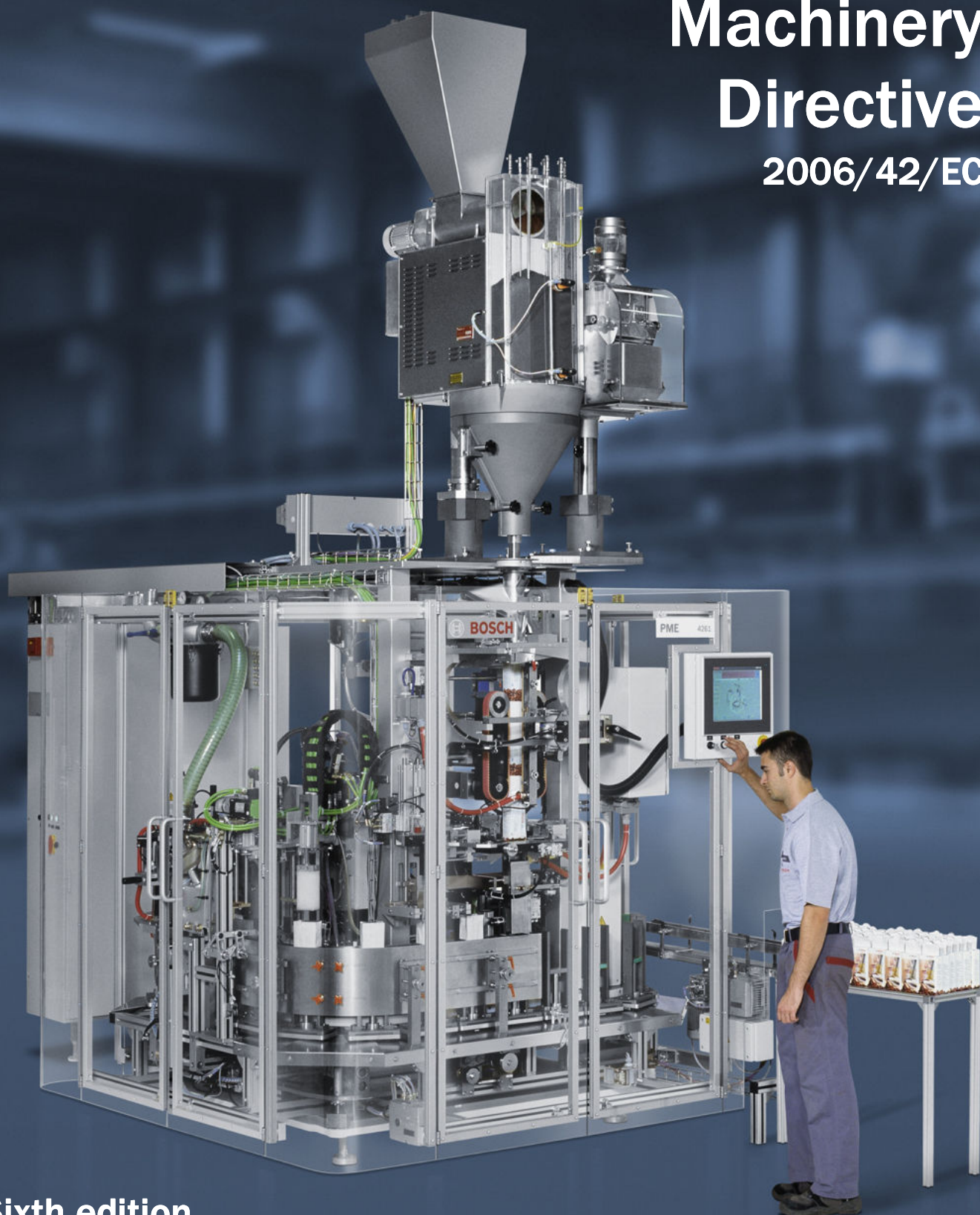


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Guide to The New Machinery Directive 2006/42/EC



Sixth edition

Published by Damte Ltd

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MachineBuilding.net has prepared this guide with support from Pilz Automation Technology, Procter Machine Guarding and Southco Europe; contributions made in the chapter *Industry comments* are gratefully acknowledged. Front cover image courtesy Robert Bosch Ltd www.bosch.co.uk

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Guide to the new Machinery Directive 2006/42/EC

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Introduction

Machinery Directive 2006/42/EC became applicable on 29 December 2009, superseding the Machinery Directive 98/37/EC. While the two are broadly similar, there are significant differences that affect machine builders, those performing final assembly and CE marking of machinery, and those placing imported machinery on the market in the European Economic Area (EEA), Switzerland and Turkey.

This guide highlights differences between the new and old Directives and provides information that will aid compliance with the new requirements. However, it remains the reader's responsibility to ensure compliance with the requirements of the Directive.

Background

Since 29 December 2009 Directive 2006/42/EC has regulated the placing on the market, and the putting into service, of machinery in the EEA, replacing the existing Directive 98/37/EC. This recasting of the Machinery Directive, which is a comprehensive amendment, is intended to extend the scope, improve clarity, remove some of the acknowledged flaws that existed in the old Directive, provide an optional route to conformity assessment through quality assurance for manufacturers of some types of machinery, especially prototype and bespoke machinery, and introduce provisions for market surveillance.

National Governments are required to implement the Directive through their own legislation; the UK Government has done this by introducing new Machinery Regulations.

Timescales

This is not the first time that the Machinery Directive has undergone changes. It was originally known as Directive 89/392/EEC, then it was amended by Directives 91/386/EEC and 93/68/EEC. Directive 98/37/EC was created to consolidate the original Directive and its amendments.

In 2001 the European Commission proposed to amend Directive 98/37/EC and, following protracted negotiations, an agreed text was published in late 2005.

Directive 2006/42/EC was published in the Official Journal of the European Union on 9 June 2006 as the third amendment of the Machinery Directive.

National Governments had until 29 June 2008 to transpose the Directive into their domestic legislation. Here in the UK, Statutory Instrument 2008/1597 *The Supply of Machinery (Safety) Regulations 2008* came into force on 29 December 2009 in accordance with the Directive. The new Regulations replace the Supply of Machinery (Safety) Regulations 1992, as well as the 1994 and 2005 amendments.

