



# The new Machinery Regulation

**The Machine Products Regulation (2023/1230) concerns the current Machinery Directive (2006/42/EC).**

Check it out  
[certification-experts.com](https://certification-experts.com)



**CERTIFICATION  
EXPERTS**

Part of kader group



Check it out  
[certification-experts.com](https://certification-experts.com)



# Introduction

The Machinery Regulation 2023/1230 is set to replace the current Machinery Directive 2006/42/EC. Fortunately, this transition will not occur overnight. The new Machinery Regulation became effective at 14th of June and manufacturers will have another 3.5 years to facilitate the transition from the current Machinery Directive to the Machinery Regulation. In this white paper, we explore the reasons behind the replacement of the current Machinery Directive and provide an overview of the structure of the new regulation. We also discuss the specific changes introduced in the new regulation compared to the current directive. Using a flowchart, we illustrate how to determine whether a change to an existing machine should be regarded as substantial according to the regulation. We also examine the practical implications of the new regulation.

## In the brochure, you can discover

Why is the Machinery Directive being replaced?	4
What is the impact of the Machinery Regulation for Machinery Regulation for machine builders and users?	5
How does the structure of the new Machinery Regulation look, and what has been changed?	6
When should a change be considered 'substantial'?	13
Three fictitious examples to illustrate the use of the flowchart	14
Need help with implementing the new Machinery Regulation?	22
About Certification Experts	23

### Contact

Do you have any questions after reading the information, or would you like to request a quote? Please feel free to contact us.

Phone number: +31 (0) 85 0073210  
certification-experts.com  
info@certification-experts.com

**We are here to help!**

# Why is the Machinery Directive being replaced?

The adoption of the current Machinery Directive into national legislation (Warenwetbesluit Machines in the Netherlands) has revealed instances where varying interpretations have arisen in various Member States. This has led to inadequacies and inconsistencies in the product coverage, the conformity assessment procedures and the essential health and safety requirements. Therefore, it has been decided to replace the Machinery Directive with a regulation. A regulation can be considered as European product legislation that takes effect immediately and thus eliminating the need for transposition into national legislation. This ensures that there is no longer room for divergent implementations by Member States.



# What is the impact of the Machinery Regulation for machine builders and users?

To determine the impact of the new regulation, we first revisit the purpose of the current Machinery Directive. Its objective is to facilitate the free movement of products falling under its scope within the European Economic Area (EEA), ensuring a minimum safety level for these products. This remains the starting point for the Machine Regulation. However, as explained in recital (3) of the Regulation, it was essential to improve, simplify and adapt the provisions of the existing Machinery 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. Updating the legislation to reflect the state of the art in machinery and innovation is one example of this. This is reflected, among other things, in the additional requirements introduced by the Machine Regulation, related to innovative aspects such as Machine Learning, Cybersecurity and safety-related software.

In general, the impact of replacing the current Machinery Directive with the Machinery Regulation will not be significant for most machine builders. When considering the technical requirements set by the regulation, some changes and updates have been made, but the majority of the requirements have barely changed. In the section "Essential Safety and Health Requirements", we highlight the main changes pertaining to that part of the regulation. Similarly, not much will change for the user (the buyer of a machine). They

will still purchase a machine or other product that falls within the scope of the regulation, which:

- Meets (or should meet) essential health and safety requirements.
- Bears a CE marking.
- Comes with an EU Declaration of Conformity.
- Includes a user manual.

Regarding the instructions for use, a manufacturer may, based on the Machinery Regulation, provide them in digital form as a standard. Consequently, the user of the machine does not necessarily receive a paper manual with the machine. However, the machine manufacturer must still provide the customer with a paper manual (free of charge) within one month upon the customer's request. There is a minor distinction for machines intended for non-professional users (consumers) or machines expected to be used by non-professional users. In such cases, the manufacturer must always provide all safety warnings and instructions for the safe use of the machine in paper form alongside the machine. In these situations, the other parts of the manual may still be provided digitally as the standard.



# How does the structure of the new Machinery Regulation look, and what has been changed?

The new regulation features a different structure and format compared to the current Machinery Directive. Individuals accustomed to the structure and format of the current guideline may need to invest some effort in locating specific annexes. The structure of the regulation consists of:

- Considerations;
- Articles;
- Annexes.

Most of the annexes from the Machinery Directive still exist in the Regulation. However, the structure of the annexes has been rearranged in the Machine Regulation. However there are some exceptions. For instance, the regulation no longer includes an annex containing the requirements for the CE marking (former annex III). Table 1 below provides an overview of all annexes in the Machinery Directive, with references to the corresponding annexes in the regulation.

Subject of the attachment	Machinery Directive 2006/42/EC	Machinery Regulation 2023/1230
Essential health and safety requirements	I	III
Declaration of Conformity (Doc)	II	V
CE Marking	III	Article 19 refers to EU/765/2008
Categories of hazardous machinery (High risk)	IV	I (part A and part B)
Safety components (indicative)	V	II
Technical file	VI	XI
Technisch Dossier	VII (A en B)	IV (A en B)
	VIII	VI
	IX	VII
	X	IX
	-	X
Minimum criteria for notification of inspecting bodies	XI	Article 30

Table 1 – Rearrangement of Attachments

Table 2 - Presents the rearrangement of the subjects in the articles of the Machinery Regulation in relation to the Machinery Directive.

Machinery Directive 2006/42/EC	Machinery Regulation 2023/1230	Machinery Directive 2006/42/EC	Machinery Regulation 2023/1230	Machinery Directive 2006/42/EC	Machinery Regulation 2023/1230
Article 1	Article 2	Article 11	Article 43, 44 and 45	Article 21	Article 53
Article 2	Article 3	Article 12	Article 25	Article 22	Article 48
Article 3	Article 9	Article 13	Article 11	Article 23	Article 50
Article 4	-	Article 14	Article 26 up to 42	Article 24	-
Article 5	Article 10 and 11	Article 15	Article 5	Article 25	Article 51
Article 6	Article 4	Article 16	Article 23 and 24	Article 26	-
Article 7	Article 20, paragraph 1	Article 17	Article 46	Article 27	-
Article 8	Article 6, paragraph 1 and 7	Article 18	Article 49	Article 28	Article 5, first paragraph
Article 9	-	Article 19	-	Article 29	Article 54 second and third paragraph
Article 10	Article 44, paragraph 3	Article 20	-		

Table 2 – Rearrangement of Articles

### Essential safety and health requirements

The essential health and safety requirements are the most important for machine builders/engineers. As indicated in Table 1, these requirements are now included in Annex III of the Regulation. Generally, the structure and subjects on which requirements are set have not changed. However, additional requirements have been introduced for certain subjects such as machine learning, cybersecurity, and safety software. This reflects the increasing role of automation and digitization in machines. For example, safety PLCs are being used more frequently, and machines are being equipped to communicate with remote systems. It is obvious that the regulation now establishes requirements to ensure the continued safety of machines in these aspects. Below is a summary of some amended essential requirements in the regulation. Please note that this is not a complete overview of all changes.

