UKCA Marking for Machinery

Alex Bryce, CMSE® CECE®
Pilz Automation Technology *(REVISED AS PER GOVERNMENT ANNOUNCEMENT 14/11/22)*

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Welcome

- Your presenter is Alex Bryce, and co-hosts in the questions chat-room are Jason Reed and Jamie Walton
- You can type questions using the tool bar to the right side of your screen, my co-hosts will try to answer these during or at the end of the webinar
- These slides are available on request - simply let us know in the questions section

Agenda

- UKCA marking
  - What is “Machinery“
  - Responsibilites
  - Essential Health and Safety Requirements (EHSR‘S)
  - How to UKCA mark machinery
  - The UKCA marking process
  - Useful links

UKCA Marking

What is UKCA Marking ?

The UKCA (UK Conformity Assessed) marking is the new UK conformity marking used for certain goods being placed on the GB market, in place of the CE marking which is the conformity marking used in Northern Ireland and the European Union

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UKCA Marking

What is UKCA Marking ?

Rules around physically affixing the new UKCA marking mirror those which currently apply for the application of the CE marking although, until 31 December 2027, the UKCA marking may be affixed to a label affixed to the machinery, or a document accompanying the machinery, rather than being affixed to the machinery itself (even where it is otherwise possible to affix it to the equipment itself).

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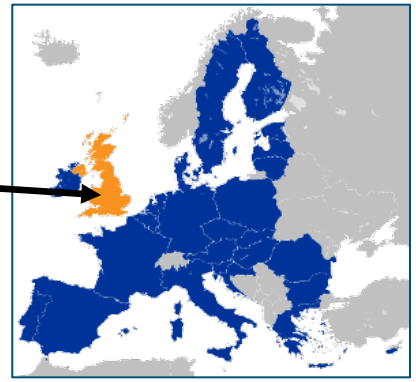
Timeline



From 1 January 2021
You can use the UKCA marking. In some cases, it will need to apply immediately.

From 16 July 2021
GB Authorised reps are no longer recognised for CE marked products

From 1 January 2025
You will need to use UKCA for most goods

Until 31ST December 2027
For most goods, you can affix the UKCA marking on a label affixed to the product or on an accompanying document

From 1 January 2028
The UKCA marking must, in most cases, be affixed directly to your product.

Note: There will be different rules for medical devices, construction products, cableways, transportable pressure equipment, unmanned aircraft systems, rail products, and marine equipment. Government departments responsible for these sectors are making sector specific arrangements.

UKCA Marking – REVISION SUMMARY 14TH November 2022

- The UK Government will continue to recognize the CE marking until **11pm on 31st December 2024**. This is to allow businesses time to prepare for UKCA marking. The UKCA mark can also be used.
- To reduce labelling costs it is also allowed to affix the UKCA marking and include importer information for products from EEA countries on an accompanying document or label until **11pm on 31st December 2027**.
- It is allowed to use conformity assessment activities for CE marking undertaken by **11pm on 31st December 2024** to be used by manufacturers as the basis for the UKCA marking until **11pm on 31st December 2027**.
- To read the full statement from BEIS: Businesses to be given UK product marking flexibility - GOV.UK (www.gov.uk)

Legislative Background

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Legislative Background

The Supply of Machinery (Safety) Regulations 2008 implemented Directive 2006/42/EC on machinery.

The EU Withdrawal Act 2018 preserved the Regulations and enabled them to be amended, so as to continue to function effectively now the UK has left the EU.

Post Brexit, the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, fixed any deficiencies that arose from the UK leaving the EU (such as references to EU institutions) and made specific provision for the GB market.

