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What is classified as Machinery?

In order to understand what is covered under the machinery directive, it is important comprehend what is meant by the term “machinery”, and hence understand the products that fall under this directive. For the scope of Directive 98/37/EC, “Machinery” means an **assembly of linked parts or components, at least one of which moves**, with the appropriate actuators, control and power circuits, etc., **joined together for a specific application**, in particular for the processing, treatment, moving or packaging of material. The term also covers an assembly of machines which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole.



This original definition was expanded to include a list of equipment considered to be machinery, among which are:

- multi-purpose equipment, for example a removable load carrying
- truck safety components

There is a list of equipment excluded from the scope of the Directive, because they are – or will be - subject to more specific regulations. They include machines for medical use, lifting equipment, mobile equipment, special equipment for use in fairgrounds and/or amusement parks, etc (*refer to Article 1 Par. 3*).

For further information regards the classification of Mechanical Equipment you are referred to this [flowchart](#), which should guide you in finding the directives which apply for your mechanical equipment.

## **What are the essential health and safety requirements relating to the design and construction of machinery and safety components?**

Directive 98/37/EC expresses the essential health and safety requirements of machinery and safety components , in terms of objectives and divides these requirements into two categories:

- **common requirements** for all machinery (*found in Annex I, Para. 1*), e.g. controls and on/off circuits, mechanical risks, requirements for protectors and protective devices, maintenance, etc.
- **additional specific requirements** (*found in Annex I, Para. 2*) that apply to machinery where there are specific risks or risks linked to particular operating constraints such as food hygiene, lifting, mobility, etc.

## What other requirements does the directive imply?

The Machinery Directive requires:

- Appropriate measures to be taken to ensure that machinery and safety components placed on the market and put into service do not endanger the health and safety of persons.
- Manufacturers or their authorized representatives to certify their machinery as conforming to the provisions of the Directive relating to essential health and safety requirements. A technical construction file must be established to demonstrate conformity. Signing an EC declaration of conformity authorizes the manufacturer or his authorized representative to affix the CE mark to the machinery, which indicates that the product is conform to the directive requirements.
- Certain types of machinery, judged as being the most dangerous or requiring special safety components, to have independent support from a notified body via an EC type examination or a certificate of adequacy for the technical construction file.
- Manufacturers or their authorized representatives to perform a risk assessment for normal and abnormal operating conditions as part of the design process.



## What is Directive 2006/42/EC?

The current EC Machinery Directive, 98/37/EC, is to be replaced by the new Machinery Directive, 2006/42/EC, with effect from 29 December 2009. Following many years of negotiation, the revised version of the directive has been adopted by the European Parliament and the Council of Ministers and was published in the Official Journal of the EU on 9 June 2006.

The **revised Machinery Directive 2006/42/EC** does not introduce any radical changes compared with the current Machinery Directive 98/37/EC but aims to consolidate the achievements of the Machinery Directive in terms of free circulation and safety of machinery while improving its application.

The Member States have until **29<sup>th</sup> June 2008** to adopt and publish the national laws and regulations transposing the provisions of the new Directive into national law. The provisions of the new Directive become applicable on **29<sup>th</sup> December 2009**. Until that date, the provisions of the current Machinery Directive 98/37/EC continue to apply.

## **What are the differences between Directive 98/37/EC and 2006/42/EC?**

As we have already noted, the changes between the current and the revised directive are minimal, in fact most of the essential health and safety requirements of the current Directive have remained unchanged and for the most part the same numbering has been retained.