Requirement paragraph regulation	Brief description of the change and/or new requirement
1.1.2	A requirement has been added stating that machine (controls) must be designed and built so that the user can test safety functions when needed. Instructions and test procedures must be provided so that the user can perform these tests.
1.1.9	When a machine is designed to be able to communicate wirelessly or otherwise) with other devices, it should not lead to dangerous situations.  There must be special attention spent on the safety controller. There are specific requirements made to prevent accidental or intentional changes to the security software can be made that could create dangerous situations. The Machine controller must 'collect evidence' (logging) of any conscious or unconscious intervention in the safety software.
1.2.1	The safety controller of the machine must be designed so that the safety functions and associated settings cannot simply be changed, beyond the limits set by the manufacturer in the risk assessment of the machine has established. This also applies to possible future changes by an operator and for changes as a result of machine learning applications.

Requirement paragraph regulation	Brief description of the change and/or new requirement
	In addition log files should be maintained regarding modifications to the security-related software, which will be uploaded by the manufacturer after commissioning. These log files should be kept at least be 5 years after uploading and must be provided of the correct version data. Although it's not literally mentioned, it seems logical that in addition from the log files also the source code of the modified software should be kept.
1.6.2	When designing the machine access and access openings should be considered. These must make it be possible that when a calamity takes place, users can be rescued out of the machine. Also pay attention to the use of any life-saving equipment.
1.7.4	In the machinery directive is explicitly mentioned that the instructions must be included in the language or languages of the member state in which the machine was placed on the market or put into service. In the regulation is stated in article 10 that the instructions must be compiled language that can easily be understood by the user, established by the member state in which the machine was placed on the market. Whether this in practice will lead to broader possibilities will have to be seen. Additionally misses this regulation the obligation to apart from the translation.
2.2	The requirement regarding hand-held and/or hand-guided portable machinery is modified to capture or reduce emissions of hazardous substances.
2.4	There is a completely new chapter added specific for machinery serving the production of crop protection and pesticides.
3	In the chapter specific to mobile machinery several requirements have been added related to autonomous mobile machinery, remote monitoring and battery-powered mobile machinery.
3.2.2	For mobile machinery where there is a significant risk of tipping or overturning, the regulation must prevent movement of the machine when the present belt is not in use. Otherwise an audible signal should be given when the driver isn't wearing the belt. It is also explicitly added that the design of the bely system should take the ergonomic aspects into account.
3.5.3	Relating to mobile machinery there is also an requirement that these must be provided with cabs with filter overpressure devices or equivalent safety measures when the mobile machine is intended to be used with hazardous (fine) substances.
3.5.4	Lastly there is regarding to mobile machinery a completely new requirement added to prevent accidents, when mobile machinery comes into contact with high-voltage power lines.
6.2	For machinery intended for lifting persons there is the possibility has been added to apply controls, to control the carrier to pre-selected entry/exit positions (stop position). This can of course only be done when the safety of the persons can be secured. These controls can be used instead of applying buttons with the 'hold-to-run'- principal.

Table 3 - Description of the changes and/or new requirements

### **Dangerous machinery (formerly 'Annex IV machines')**

One of the consequences of the re-arrangement of the annexes in the Machine Regulation is that the popular term "annex IV machines" cannot be used anymore. Instead, these machines are included in Annex I of the Regulation.

An important difference from the Machinery Directive is that the list is divided into two parts, each with a specific assessment procedure.

- **Part A: The manufacturer applies one of the following procedures:**
  - a) EU type-examination procedure (Module B) as described in Annex VII, followed by an internal control of production based on that type (Module C) as described in Annex VIII of the regulation. (Examination of a complete product produced in series and assessment by the manufacturer that each product conforms to the type for which it has been type-approved).;



- **b)** Conformity assessment based on full quality assurance (Module H) as described in Annex IX of the Regulation. (Assessment of the manufacturer's quality system by a notified body).

**c)** Conformity assessment based on verification of 'unit verification' (Module G) as described in Annex X of the Regulation. (Assessment of the Technical Documentation by a Notified Body).

- **Part B: The manufacturer applies one of the following procedures:**

**a)** The procedure for internal production control (Module A) as described in Annex VI of the Regulation.

**b)** The EU type-examination procedure (Module B) as provided in Annex VII, followed by an internal production control based on that type (Module C) as described in Annex VIII of the Regulation. (Examination of a complete product produced in series by a notified body and assessment by the manufacturer that each product conforms to the type for which type-approval has been granted).

**c)** Conformity assessment based on full quality assurance (Module H) as described in Annex IX of the Regulation. (Assessment of the manufacturer's quality system by a notified body).

**d)** Conformity assessment based on 'unit verification' (Module G) as described in Annex X of the Regulation. (Assessment of the Technical Documentation by a Notified Body).

Summarized, for machines listed in part A, a conformity assessment procedure must be followed at all times, requiring the involvement of a conformity assessment body (CBI, formerly Notified Body). For the "dangerous machines" as stated in part B, the same rules apply as in the Machinery Directive. This means that a conformity assessment procedure with a CBI only needs to be completed if the machine cannot be designed and built fully in accordance with machine-specific harmonized standards (type C standards).

What is also new in the regulation is that the European Commission must periodically reassess the distribution of hazardous machinery between Annex I part A and part B. This may result in:

- Machines being moved between parts A and B;
- Machines being added to part A or to part B;
- Machines being removed from part A or from part B.

This reassessment will be conducted initially two years after the regulation is into force and every five years thereafter.



