details of the practical implementation themselves. The new provision relieves the operator of this task.

#### 2.11. Mobile machinery – New feature

Autonomous machinery must have a supervisory function that can be identified and operated remotely. In the case of an autonomous machine, it must be possible for an operator to start, stop or bring the machine to a safe state – without having to go directly to the machine and therefore into a potentially dangerous area.

#### 2.12. Harmonised standards

What will happen with today's harmonised standards that are applicable for compliance with the directive?

The new EU Machinery Regulation still continues the systematics:

- Health and safety requirements are defined in the regulation.
- The corresponding harmonised standards set out the possibilities for meeting these requirements.

However, today's harmonisation refers strictly to the Machinery Directive 2006/42/EC. As such it will cease to apply in January 2027. The system must be rebuilt. At the moment, it's not completely clear what the exact procedure will be. The existing standards may possibly be suitable to meet the objectives of the Machinery Regulation largely unchanged. Nonetheless, this will need to be checked and confirmed by the responsible HAS Consultants. Even if everything is clear technically, it will still be a laborious process. Several hundred standards will need to be dealt with; a process for which it is entirely conceivable that the deadline of January 2027 will be tight. However, for this case, the Machinery Regulation leaves the door open to authorities to issue special transitional provisions.



Figure 4: Harmonised standards create safety.

#### 2.13. Substantial modification

The regulation has been extended to include the definition of a substantial modification of machinery. For machinery safety, a new conformity assessment procedure is always required when a machine undergoes major technical modifications. It is made clear (Chapter 2, Article 18) that the person who carries out the substantial modification on the machine must meet all of the obligations of the manufacturer.

Machines often undergo their first modifications shortly after they are put into service. It often remained unclear whether such modifications might influence the machine's conformity or whether, in some cases, a new conformity assessment is required – that in fact a new machine is being manufactured, with all the resulting obligations. In Germany, there has already been an early interpretation: the key points have always been whether new or greater risks arise from the modifications, and whether it was possible to protect against these risks using existing safeguards or using new, simple safeguards. Depending on the answer to these questions, the responsibility for the modification is that of a machine operator or a machine manufacturer. This view has been transported into the EU Machinery Regulation, in Article 3, point 16 for example. But beware: a significant modification can also arise without any physical changes to the machine – as a result of modifications to the software, for example. That's why programmers should also familiarise themselves with this subject.

Finally, recital 26 explains: "The person carrying out the substantial modification should not be required to repeat tests and produce new documentation in relation to parts of the machinery that are not affected by the modification." It remains to be seen whether in practice this means documentation is missing for existing machine areas.

#### 2.14. Authorised representative

Article 12 of the EU Machinery Regulation defines the role of the "Authorised representative". In the Machinery Regulation there are clear changes to this role, in comparison with the Machinery Directive. In the Machinery Directive, the authorised representative was to be entrusted with freely definable responsibilities under contract, but in the Machinery Regulation they have a more limited role. According to Article 12, they can keep the machine documentation and EU declaration of conformity or declaration of incorporation on behalf of the manufacturer, in case the national authorities should require access. However, by definition, they are not responsible for compliance with the essential health and safety requirements. That responsibility remains with the actual manufacturer.

The same applies for documentation: the authorised representative is not responsible for producing it or for its accuracy. Their only remit is to "make it available". Other activities that service providers carry out under mandate from a manufacturer are still permitted, of course – just not in the role of authorised representative.