CEN (the European standards organisation) had until 29 December 2009 to adapt approximately 650 Harmonised standards to the new Directive, though this task was not completed on time.

On 29 December 2009 the new Directive became applicable and the old Directive was repealed. There was no transition period except for cartridge-operated fixing and other impact machinery, which were previously excluded from the Machinery Directive; for these there was a transition period until 29 June 2011.

General overview

Scope

Changes to the scope of the Directive, and the fact that Article 24 of the new Machinery Directive also amends the Lifts Directive 95/16/EC, mean that construction site hoists are now included, and lifts with a travel speed no greater than 0.15 m/s are excluded from the Lifts Directive; these are now subject to the Machinery Directive instead.

Cartridge-operated fixing and other impact machinery are no longer excluded from the Machinery Directive.

Whereas the old Directive stated that the Low-Voltage Directive (LVD 73/23/EEC) should be applied in situations where the risks are mainly electrical, Article 1 of the new Machinery Directive identifies specific types of equipment to which the LVD (now 2006/95/EC) should be applied. Note, however, that the essential health and safety requirements of the LVD have become part of the Machinery Directive requirements for electrical equipment.

As with other 'New Approach' EU Directives, the new Machinery Directive applies to machinery placed on the market and put into service throughout the EEA—which consists of the EU Member States and Iceland, Norway and Liechtenstein—plus Switzerland and Turkey have harmonised their laws with the new Machinery Directive.

Partly completed machinery

Whereas the old Directive referred to 'machinery which cannot function independently' the new Directive introduces—and more clearly explains—the concept of 'partly completed machinery.' Under the new Directive, a manufacturer of partly completed machines or his authorised representative must prepare the relevant technical documentation, assembly instructions and declaration of incorporation. Note that authorities can perform market surveillance on partly completed machinery, though Article 11 is not applicable, this being the Safeguard clause that provides for unsafe machinery to be withdrawn from the market or prohibited from being placed on the market or put into service.

Essential health and safety requirements

At the heart of the Directive are the essential health and safety requirements (EHSRs) and these have been clarified and placed in a more logical order. Because of the inclusion of construction site hoists and slow-moving lifts in the revised scope, there are new EHSRs relating to risks associated with lifts serving fixed landings.

The list of standards harmonised to the Machinery Directive 2006/42/EC was first published in the Official Journal on 8 September 2009, though a revised list and additional amendments have been published more recently (see Further information).

It was agreed in the EU Machinery Working Group that prior to 29 December 2009 if a product complied with both Directives the Declaration of Conformity could reference both Directives but should state that 98/37/EC applied until 28 December 2009 and 2006/42/EC applied after that date.

Fixed guards

Something that will affect virtually all machine builders is the change to the way fixed guards must be fastened to the machine. Fixings can no longer be loose; the new Directive states that they must remain attached to either the guards or machinery when the guards are removed.

Conformity assessment

One of the key changes in the new Directive is the liberalisation of the conformity assessment procedures for some types of machinery (listed in Annex IV). If machinery is designed in accordance with the relevant harmonised standards, the new Directive gives manufactures the option to self-certify machinery, thereby avoiding the requirement to deposit the technical file with a Notified Body. For other Annex IV machinery, manufactures can either request EC type-examination by a Notified Body or have a Notified Body approve a full quality assurance system covering design, manufacture, final inspection and testing.



There are changes relating to the Technical File and Declaration of Conformity, and a new Declaration of Incorporation for partly completed machinery.

Market surveillance

The new Directive is more explicit about the duties of the Member States to organise market surveillance (enforcement). Obligations include co-operation between the market surveillance authorities and respect for confidentiality and transparency. In addition, the new Directive draws on material in the General Product Safety Directive, enabling the European Commission to adopt a decision, after consultation of the Machinery Committee, to prohibit or restrict the placing on the market of a category of machines presenting risks to health and safety due to shortcomings in the relevant harmonised standard(s) or by virtue of their technical characteristics, or to make such machinery subject to special conditions.

Certification

Manufacturers that have obtained EC type-examination certificates for their machinery under the old Directive need to request a review of the certification by the Notified Body, as new certificates, issued in accordance with the new Directive, need to be in place for machinery placed on the market after 29 December 2009.

For machinery certified in accordance with Article 8(2)(c) of the old Directive (ie Annex VI machinery for which a technical file has been sent to a Notified Body or a certificate of adequacy issued), manufacturers now need to apply one of the procedures from Article 12(3) and (4) of the new Directive, as the old route to certification no longer exists in the new Directive.

Detailed analysis

Preamble

(5) Construction site hoists intended for lifting persons and persons and goods are now included.

(6) Portable cartridge-operated fixing and other cartridge-operated impact machinery designed for industrial or technical purposes (which had been excluded from the original Machinery Directive by the amending Directive 91/368/EEC) is reintroduced into the scope of Machinery Directive 2006/42/EC.

(9) Provides for the legal framework within which market surveillance (enforcement) can proceed harmoniously.

Article 1 - Scope

1(1) The scope is now:

- (a) machinery
- (b) interchangeable equipment
- (c) safety components
- (d) lifting accessories
- (e) chains, ropes and webbing
- (f) removable mechanical transmission devices
- (g) partly completed machinery



1(2) Exclusions

The new Directive changes the location of the exclusion relating to machinery for which the only power source is directly applied human effort. Hence although the exclusion is absent from 1(2), such machines are in fact still excluded unless they are used for lifting. See Article 2(a) below.

Medical devices are no longer specifically excluded, as the general exclusion for machinery types that are covered by more specific Directives applies. In this case such machinery would normally be covered by the Medical Devices Directive 93/42/EEC, though Article 3 of the M5 version (which became applicable from 21 March 2010) states that where a relevant hazard exists then the machinery shall also meet the essential health and safety requirements in Annex I of the Machinery Directive if they are more specific to the machinery than those in the Medical Devices Directive.

