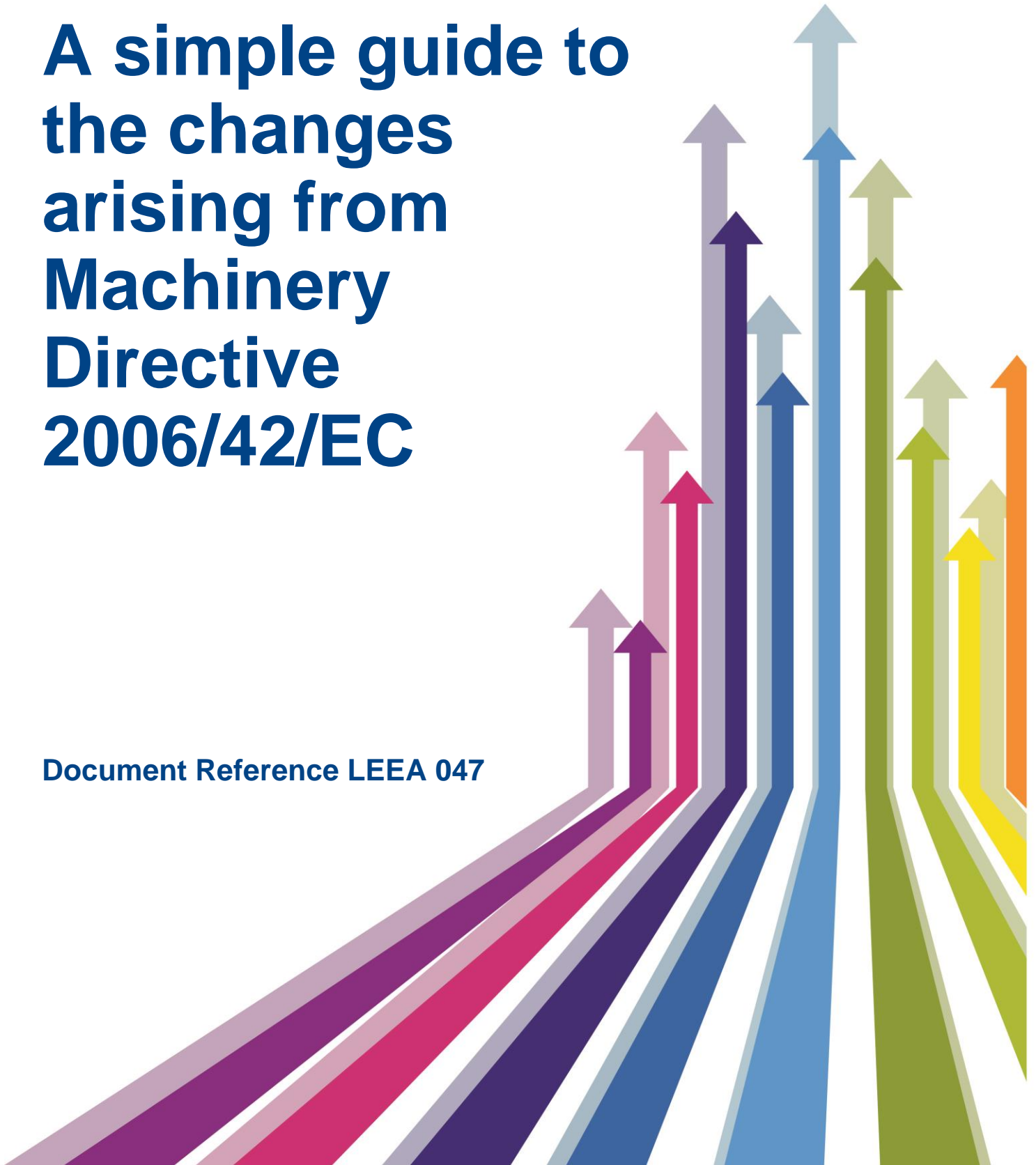


# A simple guide to the changes arising from Machinery Directive 2006/42/EC

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## 1.0 Introduction

The Machinery Directive 2006/42/EC replaces the original Directive and various amendments dating from 1992. It makes some changes to the requirements which are relevant to lifting equipment. This guide is intended to highlight those changes and, where necessary, provide clarification of the requirements.

For the first time there is an official guide to the application of the Directive published by the European Commission. It is available on their web site at:

<http://ec.europa.eu/enterprise/sectors/mechanical/machinery/>

For anyone who is not familiar with European Directives, this guide starts with an overview of the principles on which the Machinery Directive is based.