Obligations (Article 10)	Manufacturer	Authorised representative
Risk assessment	~	x
Produce the technical documentation, carry out the conformity assessment	$\checkmark$	x
Obligation to keep technical documentation	$\checkmark$	$\checkmark$
Quality assurance requirement	$\checkmark$	x
Attach the CE mark	$\checkmark$	✓
Produce the instructions for use	$\checkmark$	x
Provide the instructions for use	$\checkmark$	~
Produce the declaration of conformity	$\checkmark$	~
Obligation to monitor the product	$\checkmark$	x
Obligation to work with authorities	$\checkmark$	~
Apply for EC type-examination, quality assurance etc.	$\checkmark$	$\checkmark$

Table 2: Manufacturer and authorised representative – Transfer of obligations

#### 2.15. Obligations of distributors/importers

Articles 13 to 17 define the obligations of economic operators other than the manufacturer. As such the Machinery Regulation is aligning itself with the <u>Market Surveillance Regulation</u> <u>2019/1020</u>. Reference is made to importers or distributors. The Machinery Regulation defines the requirements of those economic operators that were not previously referred to in the Machinery Directive. So what do distributors and importers face?

Importers: Importers shall place only compliant products on the market. That is the very first obligation from Article 13. However, further obligations go beyond the usual checking that the declaration of conformity and CE mark exist. The importer must ensure that all of the machine documentation has been drawn up, that the user information is enclosed, the CE mark affixed and the manufacturer's identification is stated, including a digital contact. As part of his activities, should an importer come to the view that an imported, CE-marked product is not compliant, they must inform the relevant authorities and take appropriate measures. The importer must always provide details of their own identification, in addition to that of the manufacturer.

In future, importers shall also be obliged to carry out sample testing of products already made available on the market, to check their conformity, and, in the event of any problems, to keep distributors informed of the results. The same applies to product recalls. However, this obligation is introduced with: "When deemed appropriate ...". It remains to be seen how this will work in practice.

The importer must also keep a copy of the EU declaration of conformity available for ten years after the product has been placed on the market. They must also ensure that all the technical documentation is available. Here they have the same obligations named in the declaration of conformity for a person established within the EU in accordance with the Machinery Directive (or, as now described in the Machinery Regulation, the authorised representative). Whether it is enough for the importer to reference the authorised representative in order to meet this obligation, remains to be seen.

**Distributors:** The distributor is obliged to check the existence of the CE mark, the EU declaration of conformity, the instructions for use, and the proper product identification, including the name and address of the manufacturer or importer. Of course, distributors are also obliged to report any non-compliant products that they have made available on the market to the authorities and to take appropriate measures. Distributors must also make all information and documents necessary to demonstrate the conformity of the machine available in a language that can be easily understood by the relevant authority. A requirement that can be interpreted widely, which will certainly need to be brought to life in practice.

The obligations stated in this section apply similarly to both completed and partly completed machinery. As before, all parties (and therefore also distributors and importers) shall be regarded as the manufacturer when they have just placed their own identification on the product, or when they have substantially modified the product.

#### 2.16. Conclusion

Generally we recommend that our customers in engineering and special purpose machinery building check the changes that will affect them as quickly as possible. A specific action plan will help incorporate and implement the necessary adjustments and optimisations in the CE marking process in good time. So machine builders can guarantee that the plant, machinery and products that they place on the market continue to be legally compliant and above all safe, even once the transition period has expired.



Figure 5: Safety for human and machine

### 3. How can Pilz help you?

As machine manufacturers and operators, the new machinery safety specifications require that you make specific process adjustments. Now is the time to act. Use the time you have until application of the new EU Machinery Regulation becomes mandatory to make the best possible preparations for the changes.

### Pilz will accompany you through the process of converting from the Machinery Directive to the Machinery Regulation.

Having focused heavily on machinery safety, Pilz can draw on many years of experience and demonstrate expert knowledge on normative and legal specifications accordingly. We apply this knowledge and our technical competence for your success: from normative and legal requirements to training, and practice-oriented services through to product solutions, we provide comprehensive support, helping you to implement the EU Machinery Regulation efficiently and correctly in your processes.



#### Standards and Training Services **Product solutions** legal requirements Expertise regarding Learn about Risk evaluation, Safety products the interpretation machinery safety safety concept, such as sensors, and industrial implementation of and application of relays or normative and legal security, plus measures as well as controllers, through requirements for training on the validation/ to automation machinery safety application of verification for your solutions, to make product solutions machinery your machinery safe.