The new Directive excludes 'weapons, including firearms', whereas the old Directive excluded 'firearms.' Crossbows and similar weapons are therefore now excluded.

There is a clearer definition of the means of transport excluded.

Machinery specially designed and constructed for research purposes for temporary use in laboratories is excluded, but note the word 'temporary.'

The following are now excluded, as they are covered by the Low-Voltage Directive:

- Household appliances intended for domestic use
- Audio and video equipment
- Information technology equipment
- Ordinary office machinery
- Low-voltage switchgear and controlgear
- Electric motors

In addition, high-voltage switchgear, controlgear and transformers are excluded.

Article 2 - Definitions

In comparison with the old Directive, formal definitions are provided for many more terms.

2(a) The definition of 'machinery' refers to a 'drive system other than directly applied human or animal effort.' Machinery may therefore be powered by natural sources of energy such as wind or water power. Furthermore, machinery can be powered by manual effort that is not directly applied but stored (eg by means of a spring, raised weight, or hydraulic or pneumatic accumulator) so that the machinery can function after the manual effort has ceased. The fourth indent of 2(a) makes it clear that assemblies of machinery may include partly completed machinery. Note that there is now a harmonised standard for assemblies of machinery (EN ISO 11161:2007+A1:2010, *Safety of machinery. Integrated manufacturing systems. Basic requirements*) whereas no such standard was harmonised to the old Directive.

“The problem is that end users are often unaware that they are responsible for CE marking assemblies of machinery.”

(see Industry comment, page 27)

2(c) There is now a clearer definition of 'safety component' within the body of the Directive, plus there is now an indicative list of safety components in Annex V. Note that the definition of a safety component could be interpreted very broadly to include a wide variety of standard machine components that fulfil a safety function; conversely, safety components that are manufactured by the machinery manufacturer for use on the machinery are *not* subject to the Machinery Directive as such (though these components must enable the machinery to comply with the essential health and safety requirements).

2(g) 'Partly completed machinery' is defined. However, although this point states that a drive system is partly completed machinery, there is no definition for 'drive system.' An internal combustion engine placed on the market for fitting to machinery would count as partly completed machinery whereas most electric motors would not (because they are covered by the Low Voltage Directive).

2(h) Machinery is considered as placed on the market when it is made available in the Community for the first time. While the Machinery Directive does not generally apply to used or second-hand machinery, it does if that machinery is placed on the market or put into service for the first time in the Community having first been made available for distribution or use outside the Community.

2(j) 'Authorised representative' is defined as 'any natural or legal person established in the community who has received a written mandate from the manufacturer to perform on his behalf all or part of the obligations and formalities connected with the Directive.'

“Someone within Europe who can be contacted and, if necessary, made liable should an incident occur.”

(see Industry comment, page 28)

See Annex I, *Essential Health and Safety Requirements*, 1.1.1 for more definitions.

Article 5 - Placing on the market and putting into service

1(f) This states that the CE mark must be affixed. Note that this applies to the products listed in the scope, which includes the safety components listed in Annex V. But although partly completed machinery is included in the scope, it is **not** CE marked (see clause 2 of Article 5).

Article 12 - Procedures for assessing the conformity of machinery

There are some significant changes with respect to conformity assessment. First, there is no longer an option to submit a technical file to a notified body for verification and certification of adequacy. Second, there is a new quality assurance procedure, which is described in Annex X.

Article 13 - Procedure for partly completed machinery

This new Article explains what a manufacturer of partly completed machinery or his authorised representative must do before the partly completed machinery is placed on the market.

Article 24 - Amendment of Directive 95/16/EC

This new Article amends the Lifts Directive, defines 'lift' and 'carrier' and makes it far easier to identify which Directive should be applied.

Article 27 - Derogation

This new Article provides for a transition period until 29 June 2011 for portable cartridge operated fixing and other impact machinery. However, Member States can choose whether or not to apply the derogation, so manufacturers should check the local regulations before placing such machinery on the market if it does not yet comply with the new Machinery Directive.

Annex I - Essential Health and Safety Requirements relating to the design and construction of machinery

Note that the Annex title no longer refers to 'safety components' but, for the purposes of this Annex, safety components are included because they are specified in the definition of 'machinery' given in Article 2.

General principles

The comparable section in the old Machinery Directive ('Preliminary observations') stated that the manufacture 'is under an obligation to assess the hazards' whereas the new Directive states that the manufacturer or his representative 'must ensure that a risk assessment is carried out.' It then goes on to outline the steps that shall be taken in a risk assessment and risk reduction process.

“Machine builders will therefore need to ensure that they have documented their risk assessment procedure.”

(see Industry comment, page 29)

Paragraph 3 (which is virtually identical to paragraph 2 in the old Directive) states: 'The essential health and safety requirements laid down in this Annex are mandatory; However, taking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery must, as far as possible, be designed and constructed with the purpose of approaching these objectives.' Some commentators have suggested that 'as far as possible' might be interpreted as a 'loophole' to enable machinery designed under the old Directive to remain on the market under the new Directive. Anyone considering taking this approach should think carefully about whether a failure to meet the essential health and safety requirements is really justifiable, taking account of the state of the art and the consequences of a market surveillance authority taking action to have the machinery removed from the market.

When considering the state of the art, machine builders should remember that Recital 14 states that they can take account of economic requirements. Machine builders are therefore not expected to implement safety measures that are prohibitively expensive.

Chapter 1 - Essential Health and Safety Requirements

1.1.1 Definitions The new EHSRs (Essential Health and Safety Requirements) contain nine definitions compared with three in the old EHSRs. In particular, paragraph (f) now defines a guard as 'a part of the machinery used specifically to provide protection by means of a physical barrier.' Note, however, that this definition differs from that in the harmonised standard EN 953 (*Safety of machinery. Guards. General requirements for the design and construction of fixed and movable guards*). Moreover, interpreting the term 'specifically' from the Directive in order to relax the requirements relating to parts of the machine such as weatherproof covers and chutes would be incorrect, as they often provide protection, if only as a secondary function.