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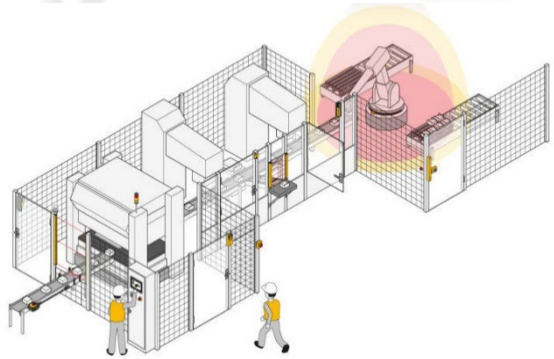
Legislative Background

The 2008 Regulations replaced the Supply of Machinery (Safety) Regulations 1995 and were amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 to apply solely to the GB market.

The Regulations make it an offence for a ‘responsible person’ to supply machinery, partly completed machinery or safety components unless they comply with the 2008 Regulations.

Compliance with the 2008 Regulations includes ensuring that the essential health and safety requirements (EHSRs) are satisfied; carrying out the necessary conformity assessment procedures; drawing up a declaration of conformity; and ensuring the machinery has the UKCA (or alternatively until 31 December 2024 the CE) marking affixed.

Who is responsible for UKCA marking?



The responsibility for demonstrating that the machinery satisfies the Essential Health and Safety Requirements of the applicable Regulations and can be UKCA Marked rests on:

- Original Equipment Manufacturers (OEM's) and System Integrators (SI's)
- Agents that import machines
- Companies that directly import machines (inc. intercompany transfer)
- Persons who build machines for their own use
- Persons who substantially modify machines beyond their original specification (also known as significant change)

Supply of Machinery (Safety) Regulations 2008

Enforcement:

For products intended for workplace use, the Health and Safety Executive (HSE) has a duty to enforce of the Regulations in Great Britain.

Penalties:

A person committing an offence under the Regulations may be liable to a penalty.

Penalties can include a fine, or a prison sentence of up to two years for the most serious offences. It is matter for the enforcement authority to decide what action is appropriate in each case, taking into account the circumstances of the case, and the enforcement authorities' own policies, operational procedures, and practices in line with the Regulators Code.

Should a prosecution take place, it is at the discretion of the court to decide the penalties imposed on the offender.

Definitions of Machinery

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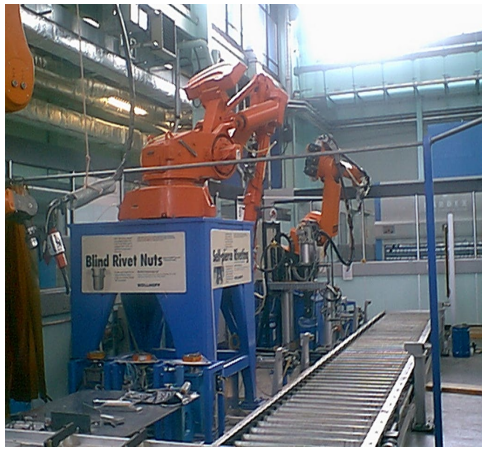
‘Machinery’ means

In accordance with the Regulations, the basic definition for a machine is;

An assembly, fitted with, or intended to be fitted with, a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application.

Example: Mixer without a drive system (motor or geared motor)



Machinery - Assemblies

An assembly referred to in definition 1, missing only the components to connect it on site, or to sources of energy and motion..

Example : Machines where connecting elements for wiring or pipes are missing (e.g. pumps, ventilation technology machinery)

Machinery – Mounted on means of Transport

An assembly referred to in definition 1 and 2, ready to be installed, and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure.

Example: Cranes or tail lifts for vehicles, power operated doors etc

Machinery – Assemblies of Machinery

Assemblies of machinery referred to in definition 1, 2 and 3, or specific partly completed machinery which, in order to achieve the same end, are controlled so that they function as an integral whole.

Example:- Production line

Machinery – Lifting loads Manual Effort

An assembly of linked parts or components, at least one of which moves, and which are joined together intended for lifting loads, and whose only power source is directly applied human effort.