## 2.0 Overview of the principles

The Machinery Directive is one of a series of product Directives intended to remove technical barriers to trade within the European Economic Area. It applies to all power operated machinery and to manually operated lifting machines and lifting accessories. An item within the scope of the Directive must comply with the requirements before it can legally be placed on the market in the EEA. However no member state can add to those requirements. Hence any item which complies can be sold in any member state without further technical hindrance.

Directives do not apply directly to individual citizens. Instead they require member states to implement them within the state's legal system. In the UK the Machinery Directive is implemented by The Supply of Machinery (Safety) Regulations 2008. This is Statutory Instrument (SI) 2008 number 1597. These regulations came into force on 29<sup>th</sup> December 2009 and replaced earlier regulations with a similar name.

The Directive contains 'essential health and safety requirements' (EHSRs) which are replicated word for word in the UK regulations. The essential health and safety requirements are the objectives to be met rather than the method of meeting them. This approach ensures a good minimum standard of health and safety whilst allowing manufacturers to innovate and improve their technology. It does, however, place the responsibility to comply on the manufacturer or, for products imported into the EEA, whoever is responsible for first placing them on the market in the EEA.

The manufacturer is required to identify the potential hazards associated with his product and the risks arising from them. He must then eliminate the risks or reduce them to an acceptable level in a hierarchical manner starting by designing out the hazard wherever possible, guarding those which cannot be designed out etc. The last resort is the instructions for use.

The manufacturer must keep the ingredients of a technical file which in effect is the evidence that his product meets the essential health and safety requirements. The information to be contained in this file is specified in the UK regulations. (See Schedule 2 Part 7)

To show that his product complies, the manufacturer must issue an EC declaration of conformity and affix the CE marking. The information required in this declaration is specified in the UK regulations. (See Schedule 2 Part 2)

To assist manufacturers in meeting their responsibilities, there are standards with a special legal status. These are the harmonised European Standards. If a product complies with a harmonised standard it is deemed to comply with the Directive in so far as the standard addresses the requirements of the Directive. In practice most harmonised standards do address all the relevant requirements but, in any case, every harmonised standard includes information about the requirements they address.

Compliance with a harmonised standard is an option and is not mandatory. However they do act as a benchmark of accepted technology by which any alternative specification may be judged.

### **3.0 Changes introduced by Machinery Directive 2006/42/EC**

In the context of lifting equipment, the significant changes arising from the new Directive are briefly described in the following sections.

#### 3.1 General

The Directive has been restructured to properly integrate lifting equipment which was a later addition to the original Directive. Hence the definitions relevant to lifting equipment which were in section 4 of the EHSRs have been moved to Article 2. Similarly the documentation and marking requirements specific to lifting equipment are now presented as an addition to the general requirements whereas previously they were instead of the general requirements.

#### 3.2 Scope

The scope of the Directive includes lifting accessories. Previously, although there were essential health and safety requirements applicable to lifting accessories, they were not mentioned in the scope, leading to some confusion. Previously there were also 'separate lifting accessories'. That term is no longer used.

The scope includes partly completed machinery for which an EC declaration of incorporation is required. Previously the purpose of the declaration of incorporation was unclear.

#### 3.3 Definitions

Unfortunately the Directive uses the term 'machinery' in two ways. First as a generic term to mean everything within scope except for partly completed machinery. In this sense it includes slings and other lifting accessories. Second it is used as a specific term to mean machinery in normally accepted sense, that is an item with parts which move under some source of power. Because of this dual use, some guidance is necessary when reading the essential health and safety requirements.

The definition of 'lifting accessory' ends with "slings and their components are also regarded as lifting accessories". Again guidance is necessary to correctly understand this statement and is explained later in this document.

The definition of 'manufacturer' allows for own branding of machinery manufactured by others. In effect the manufacturer is the natural or legal person taking responsibility for the machinery. Official guidance § 79 explains this further.

#### 3.4 EC declaration of conformity or incorporation

There are three significant additions to the information to be included in these documents.

- (a) The name and address of the person authorised to compile the technical file, who must be established in an EEA state.
- (b) The place and date of the declaration.
- (c) The identity and signature of the person empowered to draw up the declaration on behalf of the responsible person (previously the requirement for a signature was only implied). The official guide explains that the identity of the person is understood as comprising his or her name and position.

In addition the declaration of incorporation must include information about the extent to which the EHSRs have been addressed. (See Schedule 2 Part 2 1B4 of the UK Regulations)

A copy of the declaration of conformity or incorporation, as appropriate, must accompany the machinery and the original must be retained for at least 10 years from the date of last

manufacture. Previously, although there was a requirement to issue the appropriate declaration, it was never stated to whom it should go.

The official guidance is that the copy which must accompany the machinery is a physical document. An electronic document alone is not acceptable.