1.1.2(a) Principles of safety integration This section refers to the 'foreseeable lifetime' and includes within this the phases of 'transport, assembly, dismantling, disabling and scrapping.' In comparison, the old Directive mentioned only assembly and dismantling.

1.1.6 Ergonomics This new section states that 'discomfort, fatigue and physical and psychological stress faced by the operator must be reduced to the minimum possible.'

“In addition, ergonomics should be addressed under many of the other essential health and safety requirements.”

(see Industry comment, page 30)

1.1.7 Operating positions and 1.1.8 Seating These new sections cover these safety-related requirements for operators.

1.2 Control systems This section has changes as outlined below.

1.2.1 Safety and reliability of control systems This section has been expanded. Note that the requirements in this section apply to *all* parts of a control system (not just parts of the safety-related control system) that, in the event of a failure, could lead to the machinery behaving in an unexpected or unintended way.

1.2.2 Control devices This section now states that from 'each' control position the operator must be able to check the danger zones, whereas the old Directive referred only to the 'main' control position. This has implications for machines with multiple control positions, pendant or wireless controls.

1.2.3 Starting This section has been expanded.

1.2.4.2 Operational stop This new section describes the situation where, for operational reasons, a stop is required that does not isolate the energy supply to the actuator(s). Such stop conditions must be monitored and maintained.

1.2.4.4 Assembly of machinery This is essentially the same as the section in the old Directive for 'Complex installations,' with the term 'assembly of machinery' improving clarity.

1.3.9 Risks of uncontrolled movements This new section refers to movements that might occur after a part of the machinery has stopped.

1.4 Required characteristics of guards and protective devices This section contains some important changes as outlined below.

1.4.1 General requirements This section now states explicitly that 'guards must, where possible, protect against the ejection or falling of materials or objects and against emissions generated by machinery.' In the old Directive, there were similar requirements elsewhere for movable and adjustable guards to protect against ejection, and 'emissions of dust, gases, etc' was covered in section 1.5.13

1.4.2.1 Fixed guards This section now states that 'fixing systems must remain attached to the guards or machinery when the guards are removed.' Various types of captive screws, quarter-turn fasteners and other fasteners are available, but machine builders will need to specify these with care if they are to find the optimum combination of purchase cost, installation cost and ease of use.



“It is overkill to require ALL such fixings to be captive.”

(see Industry comment, page 31)

Using wording that is virtually identical to the text in the old Directive, the New Directive states that 'Where possible, guards must be incapable of remaining in place without their fixings.'

“The absurdity of this has been pointed out on several occasions.”

(see Industry comment, page 31)

When considering what type of fixings to use for fixed guards, bear in mind that the definition of a guard in the Machinery Directive is different from that in the harmonised standard EN 953 (*Guards. General requirements for the design and construction of fixed and movable guards*). Furthermore, EN 953 states: 'Where it is foreseen (eg maintenance) that the fixed guard will be removed then the fastenings shall remain attached to the guard or to the machinery.' The standard can therefore be interpreted as **not** requiring retained fasteners to be used if it is not foreseen that the guards will be removed for maintenance, cleaning or other reasons. Of course, the final choice of fixings and tools will depend on the outcome of the risk assessment.

1.4.2.2 Interlocking movable guards This section replaces Section 1.4.2.2 'Movable guards' of the old Directive. Whereas movable guards were previously divided into Type A and Type B guards, the new text refers to interlocking movable guards and movable guards used in association with a guard locking device and an interlocking device. A new addition to this section states: 'Where it is possible for an operator to reach the danger zone before the risk due to the hazardous machinery functions has ceased, movable guards must be associated with a guard locking device in addition to an interlocking device that: prevents the start of hazardous machinery functions until the guard is closed and locked; and keeps the guard closed and locked until the risk of injury from the hazardous machinery has ceased.'

1.5.1 Electricity supply This section now states that 'the safety objectives set out in Directive 73/23/EEC shall apply to machinery.' Note that Directive 73/23/EEC, the Low-Voltage Directive (LVD), has recently been the subject of a codification, requiring a new number 2006/95/EC.

1.5.7 Explosion This section contains less than before, but note that it refers to 'provisions of the specific Community Directives,' ie the ATEX Directives.

1.5.8 Noise and 1.5.9 Vibrations These sections now state that levels of noise and vibrations, respectively, may be assessed with reference to comparative emissions data from similar machinery.

1.5.15 Risk of slipping, tripping or falling This section now refers explicitly to handrails.

1.5.16 Lightning This new section states that 'machinery in need of protection against the effects of lightning while being used must be fitted with a system for conducting the resultant electrical charge to earth.'

1.7 Information This section, previously 'Indicators,' is now more explicit about the format in which information and warnings must be displayed on the machinery.

1.7.1 Information and warnings on the machinery Information written on the machinery (or displayed on a screen or provided via recorded voice messages or a voice synthesiser) must be provided in the official language or languages of the Member States in which the machinery is placed on the market and/or put into service. If the machine user also requires such information in another language then this may be requested but it is outside the scope of the Machinery Directive.

1.7.2 Warning of residual risks Warnings marked on the machine must comply with the same requirements as in 1.7.1.

1.7.3 Marking of machinery The fourth paragraph refers to information that is essential for safe use of the machinery. This information must comply with the same requirements as in 1.7.1.

1.7.4 Instructions Machine suppliers should not assume that users have facilities for reading health- and safety-related instructions that are in an electronic format. A paper copy should be supplied. However, electronic documents offer advantages in terms of security and updates, so it is helpful to provide the instructions in an electronic format as well.

Instructions must be provided in the official language or languages of the Member States in which the machinery is placed on the market and/or put into service. However, instructions that are intended for use by specialised personnel for servicing and similar activities can instead be supplied in a language understood by those users.

1.7.4.1 General principles for the drafting of instructions This new section covers material contained in the old Clause 1.7.4 and contains clearer information about the 'Original instructions' and the 'Translation of the original instructions' supplied with the machinery.