Annex I - Categories of machinery or machinery products to which one of the procedures referred to in Article 21 paragraph 2 and 2a must be applied

No.	Part A (procedures as described in Article 25 paragraph 2 are applicable):	Part B (procedures as described in Article 25 paragraph 3 are applicable)
1		Circular saws (single-leaf and multi-leaf), for the machining of wood and materials with similar physical properties or for the machining of meat and materials with similar physical properties. [see the regulation for a complete listing]
2		Surface planers with manual feed for woodworking.
3		Single-sided planers with integrated feed, with manual feed and/or discharge for woodworking.
4		Band saws for the following type: with manual feed and/or discharge for processing wood and materials with similar physical properties. Or for the processing of meat and materials with similar physical properties. [see the regulation for a complete listing]
5		Combined machinery of the points 1 to 4 and 7 types for the machining of wood and materials with similar physical properties.
6		Tenoning machines with different spindles with manual feed for woodworking.
7		Milling machines with vertical axis, with manual feed for the machining of wood and materials with similar physical properties or for the machining.
8		Portable chainsaws for woodworking.
9		Presses, including bending machines, for cold metal working, in which the material is fed and/or removed by hand and the and the movable tools can have a stroke length of more than 6 mm and a speed of more than 30 mm/s.
10		Machines for injection and compression molding of plastics with manual feed or discharge of the material.
11		Machines for injection and compression molding of rubber with manual feed or discharge of the material.
12		Machines for underground works of the following types. [see the regulation for a complete listing]
13		Hand-loaded garbage trucks with press system.
14	Removable mechanical transmission systems, including their	
15	Shields for removable mechanical transmission systems	
16	Lifts for vehicles	
17		Hoisting and lifting equipment for lifting of persons or for lifting of persons and goods for which a danger of free fall of more than three meter exists.
18	Portable fastening devices with explosive charges and other striking tools.	
19		Protective devices for the detection of persons.
20		Power-operated interlocking movable guards for the protection in items 9 (part A), 10 and 11 (part B) meant machinery.
21		Logic units to ensure safety functions.

Annex I - Categories of machinery or machinery products to which one of the procedures referred to in Article 21 paragraph 2 and 2a must be applied

No.	Part A (procedures as described in Article 25 paragraph 2 are applicable):	Part B (procedures as described in Article 25 paragraph 3 are applicable)
22		Tilt protection devices (ROPS)
23		Falling Structures to protect against falling objects (FOPS)
24	Safety components with full or partially self-learning behavior (AI) utilizing machine learning, intended to be applied in safety functions.	
25	Embedded systems for machines with full or partial self-learning behavior (AI) using machine-learning, intended to be applied in safety functions but which have not been brought to market separately.	

Table 4 – Overview of Categories of Hazardous Machines from Annex I, Parts A and B



### EU declarations (Annex V of the regulation)

Similar to the Machinery Directive, the Machinery Regulation includes two declarations of conformity that are subject to the requirements in Annex V:

- The EU declaration of conformity (for all machines and machine products falling under the directive).
- The EU declaration of incorporation for partly completed machines.

The essence of these statements remains the same in the Regulation compared to the Machinery Directive. Manufacturers declare, under their own responsibility, the compliance of the relevant machine with product legislation and the applied (harmonised) standards. However, there are minor differences and additional items. Here's a brief summary of the differences per statement:

#### General changes apply to both statements:

- The regulation has established a template specifying the content requirements for the statement.
- Additionally, the option to assign a unique number, "No...", to the statement has been introduced.
- It is now specified that a color photo clearly depicting the relevant machine may be used for its identification.
- When referring to the applied (harmonised) standards, it is explicitly indicated that the year/version of the standard must also be stated. While most manufacturers already did this, it is now clearly emphasized.
- Another change is the requirement to indicate which parts of a (harmonised) standard have been met when a standard has only been partially applied. This requirement, although sometimes already met by manufacturers, has now been explicitly included.

#### Changes to the EU Declaration of Conformity (for all machines and machine products):

- If an EU Declaration of Conformity is issued for a 'substantially modified' machine, it must be clearly stated on the declaration what the original machine was.

- For hoisting and lifting machines intended to be permanently installed in a building or construction, and that cannot be mounted at the manufacturer's manufacturing location, the declaration must mention the address of the final place of use where the machine will be installed.
- Finally, the statement must clearly indicate the assessment procedure that has been applied. This requirement applies not only when a procedure with a notified body has been completed (module B/C, G, or H), but also when the manufacturer has assessed that the machine complies with all applicable requirements. In the latter case, it must be indicated that conformity has been assessed through internal manufacturing assessment (Module A).

#### Changes to the EU declaration of incorporation (for partly completed machines):

- The same requirement regarding the mention of (partially) applied (harmonised) standards, as with the EU declaration of conformity, has now been added to the declaration of incorporation for partly completed machines.

#### Technical Documentation (TD):

In general, the requirements for the Technical Documentation remain the same. The Technical Documentation must still be compiled and retained for at least 10 years, aiming to substantiate that the machine in question has been placed on the market or put into service in accordance with the applicable essential health and safety requirements. Some clarifications and minor additions have been made. The most significant change here (although most machine manufacturers already complied) is the inclusion of the source code of the safety-related software.



# When should a change be considered 'substantial'?

In recent years, there has been much discussion about the concept of 'substantial modification'. There is a lack of clarity about when a change should be regarded as substantial and what the consequences are. One of the causes of these discussions and the lack of clarity is that there is no 'legal definition' of a substantial modification. There is currently no definition for both product legislation and occupational health and safety legislation. Only in guide documents such as the Blue guide 2022 and the guide to application of the machinery directive 2006/42/EC edition 2.2 is the concept of substantial modification summarily described. This means that there are no exact criteria for determining whether or not a change should be regarded as substantial. In addition, these guide documents have no legal status, which leaves a lot of room for interpretation. In line with consideration 3 in the Machinery Regulation (improvement, simplification and adaptation to market needs), the Machinery Regulation now includes a definition of a substantial modification in Article 3 paragraph (16).

This definition reads as follows:

A "substantial modification means a modification of a machine or related product by physical or digital means after that machinery or related product has been placed on the market or put into service, which is not foreseen or planned by the manufacturer, and which affects the safety of that machinery or related product by creating a new hazard or by increasing an existing risk, which requires:

- (a) The addition of guards or protective devices to that machinery or related product the processing of which necessitates the modification of the existing safety control system, or;
- b) The adoption of additional protective measures to ensure the stability or the mechanical strength of that machinery or related product;

This definition lends itself perfectly to be presented in a flowchart. This flowchart can be used as an aid to determine whether an intended change to an existing (in use) machine should be regarded as a substantial modification. See Figure 1 for this flowchart. Depending on the answers to a number of questions, this can be used to determine whether a change should be regarded as a 'substantial modification' or not.