#### Pilz training – Because knowledge protects!

Machinery Regulation made simple! Machinery safety training specifically on CE marking sets you up perfectly to fundamentally understand and implement the new requirements. That's why, from January 2024, we will be updating our training offer as per the EU Machinery Regulation, so that you can start early to build up knowledge about the changes and requirements, and therefore your capacity to act.

Specifically with regard to the forthcoming industrial security requirements, training is an ideal way to acquire in-depth understanding and competence. We particularly recommend our new training course, developed in cooperation with TÜV Nord: Certified Expert for Security in Automation, CESA for short. Learn about the specific, normative industrial security requirements you need to meet, and protect your machinery from cyber attacks, manipulation and misuse, for greater safety and productivity. As with our other multi-day expert training courses for Certified Machinery Safety Expert, Certified Expert in CE Marking and Certified Expert in Functional Safety, once you have passed the examination you will have your own personal, internationally recognised certification.

#### Pilz services – Let's wrap this up together!

How will you carry out CE marking in future? Which processes need to be adapted? How do you ensure that you comply with all the specifications and requirements?

Pilz services can help you here! Pilz will undertake all the steps for you, from risk assessment to validation in accordance with normative and legal specifications and, to be completely up to date, also in accordance with the requirements of the EU Machinery Regulation. And of course, we'll also support your through process changes, so that your projects can be adjusted and planned to the new specifications in good time. In the engineering sector, on request you can receive data information that's relevant to industrial security as part of your project documentation, for example, to prepare you for an industrial security risk evaluation that will examine your machinery for vulnerabilities.

Equally you can benefit from our new Industrial Security Consulting Service: unless you comply with the security requirements, there will be no more CE mark in future. The new service from Pilz examines your machinery for cyber weaknesses and accompanies you through the required implementation of industrial security on your machinery.

The new EU Machinery Regulation is certainly a challenge, but it also offers new possibilities. Preparation through training and services counts – the earlier the better.

### 4. Contact form

Further information on the Machinery Regulation is available on our website at <u>www.pilz.com/mr</u> You can also use the QR code or **reply by E-Mail to**  $\rightarrow$  **kommunikation@pilz.de** 

Please contact me:

By E-Mail 🛛 By phone 🖵

Subject:

□ Machinery Regulation (MR)

Day with a consultant - The first step towards safety

□ Plant and machine retrofit

Training and seminars on machinery safety/industrial security

Company	
Street	Post code/Town
Title I Mr I Mrs/Ms	Country
First name	Phone number
Surname	Telefax
Function	E-Mail
Department	Industry

**Yes**, I agree that Pilz GmbH & Co. KG can contact me regularly about products and events via E-Mail, at the following E-Mail address:

E-Mail address

Date/signature

**You can withdraw consent at any time!** Each E-Mail contains an unsubscribe function, which you can use to unsubscribe from the E-Mail distribution list. Information on Pilz's data protection provisions can be found at <u>www.pilz.com/privacy</u>

### 5. Contents of EU Machinery Regulation 2023/1230

For better orientation, we have drawn up a table of contents for the published EU Machinery Regulation, in order of chapter, article and annex. This is missing from the published regulation.

Chapter I	General provisions
Article 1	Subject matter
Article 2	Scope
Article 3	Definitions
Article 4	Free movement
Article 5	Protection of persons during installation or use of machinery
	or related products
Article 6	Categories of machinery and related products listed in Annex
	I subject to relevant conformity assessment procedures
Article 7	Safety components
Article 8	Essential health and safety requirements for products within
	the scope of this Regulation
Article 9	Specific Union harmonisation legislation
Chapter II	Obligations of economic operators
Article 10	Obligations of manufacturers of machinery and related
	products
Article 11	Obligations of manufacturers of partly completed machinery
Article 12	Authorised representatives
Article 13	Obligations of importers of machinery and related products
Article 14	Obligations of importers of partly completed machinery
Article 15	Obligations of distributors of machinery and related products
Article 16	Obligations of distributors of partly completed machinery
Article 17	Cases in which obligations of manufacturers apply to
	importers and distributors
Article 18	Other cases in which obligations of manufacturers apply
Article 19	Identification of economic operators
CHAPTER III	Conformity of products within the scope of this Regulation
Article 20	Presumption of conformity of products within the scope of
	this Regulation
Article 21	EU declaration of conformity of machinery and related
	products
Article 22	EU declaration of incorporation of partly completed
	machinery
Article 23	General principles of the CE marking
Article 24	Rules for affixing the CE marking to machinery and related
	products
CHAPTER IV	Conformity assessment
Article 25	Conformity assessment procedures for machinery and
	related products
Article 26	Notification of conformity assessment bodies
Article 20	Notifying authorities
	Requirements relating to notifying outborities
Article 20	
Article 29	Population obligation of notifying authorities
Article 30	Requirements relating to notified bodies
Article 31	resumption of conformity of notified podies