1.7.4.2 Contents of the instructions This new section covers material from the old Section 1.7.4 and is clearer, more explicit and more extensive. For example, it states that each manual must contain, where applicable, (e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery and for checking correct functioning, (l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures employed, (o) the conditions in which the machinery meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns, and (t) the specification of the spare parts to be used, when these affect the health and safety of operators. Paragraph (3) states that the Declaration of Conformity (DoC) or a document setting out the contents of the DoC must be included, though this can be generic, as it does not need to contain the serial number and signature. Note, however, that Annex II still requires the DoC (or Declaration of Incorporation for partly completed machinery) to be drawn up and Article 5 (*Placing on the market and putting into service*), paragraph (e), states that before the machinery is placed on the market and/or put into service the manufacturer or his authorised representative shall 'draw up the EC declaration of conformity in accordance with Annex II, part 1, section A and ensure it accompanies the machinery.'

There is an important change to the requirements relating to information about airborne noise emissions, found in (u). Under the old Directive the sound power level had to be stated when it exceeded 85 dB(A), but the requirement now applies when the sound power level exceeds 80 dB(A).

1.7.4.3 This new section covers material contained in the old Section 1.7.4 and states that sales literature must not contradict the health and safety aspects of the instructions, and sales literature quoting performance characteristics must contain the same information on emissions as the instructions.

Chapter 2 - Supplementary EHSRs for certain categories of machinery

2.1 This section now applies to machinery for foodstuffs, cosmetics and pharmaceutical products, whereas the old Directive referred only to agri-foodstuffs.

2.2.2 This new section relates to portable fixing and other impact machinery, which were excluded from the old Directive.

Chapter 3 - Supplementary EHSRs to offset hazards due to the mobility of machinery

This chapter has been largely rewritten for clarity, but there are also some changes and additions such as references to control systems.

Chapter 4 - Supplementary EHSRs to offset hazards due to lifting operations

The opening remarks of this section in the new Directive do not contain the following sentence from the old Directive: 'The load may consist of objects, materials or goods.' The implication is that persons are now included. In addition, the new Directive contains an additional definition for 'carrier,' which refers specifically to 'persons and/or goods' (Section 4.1.1(g)).

4.1.2.8 Machinery serving fixed landings This new section contains five sub-sections.

4.1.3 Fitness for purpose This is a new section.

Chapter 6 - Supplementary EHSRs for machinery presenting particular hazards due to the lifting of persons

6.1.1 Mechanical strength This section now states that 'If ropes or chains are used to suspend the carrier, as a general rule, at least two independent ropes or chains are required, each with its own anchorage.'

Much of Chapter 6 has been rewritten for reasons of clarity, but there is also a new section **6.4 Machinery serving fixed landings** with three sub-sections.

Annex II - Declarations

Note that there is no longer a separate declaration of conformity for safety components. Because safety components are now listed in the scope of the Directive as item (c), and the definition of 'machinery' includes items (a) to (f) of the scope, the declaration of conformity for safety components is the same as that for 'machinery' (see 1.A below).

1. A. EC Declaration of Conformity of the machinery

The EC Declaration of Conformity must now state the place and date of the declaration.

When listing the harmonised standards used, in the event of a standard not being applied in full the manufacturer should state which specifications have or have not been applied.

“The version dates and technical content of the standards originally used will, in the majority of cases, have changed since that declaration of conformity was last updated.”

(see Industry comment, page 29)

1. B. Declaration of Incorporation of partly completed machinery

This is new, as partly completed machinery was not part of the old Directive's scope. Note that there is no requirement to list the harmonised standards applied but, in most cases, to do so would assist the person compiling the technical file and CE marking the completed machine.

2 - Custody

There is a new requirement for the manufacturer of the machinery (or partly completed machinery) or his authorised representative to keep the original EC declaration of conformity (or declaration of incorporation) for at least 10 years from the last date of manufacture of the machinery (or partly completed machinery).

Annex III - CE marking

This Annex now states that the CE mark must be affixed 'in the immediate vicinity of the name of the manufacturer or his authorised representative, using the same technique.'

In addition, where the full quality assurance procedure referred to in Article 12(3)(c) and 12(4)(b) has been applied, the CE marking must be followed by the notified body's identification number.



“CE marking will be required for ALL of the products subject to the Directive, with the exception of partly completed machinery.”

(see Industry comment, page 32)

Annex IV - Categories of machinery to which one of the procedures referred to in Article 12(3) and (4) must be applied

Some items are reworded for clarity, but other more significant changes are as follows:

- Internal combustion engines for underground working are no longer listed, as they are now treated as partly completed machinery.
- Bimanual controls are no longer listed.
- Logic units to ensure safety functions are now included.
- Portable cartridge-operated fixing and other impact machinery are now included.
- Machinery for the manufacture of pyrotechnics is no longer listed.

Note that the list in Annex IV is exhaustive, so machinery not included within the categories listed, even if similar or presenting similar hazards, is subject instead to the procedure for assessment with conformity checks as set out in Article 12 (2).

Annex V - Indicative list of the safety components referred to in Article 2(c)

This new Annex includes some of the items from Annex IV (such as guards for removable mechanical transmission devices, protective devices designed to detect the presence of persons, roll-over protective structures, and falling object protective structures), plus various types of guard, valves, extraction systems, monitoring devices, restraint systems, energy limiters, noise/vibration reduction systems, and various lift components. Note that the list of items is indicative, so other products can be defined as 'safety components' by reference to Article 2(c); the list can also be updated by the Commission in accordance with Article 8(1)(a).



“The list includes equipment that may previously not have been considered to be a safety component.”

(see Industry comment, page 28)

Annex VI - Assembly instructions for partly completed machinery

This new Annex contains a simple description of what the instructions must contain in relation to incorporating the partly completed machinery in the final machinery. It also states that the instructions must be in an official Community language acceptable to the manufacturer of the machinery in which the partly completed machinery will be assembled, or his authorised representative.

Annex VII

Part A - Technical file for machinery

The information contained in this new Annex was previously incorporated within the old Annex V 'EC Declaration of Conformity.' Note, however, that the new Directive states that the technical file must contain a general description of the machinery, even though this is also required in the instructions, a copy of which must be included in the technical file.