### **Extended Scope**

The proposal extends the present scope of Directive 98/37/EC to

- 1) Portable cartridge operated devices, such as fixing tools, stunning pistols, marking guns etc., where the cartridge is not direct-acting and which are designed for industrial or technical purposes only. Appliances in which the cartridge is direct-acting are considered as firearms and remain outside the scope of the Machinery Directive;
- 2) Construction site hoists intended for lifting persons or persons and goods; and
- 3) Devices for lifting of persons with reduced mobility.
- 4) Incomplete machinery

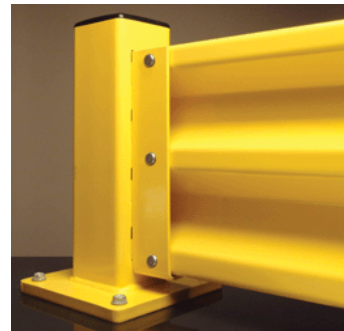


The revised machinery directive also clarifies the relationship between the Low Voltage Directive (73/23/EEC) and the Machinery Directive to avoid the danger of overlapping.

Furthermore, it introduces an amendment to the Lifts Directive so as to exclude those lifting devices which are covered in the Machinery Directive.

### **Additional Essential Requirements**

The main changes concern additions to the essential requirements like more thorough requirements on ergonomics, noise measurement and vibration, and more stringent requirements for the fixings on fixed guards. In future the fixings for fixed guards will either have to stay attached to the machine when the guard is taken off, or stay attached to the guard.



Further, additions to the list of machines for which more stringent conformity assessment are to be applied, are also present in the reviewed directive.

### **Other Amendments**

The Directive also entails the addition of a full quality assurance procedure to the present possibilities for conformity assessment. This will enable a manufacturer to establish a quality assurance system rather than submit every new machinery for an EC type-examination by a notified body.

Another subtle difference between the old and new Directive that will affect machine importers is that 2006/42/EC requires that the technical documentation file and a copy of the Declaration of Conformity is kept in the European Economic Area by the “authorized representative of the manufacturer”. This brings the Machinery Directive into line with other CE Directives which already require this.

## **Is there a transition period for application of Directive 2006/42/EC?**

In general, there is no transition period, in the sense of a period during which both the current Machinery Directive and the new Machinery Directive are applicable (with one exception: there is a transition period until 29th June 2011 for the particular case of portable cartridge-operated fixing and other impact machinery).

However there is a period of adaptation, since the provisions of the Directive 2006/42/EC become applicable on 29th December 2009. During this period, all of the stakeholders concerned will be able to take the necessary steps to ensure a smooth transition from the current Directive to the new Directive.

## **Can manufacturers anticipate application of the new Machinery Directive?**

Yes and no. Manufacturers can and should anticipate application of Directive 2006/42/EC from a practical and technical point of view, however, from a formal, legal point of view, the Directive cannot be applied before 29th December 2009.

From the practical and technical point of view, manufacturers are encouraged to review their products without delay and adapt them as necessary to take account of the requirements of the new Directive. While machinery placed on the market before 29th December 2009 must continue to comply with Directive 98/37/EC, it can be assumed that a product that complies with the essential requirements of the new Machinery Directive continues to comply with the current Directive.

## **Do the Directives apply to second-hand machinery?**

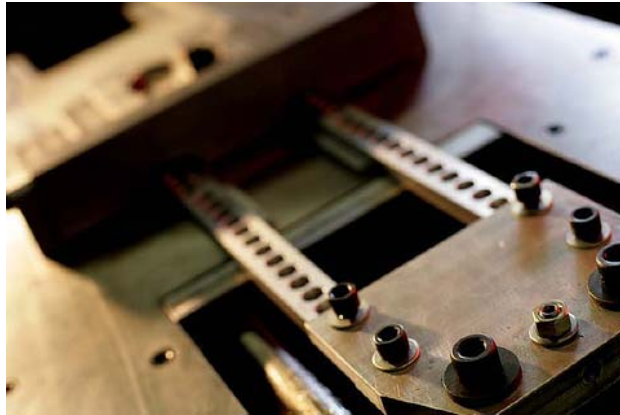
The answer to this query depends on the origin of the second hand machinery.