Article 32	Use of subcontractors and subsidiaries by notified bodies	
Article 33	Application for notification	
Article 34	Notification procedure	
Article 35	Identification numbers and lists of notified bodies	
Article 36	Changes to notifications	
Article 37	Challenge of the competence of notified bodies	
Article 38	Operational obligations of notified bodies	
Article 39	Appeals against decisions of notified bodies	
Article 40	Information obligation of notified bodies	
Article 41	Exchange of experience	
Article 42	Coordination of notified bodies	
	Union market surveillance and union safeguard procedures	
Article 43	Procedure at national level for dealing with products within	
	the scope of this Regulation presenting a risk	
Article 44	Union safeguard procedure	
Article 45	Compliant products within the scope of this Regulation which	
	present a risk	
Article 46	Formal non-compliance	
CHAPTER VII	Delegated powers and committee procedure	
Article 47	Exercise of the delegation	
Article 48	Committee procedure	
	Ocufidentiality and negative	
CHAPTER VIII	Confidentiality and penalties	
Article 49	Departies	
	Penalles	
CHAPIER IX	I ransition and final provisions	
Article 51	Transitional provisiona	
Article 52	Function and provisions	
Article 53	Evaluation and review	
	Entry into force and application	
	procedures referred to in Article 25(2) and (3) shall be applied	
PART A	Categories of machinery or related products to which a	
	procedure referred to in Article 25(2) shall be applied:	
	1. Removable mechanical transmission devices	
	including their guards.	
	2. Guards for removable mechanical transmission	
	devices.	
	3. Vehicle servicing lifts.	
	4. Portable cartridge-operated fixing and other impact	
	machinery.	
	5. Safety components with fully or partially self-evolving	
	behaviour using machine learning approaches	
	ensuring safety functions.	
	6. Machinery that has embedded systems with fully or	
	partially self-evolving behaviour using machine	
	learning approaches ensuring safety functions that	
	have not been placed independently on the market,	
PARIB	Cotogorioo of mochinery or related are ducto to which we of	
	Categories of machinery or related products to which one of	
	Categories of machinery or related products to which one of the procedures referred to in Article 25(3) shall be applied:	
	Categories of machinery or related products to which one of the procedures referred to in Article 25(3) shall be applied: Indicative list of safety components	
	Categories of machinery or related products to which one of the procedures referred to in Article 25(3) shall be applied:     Indicative list of safety components     1. Guards for removable mechanical transmission devices.     2. Protective devices designed to detect the presence of	
	Categories of machinery or related products to which one of the procedures referred to in Article 25(3) shall be applied:     Indicative list of safety components         1. Guards for removable mechanical transmission devices.         2. Protective devices designed to detect the presence of persons.	