Whereas the old Directive only implied that a copy of the risk assessment should be included in the technical file, the new Directive states it explicitly.

The new Directive states that a copy of the EC Declaration of Conformity must be included in the technical file (the old Directive states that the technical construction file must be compiled before the Declaration of Conformity can be drawn up). For partly completed machinery, the technical file must contain both the declaration of incorporation and the relevant assembly instructions.

In the case of series manufactured machinery, the technical file must contain the internal measures that will be implemented to ensure that the machinery remains in conformity with the Directive.

Part B - Relevant technical documentation for partly completed machinery

This part of the Annex is new and its contents are broadly similar to Part A for machinery. However, note the subtle difference in terminology: machinery requires a 'technical file' whereas partly completed machinery requires 'technical documentation.'

Annex VIII - Assessment of conformity with internal checks on the manufacture of machinery

This new Annex appears to relate to series machines (but see industry comment). In essence, it states that for each machine a technical file shall be drawn up, and the manufacturer must take all measures necessary to ensure that the manufactured machinery complies with the technical file.

“The requirements of Annex VIII apply whether machines are manufactured as a single item with a unique specification or as a series of identical units.”

(see Industry comment, page 33)

Annex IX - EC type-examination

This new Annex is similar to the old Annex VI but requires both the notified body and the manufacturer to be more proactive (see section 9.1, for example).

Sections 4 and 9.3 require both the manufacturer and the Notified Body to retain a copy of the EC type-examination certificate, the technical file and related documents for 15 years from the date

when the certificate was issued (or re-issued, in the case of 9.3). The period of 15 years ensures that the documents are available for 10 years (the same period as for machinery CE marked using the other procedures) after the expiry of the EC type-examination certificate, which is the last date on which the certified type of machine may be manufactured. The old Directive did not require certificates to be reviewed every five years (see Section 9.3), so there was no corresponding requirement to retain the certificate and documentation for 15 years.

Section 9.1 states that 'the notified body has the ongoing responsibility of ensuring that the EC type-examination certificate remains valid. It shall inform the manufacturer of any major changes which would have an implication on the validity of the certificate.' This would include, for example, new or revised harmonised standards that have implications for the machinery examined.

Section 9.2 states that the manufacturer 'has the ongoing responsibility of ensuring that the said machinery meets the corresponding state of the art.'

In addition, section 9.3 requires that 'the manufacturer shall request from the notified body the review of the validity of the EC type-examination certificate every five years.'

“Annex IX of the new Directive has introduced a requirement to validate the EC Type Examination Certificate every five years, with the possibility of a five-year extension each time.”

(see Industry comment, page 29)

Annex X - Full quality assurance

This new Annex describes the conformity assessment of Annex IV machinery manufactured using a full quality assurance system, and the procedure whereby a notified body assesses and approves the quality system and monitors its application.

This has the potential to be a more cost-effective route to compliance than EC type-examination, though the manufacturer will have to determine whether or not this is the case.

Annex XI - Minimum criteria to be taken into account by Member States for the notification of bodies

This new Annex is very similar to the old Annex VII but there are two new sections. Section 8 states that notified bodies shall participate in co-ordination activities and be involved directly or represented in the European standardisation process in order that they 'know the situation in respect of relevant standards.'

Section 9 states that Member States must take all necessary steps to ensure that a notified body's customer files are handed over to another notified body or made available to the Member State in the event of the notified body ceasing its activities.

Annex XII - Correlation table

This table lists the correlations between the old and new Directives, though in some cases the contents of the correlating articles are not identical, and there is no means of identifying where new material has been added.

Industry comment

As well as the information that can be gleaned directly from comparing the old and new Directives, some less obvious but nevertheless useful interpretation is provided here by industry experts.

Assemblies of machinery

Robin Carver is the principal of Health & Safety Compliance Engineering and a member of the BSI Safety of Machinery MCE/003 committee. He writes:

The European Machinery Directive, throughout its various incarnations, has always recognised 'assemblies' of machines but, in its latest manifestation as 2006/42/EC, it now clearly specifies the essential health and safety requirements for such assemblies. These assemblies must be considered to be whole new machines and must therefore be CE marked. Supporting guidance for manufacturing system assemblies has recently been published in the form of a harmonised standard EN ISO 11161:2007+A1:2010, Safety of machinery. Integrated manufacturing systems. Basic requirements.

An Integrated Manufacturing System (IMS) is an assembly of machines that together perform a specific manufacturing function—for example, bottling lines, canning lines, cartoning lines, packaging lines, component assembly systems, palletising systems, de-palletising systems, etc. These may comprise new, partly completed and/or used machines arranged and controlled to function as an 'integral whole.' Often it is the end user that takes on the task of integrating the various machines to create the complete line. Because an integrated assembly of machines must be considered to be a whole new and different machine rather than just individual machines combined, it is, therefore, the integrator that must bear the burden of assessing and ensuring compliance of the final construction and declaring its compliance as an 'integral whole' by CE marking it in accordance with the Machinery Directive 2006/42/EC. The problem is that end users are often unaware that they are responsible for CE marking assemblies of machinery or, if they do understand their obligations, they lack the competences to fulfil them.

Implications of the new Machinery Directive

Paul Laidler, managing director of Laidler associates, writes:

The new Machinery Directive brings in many changes from what we are used to working to. Many of these are to the essential health and safety requirements and it is too easy to get hung up on these without worrying about the less noticeable but equally significant changes.

The first of these to highlight is the definition of the Authorised Representative which is now said to be 'any natural and legal person in the Community,' the key here being natural and legal. There are also changes to the requirements of the Declaration. One of the major changes here is that the Declaration must now include the name and address of the person who compiles the Technical File, ie carries out the CE Marking process, not just the person who signs the Declaration.

It appears that the European Union is trying to make sure that there is someone within Europe who can be contacted and, if necessary, made liable should an incident occur.

Changes to the exemptions list and also the newly added list of safety components make the position of some types of machine much clearer. However, the safety component list includes equipment that may previously not have been considered to be a safety component. Are manufacturers of these aware that they must now comply with the Machinery Directive?