Some manufacturers issue a generic DOC. Official guidance § 383 allows this. It states “In the case of machinery produced in a large series, it is possible to draw up a single EC DOC covering a range of series numbers or batches, in which case the range covered by the declaration must be specified . . .” and is followed by “In any case, the necessary identification must be provided to ensure the link between each item of machinery and the EC DOC that applies to it.”

The declarations must be in one of the official languages of the member state where the machinery is placed on the market. Official guidance §246 lists the official languages of the EU and EEA states.

### 3.5 CE marking

The CE marking is affixed to show that a product complies with the relevant Directive(s). It has always been an offence to affix the CE marking to any product which does not comply with the EHSRs. The new Directive also makes it an offence to affix it to a product which is not within the scope of a Directive. There has been confusion about the marking of some components which has now been clarified. (refer to section 4.2 point 3 of this guidance)

### 3.6 Control systems (EHSR 1.2.1)

There is a new requirement for cable-less control systems (ie remote controls) to have an automatic stop which must be activated when correct control signals are not received, including loss of communication.

### 3.7 Marking of machinery (EHSR 1.7.3)

These general requirements apply to all machinery and now include the business name and full address of the manufacturer and, where applicable, the manufacturer’s authorised representative. The guidance states that for products too small to bear legible markings of all the information required, the marking can be on a durable label attached to the product. Alternatively information such as the full address may be provided in the form of a code provided the full address is given in the instructions supplied with the product. (See official guidance §250)

The marking must include the year of construction, that is the year in which the manufacturing process is completed. It is an offence to pre-date or post-date the machinery when affixing the CE marking.

For further guidance on marking requirements, refer to LEEA 059.

### 3.8 Instructions

The instructions must accompany the machinery and be in the official Community language(s) of the EEA state in which it is placed on the market or put into service. There is an exception allowed for maintenance instructions intended for use by specialised personnel.

There is a new requirement to include the words “Original instructions” or “Translation of original instructions” as appropriate. When a translation is supplied it must be accompanied by the original instructions. The content of the instructions is more detailed than previously. (See EHSR 1.7.4.2)

The instructions for lifting accessories must include the static test coefficient used. (See EHSR 4.4.1) This is the value used for design and the minimum required for test purposes. It is not

the actual value measured in a test and will not, therefore, change from batch to batch. Such instructions may be in a commercial document such as a catalogue. However if so a copy of the catalogue must be provided with each lifting accessory or batch of lifting accessories. (See official guidance §360)

### 3.9 Fitness for purpose (EHSR 4.1.3)

This EHSR adds a new requirement to perform the static and dynamic tests on all lifting machinery. Previously the static test requirement was expressed as a design criteria. (refer to 4.2 paragraph (1)).

## **4.0 Official guidance on Machinery Directive 2006/42/EC and further explanation**

The official guidance to the new Directive was first published in December 2009, only a few days before the Directive came into force. Even then it was not completely clear about some matters such as the documentation and marking requirements applicable to chains, ropes, webbing, lifting accessories and components for slings. Additional official guidance was published in June 2010 which clarified most matters.

The following sections outline the relationship between the Machinery Directive and specific components or forms of lifting equipment.

To keep this guidance brief, the justification included in the official guidance has been omitted.

### 4.1 Chains, ropes and webbing

- (1) Only chains, ropes and webbing designed and constructed for use in lifting equipment are within the scope of the Directive and subject to the requirements.
- (2) An EC declaration of conformity must be issued by the manufacturer or his authorised representative.
- (3) The chain, rope or webbing must be marked with the information required by 1.7.3 and 4.3.1. This includes the CE marking.
- (4) 4.3.1 (c) requires *'the test method used.'* If the test method specified in a harmonised standard is used, it is sufficient to state the standard.
- (5) 4.3.1 (d) requires *'the maximum load to which the chain or rope should be subjected in service.'* Stating the minimum breaking force will fulfil this requirement.
- (6) The documentation and marking requirements apply only to the initial placing on the market and do not apply to lengths cut from them by distributors or others in the supply line. However the information will be required by whoever uses the cut lengths. Therefore distributors of chains, ropes and webbing must ensure that the relevant EC declaration of conformity, the reference of the certificate setting out the characteristics of the chain, rope or webbing and the manufacturer's instructions are passed on with the cut lengths supplied to manufacturers of lifting machinery or lifting accessories or to users.

### 4.2 Lifting accessories and components

- (1) Paragraph 2 of 4.1.3 requires *'the static and dynamic tests referred to in section 4.1.2.3 must be performed on all lifting machinery ready to be put into service.'* In this context, machinery has the specific meaning defined in Article 2 and does not apply to lifting accessories.