# Three fictitious examples to illustrate the use of the flowchart

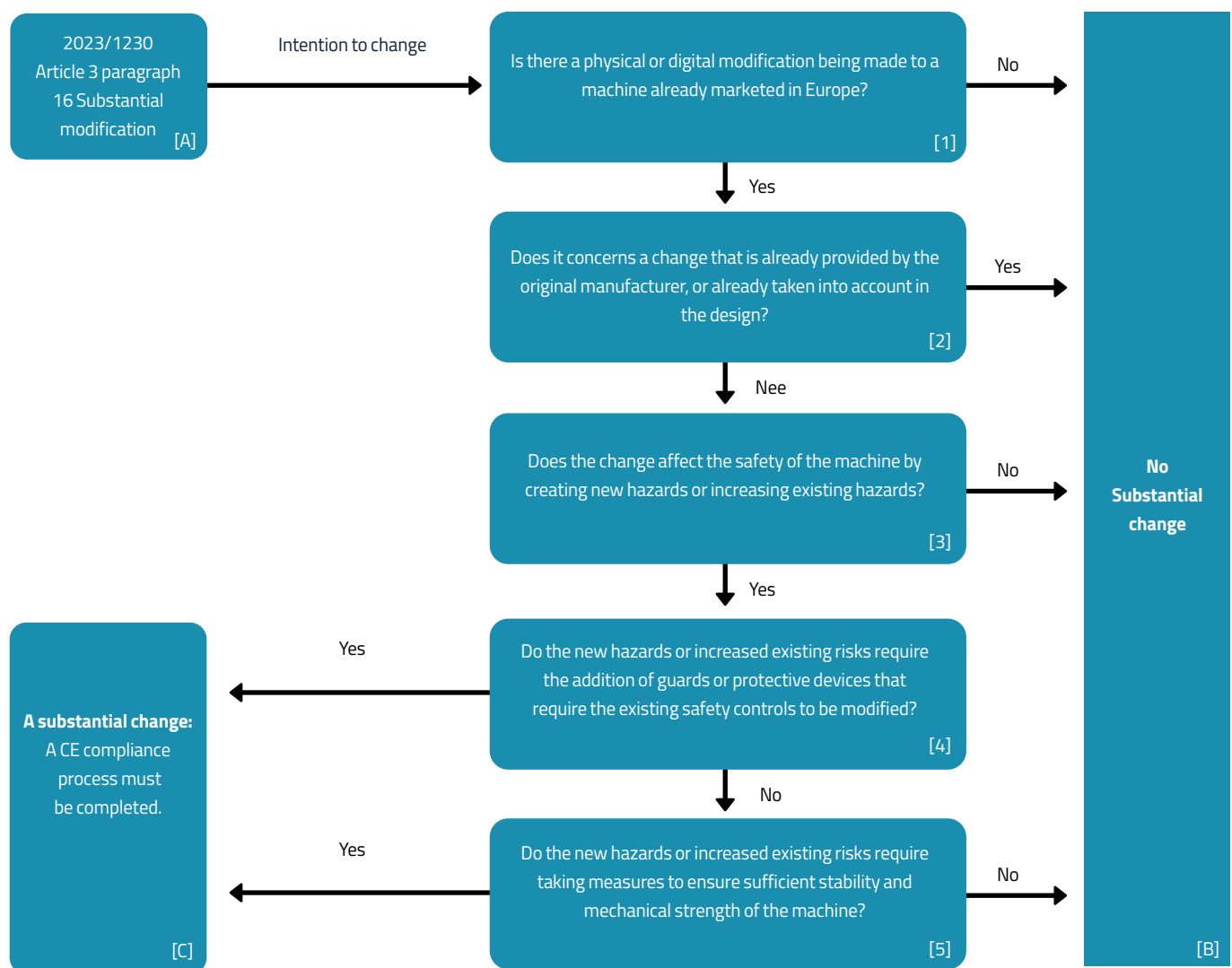


Figure 1 – Flowchart for Substantial Modification Based on the Machinery Regulation

Below is a brief explanation of each block in the flowchart in Figure 1.

Reference to figure 1	Explanation
[A]	Here is being referred to the definition of the substantial change which is included in the machine regulation (2023/1230) in Article 3 paragraph 16. This is the definition as cited in the text above.
[1]	<p>The first questions can be subdivided in two-sub questions namely:</p> <ul style="list-style-type: none"> <li>▪ Is the machine which is going to be changed already in Europe (read European economical space) on the market/ put into service?</li> <li>▪ Is there going to be a physical or digital change to that machine?</li> </ul> <p>The first question is relevant because a substantial change is only applicable on the machines that are already on the market in Europe. When it namely concerns an existing machine that has not yet been placed on the European market, would for this machine, according to recital 9 of the regulation, a CE-track based on the machinery ordinance would have to be completed anyway.</p> <p>When you want investigate if an intended change of a machine should be seen as a substantial change, the second-paragraph can already be answered by default with 'yes'. In principle is after all every change of a machine a physical or digital change. Important here is the realization that only a change in the software or possibly even in parameters of, for example, a frequency converter or servo-drive, could theoretically lead to a substantial change. In practice this will be due to the questions in blocks [4] and [5] only be the case when a change that results in a modification of the safety control is necessary. Or when additional measures must be taken to ensure the stability and safety.</p>
[2]	<p>In theory it can be the case that the manufacturer of the original machine may already have taken the intended change into account. Sometimes a manufacturer has already taken any future enhancements or options into account. In addition the machine will often be sized more liberally in the design than required for the specific application.</p> <p>In those cases where the change actually stays inside the original design principles and preconditions of the machine, the change doesn't need to be considered as a substantial change. When this isn't evidenced by the instruction manual and the original manufacturer is no longer in the picture or does not want to comment on this, so that this question can't be answered 'yes' with certainty, the question has to be answered with 'no'.</p>

<sup>2</sup> Regardless of whether the machine already has a CE marking or was placed on the market before 1995.