On top of the changes to the Directive, all harmonised standards are being updated to reference both the new Directive and the amended standards. Businesses need to be aware that the standards they are currently using may be out of date, if not now, then very soon. Now is the time to act to update your systems and procedures.

Risk assessment, conformity and EC Type Examination

Ian Murgatroyd, the European product manager for safety components at Rockwell Automation, writes:

The new Machinery Directive 2006/42/EC does not introduce any radical changes over the Directive that it will replace, namely 98/37/EC; however, any company needing to comply with the new Directive should consider the following.

There is a subtle change to the requirement for risk assessment, which is now specifically detailed in the General Principles section of Annex I. Previously there was a need to assess the hazards, but now the full risk assessment process is included. In practise most organisations carry out a full risk assessment anyway, but now Annex VII also requires the full risk assessment to be included in the technical file, whereas previously only the methods used to reduce the risks were needed. Machine builders will therefore need to ensure that they have documented their risk assessment procedure.

Another consideration for meeting the requirements of the new Machinery Directive will be for manufacturers of machinery to spend time and money in updating their EC declarations of conformity. The version dates and technical content of the standards originally used to demonstrate compliance with the essential health and safety requirements will, in the majority of cases, have changed since that declaration of conformity was last updated. In a few cases the standard's number may also have changed (for example, EN 954-1 is transitioning to EN ISO 13849-1). Although this work would need to have been undertaken without the change in the Directive, the introduction of the new Machinery Directive is a good time to update these details.

If the manufacturer is using the EC Type Examination route he will now have to obtain a new EC Type Examination Certificate, which will require compliance with the essential health and safety requirements of the new Directive (and, most likely, the latest standards). Furthermore, Annex IX of the new directive has introduced a requirement to validate the EC Type Examination Certificate every five years, with the possibility of a five-year extension each time.

Ergonomics and the Machinery Directive

Jon Severn, the Editor of MachineBuilding.net, writes:

Ergonomics was covered, somewhat briefly, in the old Machinery Directive 98/37/EC in Annex I, section 1.1.2 d, as follows: "Under the intended conditions of use, the discomfort, fatigue and psychological stress faced by the operator must be reduced to the minimum possible taking ergonomic principles into account." In the new Machinery Directive 2006/42/EC, this sentence remains in section 1.1.6, but with an additional reference to physical stress and five indents giving examples of the types of ergonomic principles to be taken into account (note that this list is not exhaustive):

- allowing for the variability of the operator's physical dimensions, strength and stamina,
- providing enough space for movements of the parts of the operator's body,
- avoiding a machine-determined work rate,
- avoiding monitoring that requires lengthy concentration,
- adapting the man/machinery interface to the foreseeable characteristics of the operators.

In addition, ergonomics should be addressed under many of the other essential health and safety requirements (EHSRs) applicable to all machinery types—such as 1.1.4 (Lighting), 1.1.7 (Operating positions), 1.1.8 (Seating), 1.2.2 (Control devices), 1.5.8 (Noise), 1.5.9 (Vibration), 1.6.2 (Access to operating positions and servicing points), 1.7 (Information)—plus numerous supplementary EHSRs relating to specific machine types (a full list is provided in the official guidance).

The 2nd Guide to Application of the Machinery Directive 2006/42/EC (ie the official guidance) is helpful in that it points out the ergonomic requirements, but it provides little advice on the steps to be taken when designing machinery. As usual, a good starting point is the Harmonised Standards, compliance with which gives a presumption of conformity to the relevant EHSRs.

More guidance has been developed by ErgoMach, a group of European experts on ergonomics and machinery. This group contributed to the official guidance mentioned above and has prepared a series of Information Sheets that can be downloaded as PDF files from the ErgoMach website at www.ergomach.eu.

Fixings for fixed guards

Jeremy Procter is the Managing Director of Procter Machine Guarding, a Member of BSI's MCE/3 committee and has 25 years' experience of drafting machine safety standards. He writes:

There are two aspects of the essential health and safety requirements in Annex I sub-clause 1.4.2.1 Fixed guards that give cause for concern. First, the Directive states that 'fixing systems must remain attached to the guards or to the machinery when the guards are removed'—and there are no exceptions stated. While captive fasteners offer clear advantages in some circumstances, in particular for guard sections that are designed to be removed on a routine basis, such as in the food industry, it is overkill to require ALL such fixings to be captive. Adhering to this requirement will result in additional expense for machine builders, and more difficult replacement in the event of a fixing being damaged.

Second, the Directive requires that 'guards must be incapable of remaining in place without their fixings.' This is qualified with the phrase 'where possible,' which covers almost every conceivable fixed guard. Roof panels and other horizontal panels will therefore bizarrely appear to need fitting with springs or some other means of preventing them from remaining in place when the fixings are removed. Although the absurdity of this has been pointed out on several occasions, it is likely that the Directive will remain unchanged and the standard EN 953 Safety of machinery. Guards. General requirements for the design and construction of fixed and movable guards has already been revised accordingly.

In British health and safety legislation the concept of 'reasonable practicability' allows risk to be weighed against the money, time and trouble needed to control it. If the phrase 'where practicable' could be used in the two aforementioned sentences in sub-clause 1.4.2.1 of the Directive Annex and the corresponding sub-clause in the standard, the situation would be much improved. Unfortunately, the concept of reasonable practicability is not accepted in European legislation and standards, so these particular shortcomings of the Machinery Directive will probably remain, resulting in increased costs for machine builders and a negligible improvement in safety or more likely nobody outside the UK will take any notice of these requirements.

(See also Further information.)

CE marking of safety components

Martin Palmer, the training manager at Pilz Automation Technology, writes:

Under the existing Machinery Directive safety components are required to have a Declaration of Conformity but not be CE marked. However, safety components that incorporate electrical/electronic componentry—such as safety relays—will be CE marked under the LVD and EMC Directives. When the new Machinery Directive comes into force, CE marking will be required for ALL of the products subject to the Directive, with the exception of partly completed machinery.