- (2) 4.1.2.5 (f) requires tests to be carried out in order to verify that the components of lifting accessories have been designed and constructed with an adequate working coefficient. For chains, ropes or webbing, the minimum breaking force should be specified by the manufacturer in the relevant certificate. For other components, the tests can be carried out by the component manufacturer or the manufacturer of the lifting accessory.

If a component or a lifting accessory is manufactured as a single item or in a small series, it may not be practicable to carry out tests that would render the item unusable. In that case, the lifting accessory manufacturer must verify by other appropriate means, such as design calculations, that the component used to make up the lifting accessory has an adequate working coefficient.

- (3) Article 2 defines a lifting accessory and ends '*slings and their components are also regarded as lifting accessories*'. However a component not assembled into a sling and which cannot be used on its own is outside the scope of the Directive. Many such components are made to the EN 1677 series of standards. This series has harmonised standard status which is not affected by the guidance as the products they are used to make are within the scope of the Directive.

Therefore components such as links, hooks and coupling components used in slings are outside the scope and not subject to the requirements. They should not be CE marked and do not require an EC declaration of conformity. However the sling manufacturer will require information about the component for his technical file. Components made to the EN 1677 series will have a manufacturer's certificate containing this information. The sling manufacturer must affix the CE marking to the complete sling and issue an EC declaration of conformity for it.

It is possible that a component, such as a master link which would normally be outside the scope of the Directive, is placed on the market as a lifting accessory. In that case, whoever places it on the market as a lifting accessory should affix the CE marking and issue an EC declaration of conformity for it.

Conversely an item, such as a shackle which is normally a lifting accessory, may be supplied to be part of a larger assembly such as a lifting beam. Nevertheless it should be CE marked and have an EC declaration of conformity.

#### 4.3 Lifting machines

- (1) Paragraph 2 of 4.1.3 requires '*the static and dynamic tests referred to in section 4.1.2.3 must be performed on all lifting machinery ready to be put into service.*' In this context, machinery has the specific meaning defined in Article 2 and therefore applies to both hand operated and power operated lifting machines. This new requirement is particularly relevant to hand operated lifting machines, many of which have not been individually tested in the past.

The guidance does allow a derogation "For some categories of machinery produced in series, where the production techniques employed and the application of a duly documented quality control system make it possible to guarantee that every machine produced will have identical characteristics when fully assembled, static and dynamic tests on adequate samples of the machinery can be considered as fulfilling the requirement set out in the second paragraph of section 4.1.3." However experience has shown that most manufacturers of hand chain blocks and lever hoists could not fulfil the requirements to qualify for this derogation.

- (2) Partly completed machines are now clearly within the scope of the Directive. This is relevant to those who, for example, sell or purchase an electric hoist without controls

to be incorporated into an overhead crane. The hoist should be accompanied by an EC declaration of incorporation and the information necessary for the end product manufacturer's technical file.

#### 4.4 Lifting structures

Lifting structures such as mobile gantries, slewing jib cranes and runways are often sold without a lifting machine. The Directive and official guidance do not deal with this situation. The matter was referred to the editor of the official guidance but we have not yet received a reply. It was then referred to the person at HSE who represents the UK on matters concerning the Directive at the European Commission. An interim response on his behalf has provided the following guidance:

1. Structures in themselves cannot be considered as partly completed machinery, unless something on the structure "moves" and is fitted with or intended to be fitted with a drive system other than directly applied human effort, thereby bringing into scope of the directive.
2. If the structure doesn't move, but forms part of the lifting equipment, then the Technical File for the completed installation would require information on the design and build of the parts of the structure which forms part of the lifting equipment. If the requirements for the structure were very simple, then it may be sufficient to include a fixing specification in the instructions..
3. Alternatively, if the "structure" can be considered as "equipment" and the lifting machine cannot operate until it is fitted to this (eg a gantry crane) then the lifting machine would be classed as partly complete machinery and the person fitting it to the "equipment" would have to carry out the final CE marking etc. This is different under the new Machinery Directive as "equipment" has been added to the items partly completed machinery needs to be added to. If "Structures" had also been added this may have solved the problem, but they were not.
4. Unless a CE mark and Declaration of Conformity has been issued for the complete lifting machine/structure then under UK legislation the installed machine is subject to a LOLER thorough examination prior to first use, to check its installation to ensure it is correct and safe to use.

This last point implies that, for example, when a trolley and block are fitted to a runway, a LOLER thorough examination is required. In this instance if the trolley and block are supplied with a EC Declaration of Conformity and the runway has a report of test and thorough examination as defined in BS 2853, the examination is a simple check of the assembly in terms of correct fitting and functionality. If the runway does not have a report of test and examination then, the installation examination would require installation thorough examination of the runway including any supplementary testing.