Reference to figure 1	Explanation
[3]	<p>This question forces the change manager to perform a risk assessment related to proposed change of the existing machine. With other words, there has to be investigated if the change has a negative influence on the safety of the original machine.</p> <p>Note, this means that there shouldn't be implanted a complete risk assessment of the entire machine, but there should be investigated (and substantiated) if because of the change new dangers origin or existing risks be increased. To decide this the complete impact of the change on the original machine should be made insightful.</p> <p>Hereby it's also important to realize that a good risk-reducing measure or security enhancement of a machine in the usage phase in most cases doesn't need to be seen as a substantial change. This aspect is currently is still sometimes seen as a barrier from the RI&amp;E of an item of work equipment implement risk-reducing measures.</p>
[4]	<p>When from the survey at point 3 is shown that the change nevertheless has a negative effect on the safety of the machine (there is a new danger introduced or an existing risk has increased) to which risk-reducing measures must be taken that have impact on the safety controls, the change must be considered as a substantial change.</p> <p>However, where because of the change for example a new danger is introduced becomes which is already adequately shielded by an existing shield or with a fixed shield in a simple manner can still be easily shielded, may consider this change as no substantial change.</p> <p>This also means that just an adjustment to the safety controller or adding guards and safeguards to an existing machine (for example, following a Risk executed Inventory &amp; Evaluation) must not be seen as a substantial change when because of that change no new dangers are introduced or existing risks are increased.</p>
[5]	<p>When the change has a negative effect on the safety of the machine, but there are no adjustments required from the safety controller (point [B]), has yet to be considered if the concerned new danger or increased risk related to the stability and strength of the machine to which additional measures should be taken to ensure sufficient strength and stability. An example of this could be a capacity increase by a higher machine speed which would require constructive adjustments must be made to ensure the stability of the machine to continue to guarantee stability.</p>
[B]	<p>When you based on the 5 questions in the flowchart come out in the block 'no substantial change', that means that the changes don't have to be executed within the scope of the machinery regulation. The changed machine doesn't have to be CE-marked (again) before it may be put back into use.</p> <p>This of course, does not mean that with the change there shouldn't be thought about (machine) safety. Only the legal framework within which the safety of the modified machine must be considered must be considered is different. In the Netherlands, an existing work equipment must comply with the Working Conditions Decree. When an item of work equipment is changed, it must be ensured that the modified work equipment still complies with the Working Conditions Decree compliant.</p> <p>In the Working Conditions Act is also indicated that risk-reducing measures resulting from an RI&amp;E (as a result of the change) must still be carried out as much as possible in accordance with the state of the technology.</p> <p>Freely translated, it can be said that all reduction measures should be implemented in accordance with European standards as much as possible.</p> <p>Obviously it can be necessary to actualize work instructions and instruct personnel properly about how there should be worked safely with the changed work tool.</p>



Reference to figure 1

Explanation

[C]

When by going through the flow chart is concluded that the change has to be seen as a substantial change, it means that a CE compliance process should be executed (again), based on the Machinery Regulation.

Besides the added definition that when the Machinery Regulation comes into effect will get a 'legal status', there are also a few considerations and practices described about how there should be dealt with a substantial change.

**Machinery Regulation (26):**

"...In order to ensure the compliance of such a product with the relevant essential health and safety requirements, the person that carries out the substantial modification should be required to perform a new conformity assessment before placing the modified product on the market or putting it into service. In order to avoid an unnecessary and disproportionate burden, the person carrying out the substantial modification should not be required to repeat tests and produce new documentation in relation to machinery or related products that are part of an assembly of machinery, and that are not affected by the modification."

This means that by a substantial change it must be made easy to understand what the influence of the change on the existing machine is. For the parts of the machine where the change doesn't have any influence, it is not required to execute the tests and tribulations again and is also not required for those parts to prepare new documentation as part of the technical file retroactively ('reversed engineering'). This view is in accordance with the 2022 published Work Instruction of the Dutch Labor Inspectorate.

However, it should be noted here that in accordance with Article 18 of the Machinery Regulation in the conformity assessment the complete changed machine should be viewed. The new CE-marking and the to be issued new EU- declaration of agreement will after all be applied on the completely changed machine and only the on the change or changed parts. The 'change manager' is hereby 'manufacturer' in within the meaning of the Machinery Regulation

When a consumer modifies a machine himself (in the barn) for his own use, that person is not seen as the manufacturer of the changed machine according to the machine regulation article 18. When a company drastically changes a machine for own use (use for own personnel) this exception does not apply and a CE- conformity process shall be completed.

As said a new EU-declaration of agreement has to be compiled by the manufacturer of the changed machine. However in accordance with annex V of the regulation it must be mentioned that is concerns a substantial changed machine. Hereby it should be made clear what the brand/type of the original machine is.



### Three fictitious examples to illustrate the use of the flowchart

#### Adding additional emergency stop buttons to a pallet wrapper

A production company with various production machines has just carried out an RI&E of the work equipment. This shows that a pallet wrapper must be fitted with additional emergency stop buttons at a number of locations. This must be done inside and outside the fencing. (see Figure 2). Pressing these emergency stop buttons must stop the pallet wrapper drive.

Based on the existing electrical diagrams, the technical service has assessed that the emergency stop buttons can be included to the existing emergency stop circuit of the machine (possibly with its own emergency stop relay).

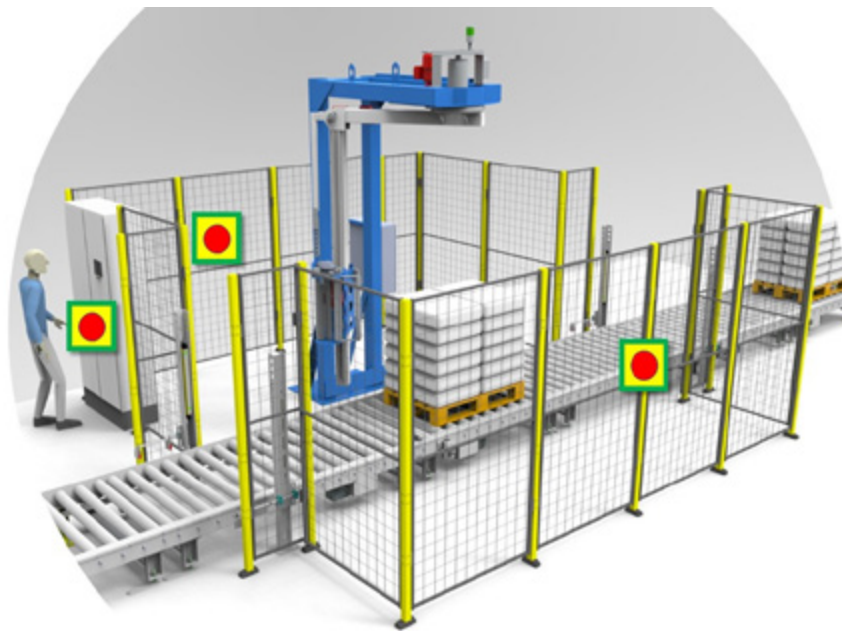


Figure 2 - Machine to which the user wants to add some emergency stop buttons

To assess whether this intended change of 'the machine pallet wrapper' should be regarded as a substantial modification, we will go through the questions from the flowchart in Figure 1 below:

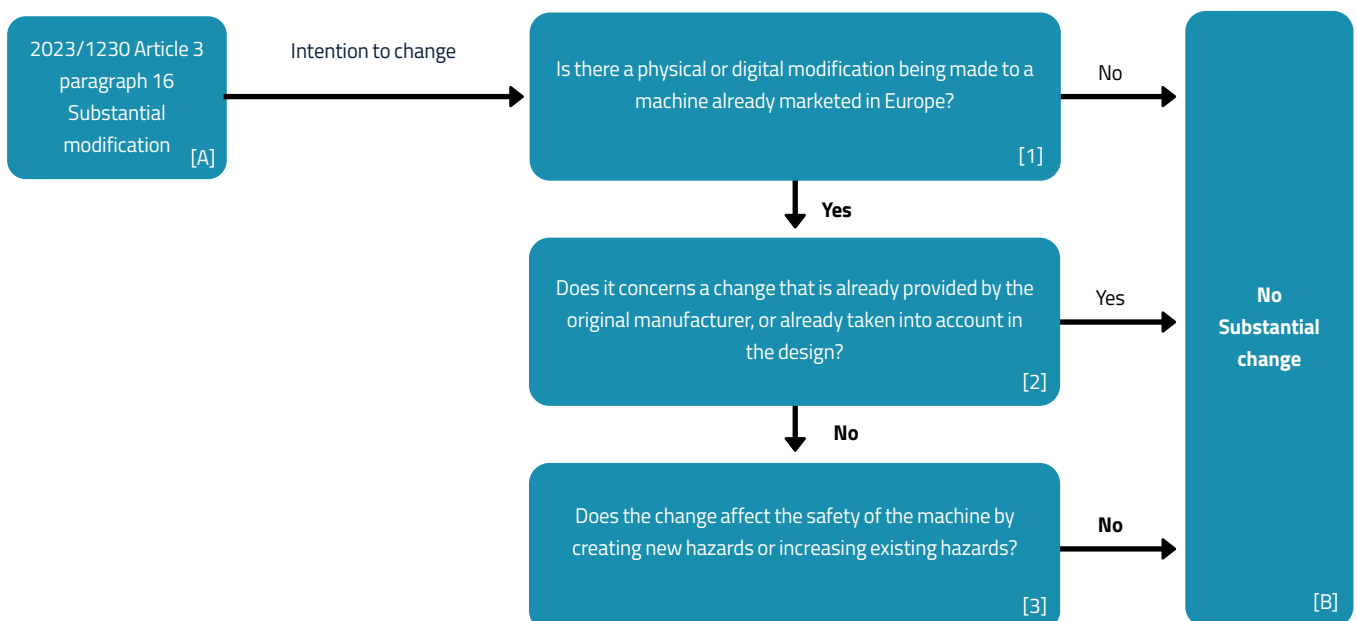


Figure 3 - Completed Flowchart for Adding Emergency Stop Buttons

Based on the assessment that adding emergency stop buttons for this specific situation does not lead to new hazards or increase existing risks, this change can be regarded as a non-substantial modification. It is of course important that the change is carried out with good craftsmanship and that the state of the art of machinery is followed as much as possible. In this case, this would practically mean that the emergency stop buttons can be added to the existing control system on the basis of the emergency stop standard (EN ISO 13850) and the Performance Level standard (EN ISO 13849-1/2). It is important that this is properly secured and that the change is documented correctly.

### **Example 2: Increasing the wrapping speed of a pallet wrapper**

A production company with various production machines wants to increase the production capacity of an existing line by 20%. To achieve this, it was decided to increase the wrapping speed of the pallet wrapper at the end of the production line. This is done by adjusting the gears.

Based on the operating instructions and existing electrical diagrams, the technical service has assessed that this should not be a problem with regard to the control. However, it has been concluded that the current construction and foundation is probably not able to withstand the changed dynamic forces. Additional measures are taken for this, such as strengthening some critical parts of the construction and by enlarging the base. In addition, the base is provided with additional braces and foundation points.

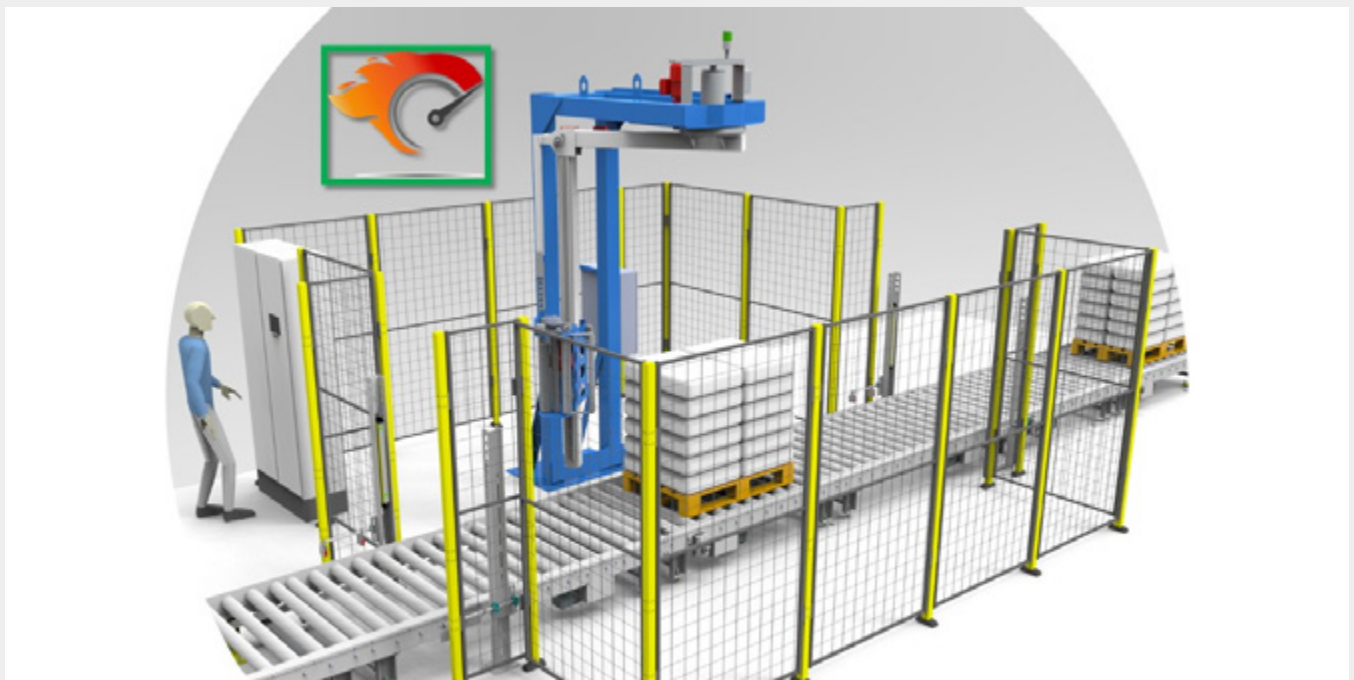


Figure 4 - Machine where the user wants to increase the winding speed

Again, to assess whether this intended change of 'the machine pallet wrapper' should be regarded as a substantial modification, we will go through the questions from the flowchart in Figure 5 below:

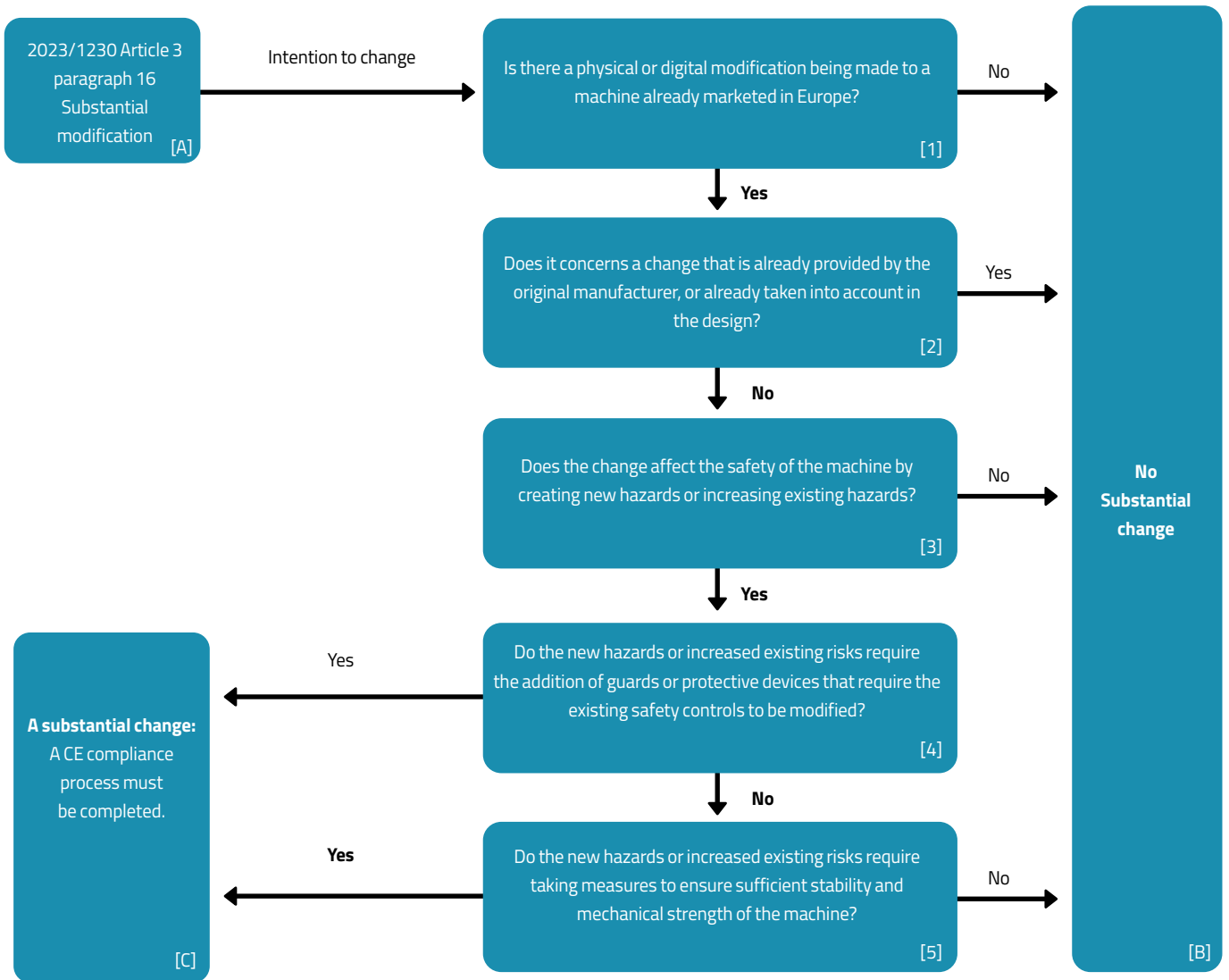


Figure 5 - Completed Flowchart for Increasing Pallet Wrapper Capacity

In this example, the company should consider the proposed change as a substantial modification, as increasing the wrapping speed may cause the pallet wrapper to become loose from the foundation. Consequently, there is a higher risk of parts breaking off, which can lead to an increased likelihood of accidents. While the manufacturer may have anticipated this risk in the original machineries design, the proposed change considerably increases the risk. Therefore, it is necessary to implement constructive safety measures to ensure that step [5] in the flowchart should be answered with "Yes".

**Example 3: Adding a heating element**

A production company with various production machines intends to use special foil for a new customer. The customer specifies that it is necessary to heat the foil before wrapping it around the products. Based on the user manual and existing electrical diagrams, the technical service has assessed that controlling the heating element should not be a problem. However, it has been identified that several new hazards will be introduced due to this modification. The addition of the heating element creates touchable hot parts, and depending on its placement and location, there is a risk of crushing between the heating element and the wrapper. To reduce these risks, the following additional measures must be taken:

- Install perforated shielding to reduce the likelihood of touching hot parts and minimize the risk of burns.
- Ensure that heating is performed using a specialized device, similar to a hairdryer. This way, warm air will only be blown against the film in one specific area, eliminating the possibility of entrapment between the heating element and the wrapper.
- Place a sign near the heating element itself (if not already provided by the manufacturer) to warn against the presence of hot parts.