Because most safety components (but not, for example, guards) already have a CE mark applied under the LVD or EMC Directives, machine builders will see no visual difference on these safety components after 29 December 2009, though the corresponding documentation will continue to reflect the version of the Machinery Directive in force at the time the component was placed on the market.

Note that safety components are excluded from the scope of the new Directive if they are supplied as identical spare parts by the manufacturer of the original machinery—see Article 1, paragraph 2(a).

Self-certification and internal checks on manufacture

Alistair McKerrell, an independent consultant and a member of BSI and European standards committees for safety of packaging machinery, writes:

Annex VIII of the Machinery Directive (Assessment of conformity with internal checks on the manufacture of machinery) is the 'module' to be used for self-certification of all non-Annex IV machines. This is comparable with the modular approach to conformity assessment used in other Directives for product supply, such as pressure equipment and ATEX 95.

Paragraph 3 of Annex VIII infers that the manufacturer must have a suitable and sufficient manufacturing quality system to ensure the safety-related aspects of the machine (or machines) specified in the technical file are incorporated correctly during construction. A simple example would be systematic checks to ensure that the specified safety relays have been correctly installed in the control circuits.

The requirements of Annex VIII apply whether machines are manufactured as a single item with a unique specification or as a series of identical units, despite the text appearing to imply series manufacture (as broadly understood in English).

Further information

Machinery Directive 2006/42/EC

A PDF copy of the full text of Machinery Directive 2006/42/EC, together with the Corrigendum and Amendment, can be downloaded from:

http://ec.europa.eu/enterprise/sectors/mechanical/documents/legislation/machinery/index_en.htm

Official guidance

The European Commission assembled an editorial board to prepare guidance on the new Directive. The first edition of the *Guide to the Application of the Machinery Directive 2006/42/EC* (running to 335 pages) was published in December 2009, though this had no commentary on Annexes III to XI; the second edition (with 406 pages), published in June 2010, included this information and some other amendments. It is intended that regular updates of the Guide will be published in order to present answers to questions agreed by the Machinery Committee and the Machinery Working Group. While the Guide provides helpful explanations of the various clauses within the new Machinery Directive, it does not seek to highlight differences between the old and new Directives.

As well as the *Guide to application of the Machinery Directive 2006/42/EC*, there are also three other guides: *Equipment used for lifting persons*; *Classification of equipment used for lifting loads with lifting machinery*; and *Manually loaded trucks for the collection of household refuse incorporating a compression mechanism*. All of these guides can be downloaded as PDF files from the following web page:

http://ec.europa.eu/enterprise/sectors/mechanical/documents/guidance/machinery/index_en.htm

In the UK the Department for Business, Innovation and Skills (previously the Department for Business, Enterprise & Regulatory Reform, BERR) has produced guidance on *The Supply of Machinery (Safety) Regulations 2008*, which can be downloaded as a PDF from:

<http://www.bis.gov.uk/files/file49954.pdf>

Ergonomics guidance

ErgoMach, a group of European experts on ergonomics and machinery, has contributed to the official guidance mentioned above and has also prepared a series of Information Sheets that can be downloaded as PDF files from its website.

www.ergomach.eu

Harmonised standards

A list of harmonised standards is available from the following web page, but bear in mind that this online list has no legal standing; only publication of a standard in the Official Journal of the European Union has legal status:

http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/machinery/index_en.htm

An up-to-date list of harmonised standards as published in the Official Journal can be downloaded as a PDF file from this page on the European Commission website:

http://ec.europa.eu/enterprise/sectors/mechanical/documents/standardization/machinery/index_en.htm

White papers

Procter Machine Guarding (see below) has published two White papers containing guidance on complying with requirements in the new Machinery Directive and are available to download as free PDF files: *CE marking of guards*; and *Fixings for fixed guards*.

MachineBuilding.net

News about the Machinery Directive, standards and products to aid compliance is available from MachineBuilding.net. The website is updated daily and can be browsed and searched via its user-friendly navigation, while the free monthly email newsletter brings the most interesting news straight to subscribers. Both the website and newsletter are focussed on the needs of those specifying, designing, building, modifying and upgrading machinery.

MachineBuilding.net
news. articles and resources for machine builders

Website: www.machinebuilding.net

Pilz Automation Technology

Pilz offers a market-leading range of machinery safety products, including: safety relays; configurable safety controllers; programmable safety systems (safety PLCs); mechanically actuated and non-contact guard switches; safety light curtains; vision-based safety sensors; emergency stop switches; and conventional and touchscreen operator interfaces. In addition, Pilz provides safety-related services, such as training, engineering, consultancy and competence management.

The Pilz logo is displayed in a large, grey, lowercase sans-serif font. The letter 'i' has a distinct dot above it.

Pilz Automation Technology

Willow House
Medicott Close
Corby
NN18 9NF
UK

Tel: +44 (0)1536 460766
Fax: +44 (0)1536 460866
Email: sales@pilz.co.uk
Website: www.pilz.co.uk

Procter Machine Guarding

With sites in Leeds and South Wales, Procter Machine Guarding is the UK's leading machinery guarding specialist. The company offers a comprehensive service to survey, design, manufacture and install standards-compliant machine guards nationwide. Bespoke guards can be supplied for machine tools and special-purpose machinery, and modular perimeter guarding is available in various types to suit application and budgetary requirements. Aluminium-framed guards can be designed and supplied either as completed units or in modules. Acoustic enclosures can be designed and manufactured to order, or noise-reducing measures can be incorporated within conventional guards.



Procter Machine Guarding

Pantglas Industrial Estate
Bedwas
Caerphilly
CF83 8XD
UK

Tel: +44 (0)2920 855 758

Fax: +44 (0)2920 887 005

Email: guards@procterbedwas.co.uk

Website: www.machinesafety.co.uk

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Southco Europe Ltd

Touch Point
Wainwright Road
Warndon
Worcester
WR4 9FA
UK

Tel: +44 (0)1905 346722

Fax: +44 (0)1905 346723

Email: info@southco.com

Website: www.southco.com

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MachineBuilding.net