**1. For Second hand machinery that was already in the EEA zone**

Here we are dealing with second-hand work equipment or protective means which has already been used in a country of the EEA and is once again being placed on the EEA market. The fact of being placed once again on the market assumes that the second-hand machinery has passed the stage of first being placed on the market and first being put into service in the EEA. Hence since it has already been placed on the EEA market, it should already be compliant with the essential requirement set out in the directive and is presumed to be so.

**2. For Second hand machinery that was in a third country**

Machinery in service in a third country has never been placed on the market in the EEA. When such machinery leaves the third country and crosses the frontier of the EEA it counts as being placed on the market in the EEA for the first time. As such, all European Directives are applicable, and the machinery must meet all the obligations of new machinery.



**Whatever the machinery origins, however, the Directive on the general safety of products is always applicable.**

The General Product Safety Directive covers products sold to users, including second-hand products. It is supplementary to "new approach" Directives and national regulations.

The main obligations imposed by the Directive on the general safety of products are:

- The supplier has the general obligation to inform the consumer.
- The supplier may be obliged to recall products.
- The supplier must meet the general obligation of safety deemed to be met by complying with the technical annexes of the respective technical harmonization Directives, with national regulations, with the state of the art, with standards and with codes of good practice

**What is reconditioned machinery? Do the Directives apply to reconditioned machinery?**

By reconditioned machinery we understand existing machinery which has undergone technical work designed to modify its condition, its performance, its safety, etc. This work may consist of modifying the machinery to a greater or lesser extent.

The applicability of the machinery directive to reconditioned machinery depends on the degree of reconditioning of the machine.

### **1. Normally Reconditioned Machines**

Since reconditioned machines have been already placed on the market, then the machinery directives do not re-apply. Apart from this it is useful to consider that "New approach" Directives were designed exclusively for new products or for products regarded as new.

The point at which a machine becomes "new" will depend on the particular circumstances of each case but in the opinion of the UK authorities it becomes new if the reconditioning changes the specification of the product, the nature of the hazards or increases the levels of risk associated with the machinery.

In addition, European Provisional Answer 22 states:

*"If the work is carried out on a new machine, it seems hard to imagine that there will be no consultation between the original manufacturer and the reconditioner. One part of the risks is dealt with by the original manufacturer and the other part by the reconditioner. Only **one** person can sign the declaration of conformity, and that person is then responsible for the finished machine's conformity with the Directive and must be qualified to respond to a substantiated request for the technical file. Only **one** CE marking is affixed to the machinery. If the work is done without the agreement of the original manufacturer, the reconditioner assumes responsibility for the entire machine and must therefore reconstitute the technical file for the assembly."*



### **2. Highly Reconditioned – "Reconstructed" or "Rebuilt"**

Where existing machinery is completely "stripped down" and only a few original parts remain, the question arises as to whether this is reconditioned machinery or new machinery consisting partly of "recovered" components. In our opinion, the "reconditioner" can decide to consider this machinery as "new". This machinery has undergone effective "reconstruction". It is ecological "new" machinery in a way in that it consists, entirely or in part, of recovered parts. "Reconstructed" machinery ties in well with clean and recycled products. In other words, the original machinery has not been used by the renovator as initial machinery, but as a source of spare parts in order to make something new.

In this case, the machinery directive is clearly applicable.

**Whatever the degree of reconstruction of the machinery, the Directive on the general safety of products is always applicable.**

The General Product Safety Directive covers products sold to users, including second-hand products. It is supplementary to "new approach" Directives and national regulations.

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### ***Relevant Legal Notices***

***LEGAL NOTICE 369 of 2004:***

<http://docs.justice.gov.mt/lom/Legislation/English/SubLeg/427/36.pdf>

### ***Relevant Guidance documents***

[http://ec.europa.eu/enterprise/mechan\\_equipment/machinery/guide/content.htm](http://ec.europa.eu/enterprise/mechan_equipment/machinery/guide/content.htm)