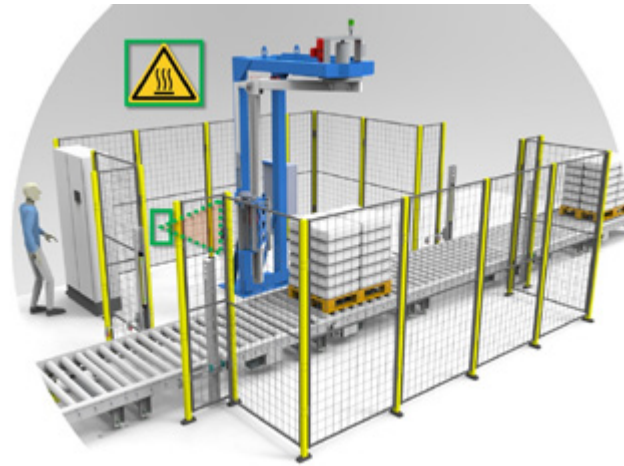


Figure 6 - Machine where the user wants to add an ionizer

Similar to the previous examples, to assess whether this intended change of 'the machine pallet wrapper' should be regarded as a substantial modification, we will go through the questions from the flowchart in Figure 7 below:

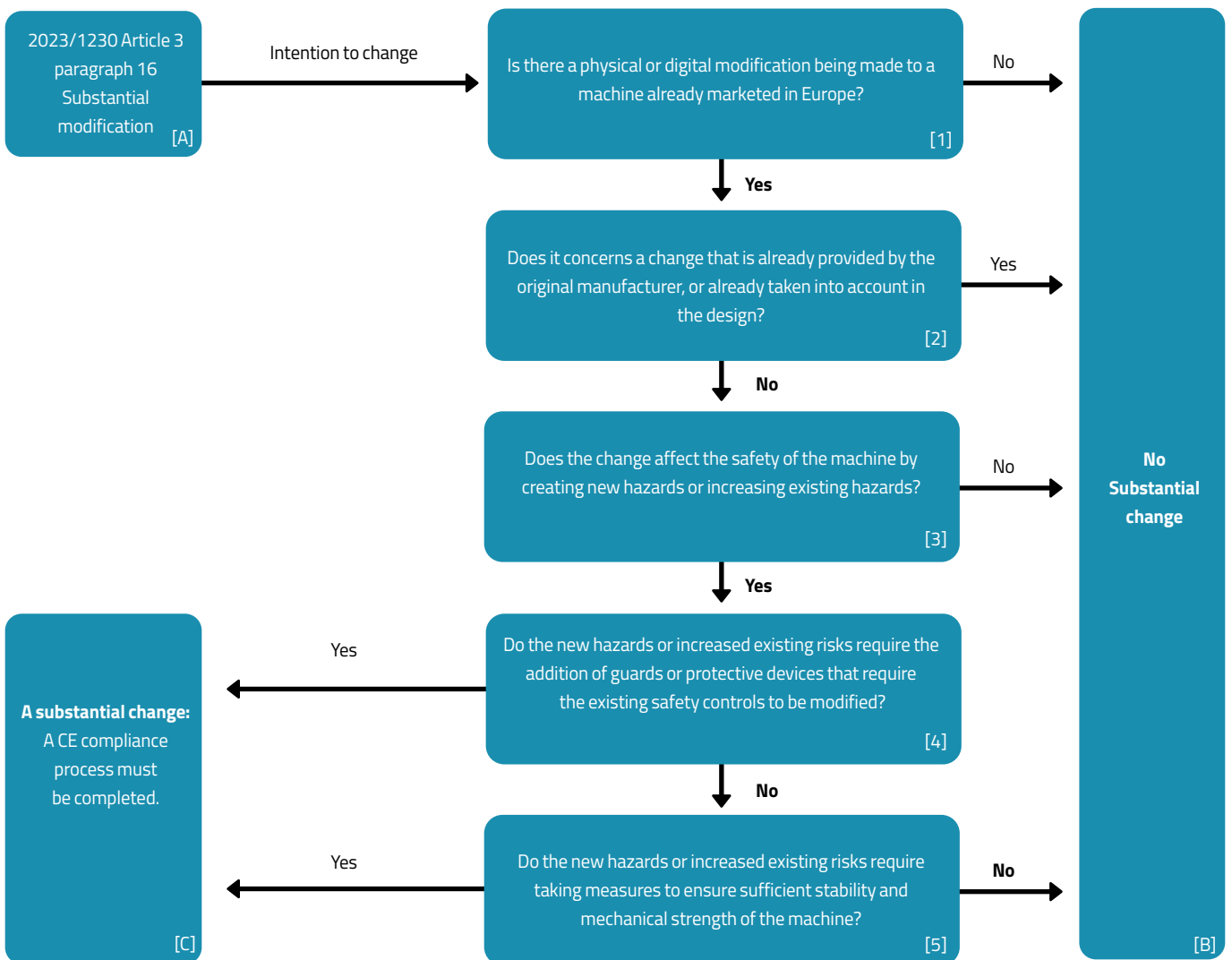


Figure 7 - Completed Flowchart for Adding a Heating Element

In this example, the intended change is not considered as a substantial modification. Despite that new hazards are introduced, the risk mitigating measures do not require a modification of the safety control [4]. No measures are required to ensure the strength and stability of the machinery [5]. Of course this means that, similar to the first example, it is still safe to use the modified machinery by the companies personnel.

# Need help with implementing the new Machinery Regulation?

Machine safety is crucial throughout the design, use, and maintenance of machinery. It is essential to ensure that employees can work safely while complying to laws and regulations. Whether it's a packaging machine or a complex locking system, regardless of size, at Kader, we provide expert advice on all types of machinery. The main areas in which we offer guidance on machine safety include CE marking, Work Equipment Directive, Testing and Inspection Plan, Functional Safety (Performance Level and Safety Integrity Level), and LOTOTO.

If you require assistance or advice on any of these topics, please do not hesitate to contact us!



# About Certification Experts

Certification Experts is part of Kader Group within the Business Unit Consultancy & Interim, Product Compliance. As an integral part of Kader Group, our mission is to assist our clients in enhancing the quality of the living environment. Since our establishment in 1995, Certification Experts has been dedicated to facilitating business expansion into new markets while ensuring the safety of our clients' products. We provide specialised expertise and compliance services covering a wide range of product safety requirements. From CE marking to US-compliance and beyond, we empower product designers, manufacturers, exporters, importers, and distributors to penetrate their target markets successfully. Our extensive knowledge comes from combining technical and legal skills, which we use in areas such as product safety, design, quality assurance, technical documentation, and testing facility utilisation. We believe safer products are better products, advancing and improving our interactions with everything around us.



**Check it out**  
[certification-experts.com](https://certification-experts.com)



[certification-experts.com](https://certification-experts.com) | [info@certification-experts.com](mailto:info@certification-experts.com)