	<ol> <li>Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11 of Annex I, Part B.</li> <li>Logic units to ensure safety functions.</li> <li>Valves with additional means for failure detection intended for the control of dangerous movements of machinery.</li> <li>Extraction systems for machinery emissions.</li> <li>Guards and protective devices designed to protect persons against moving parts involved in the process of the machinery.</li> <li>Monitoring devices for loading and movement control in lifting machinery.</li> <li>Restraint systems to keep persons in their seats.</li> <li>Emergency stop devices.</li> <li>Discharging systems to prevent the build-up of potentially dangerous electrostatic charges.</li> <li>Energy limiters and relief devices referred to in sections 1.5.7, 3.4.7 and 4.1.2.6 of Annex III.</li> </ol>
	14. Roll-over protective structures (ROPS).
	15. Falling-object protective structures (FOPS).
	10. I Wo-nand control devices. 17 The following components for machinery designed for lifting
	and/or lowering persons between different landings:
	a) Devices for locking landing doors;
	b) Devices to prevent the load-carrying unit from falling
	or unchecked upwards movement;
	d) Energy-accumulating shock absorbers, non-linear or
	with damping of the return movement;
	e) Energy-dissipating shock absorbers;
	<ul> <li>f) Safety devices fitted to jacks of hydraulic power circuits and used to prevent falls:</li> </ul>
	g) Safety switches containing electronic components.
	18. Software ensuring safety functions.
	19. Safety components with fully or partially self-evolving
	behaviour using machine learning approaches ensuring
	Filtration systems intended to be integrated into machinery
	cabins in order to protect operators or other persons against
	hazardous materials and substances, including plant
	protection products, and filters for such filtration systems.
ANNEX III	Essential health and safety requirements relating to the design
ΔΔΩΤ Λ	and construction of machinery or related products
PART R	
	1 Essential health and safety requirements
	1.1. General remarks
	1.2. Control systems
	1.3. Protection against mechanical risks
	1.4. Required characteristics of guards and protective devices
	1.5. KISKS due to other causes
	1.7. Information
	2. Supplementary essential health and safety requirements for
	certain categories of machinery and related products
	2.1. Machinery and related products for foodstuffs and
	machinery and related products for cosmetics or

	2.2. Portable hand-held or hand-guided machinery or related
	products
	2.3. Machinery or related products for working wood and
	2.4 Machinery or related products for plant protection products
	application
	3. Supplementary essential health and safety requirements to offset
	risks due to the mobility of machinery or related products
	3.2 Work positions
	3.3 Control systems
	3.4. Protection against mechanical risks
	3.5. Protection against other risks
	3.6. Information and indications
	4. Supplementary essential health and safety requirements to offset
	risks due to lifting operations
	4.1. General
	4.2. Requirements for machinery or related products whose
	power source is other than manual effort
	4.3. Information and markings
	4.4. Instructions for use
	machinery or related products intended for underground work
	5.1 Risks due to lack of stability
	5.2. Movement
	5.3. Control devices
	5.4. Stopping
	5.5. Fire
	5.6. Exhaust emissions
	6. Supplementary essential health and safety requirements for
	machinery or related products presenting particular risks due to
	the lifting of persons
	6.2 Control devices
	6.3 Risks to persons in or on the carrier
	6.4 Machinery or related products serving fixed landings
	6.5. Markings
	5
ANNEX IV	Technical documentation
PART A	Technical documentation for machinery and related products
PART B	Technical documentation for partly completed machinery
ANNEX V	EU declaration of conformity and EU declaration of
	Incorporation
PARTA	EU declaration of conformity of machinery and related products No.
	(1)
PARIB	EO declaration of incorporation of parity completed machinery No
	(2)
	FII type-examination
(Module B)	
ANNEX VIII	Conformity to type based on internal production control
(Module C)	
	Conformity based on full quality assurance
(Module H)	

ANNEX X	Conformity based on unit verification
(Module G)	
ANNEX XI	Assembly instructions for partly completed machinery
ANNEX XII	Correlation table

Table 3: Contents of EU Machinery Regulation 2023/1230

We are represented internationally. For further information, please visit our website www.pilz.com or contact our headquarters.



Headquarters: Pilz GmbH & Co. KG, Felix-Wankel-Straße 2, 73760 Ostfildern, Germany Telephone: +49 711 3409-0, e-mail: info@pilz.de, Internet: www.pilz.com