Example: Manual Hoist/Jack

Supply of Machinery (Safety) Regulations 2008 SI 2008/1597
As amended SI 2019/696
- Essential Health and Safety Regulations

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Supply of Machinery (Safety) Regulations 2008

PART 3 – General prohibitions and Obligations

Supply of machinery: No responsible person shall place machinery on the market or put it into service unless it is safe.

Before machinery is placed on the market or put into service, the responsible person must;

- ensure that the applicable essential health and safety requirements (EHSR's) are satisfied in respect of it;
- ensure that the technical file is compiled and made available in accordance with the requirements of Annex VII
- provide, in particular, the information necessary to operate it safely, such as instructions;
- follow, as appropriate, the relevant conformity assessment procedure
- draw up the UKCA declaration of conformity and ensure that;

  (i) a copy of it accompanies the machinery

  (ii) the original is retained in accordance with the requirements

  (iii) affix the UKCA marking to the machinery visibly, legibly and indelibly

Essential Health & Safety Requirements (EHSR's)

SCHEDULE 2 - ANNEXES TO THE DIRECTIVE

PART 1 Annex I: Essential health and safety requirements relating to the design and construction of machinery

1.2. Controls Systems

This section defines how control systems should be designed and constructed including i.e.

- Starting
- Stopping
- Emergency Stopping
- Mode Selection
- Power Supply failures
- Control circuit failures
- The requirements for software are also defined

Essential Health and Safety Requirements – 1.2.1 Control Systems

Above all, they must be designed and constructed in such a way that:

- They can withstand the intended operating stresses and external influences.
- A fault in the hardware, or the software, of the control system does not lead to hazardous situations.
- Errors in the control system logic do not lead to hazardous situations.
- Reasonably foreseeable human error during operation does not lead to hazardous situations.

Essential Health and Safety Requirements – 1.2.1 Control Systems continued

Particular attention should be noted:

- The machinery must not start unexpectedly
- The parameters of the machinery must not change in an uncontrolled way, where such change may lead to hazardous situations. The machinery must not be prevented from stopping if the stop command has already been given
- No moving part of the machinery or piece held by the machinery must fall or be ejected
- Automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded
- The protective devices must remain fully effective or give a stop command
- The safety-related parts of the control system must apply in a coherent way, to the whole of an assembly of machinery and/or partly completed machinery

Essential Health and Safety Requirements – 1.2.2 Control Devices

- From each control position the operator must be able to ensure that no-one is in the danger zones or
- The control system must be designed and constructed in such a way that starting is prevented while someone is in the danger zone.
- If neither of these possibilities is applicable, before the machinery starts, an acoustic and/or visual warning signal must be given etc.
- Where there is more than one control position, the control system must be designed in such a way that the use of one of them precludes the use of the others, except for stop controls and emergency stops.

Essential Health & Safety Requirements – 1.3 Protection Against Mechanical Hazards

This section deals with most mechanical problems in machine manufacture, installation and operation. This includes;

- Stability
- Risk of Break-Up during operation
- Falling or Ejected Objects
- Risks due to Surfaces, Edges and Angles
- Risks related to Combined Machinery

Essential Health & Safety Requirements – 1.3 Protection Against Mechanical Hazards continued

- Risks related to variations in operating conditions
- Risks related to moving parts
- Risk of uncontrolled movement**

**When a part of the machinery has been stopped, any drift away from the stopping position, for whatever reason other than action on the control devices, must be prevented or must be such that it does not present a hazard.

Note: This section also provides an introduction to guarding, based on the choice of protection against risk arising from moving parts.

Essential Health & Safety Requirements – 1.4 The Required Characteristics of Guards & Protective Devices

This section defines the general requirements of guards and protection devices being robust, secure, and not give rise to additional hazards, not be easily by-passed, located a suitable distance from the danger zone etc. It also identifies various types of guard such as: fixed, interlocking movable, adjustable, and the special requirements for protection devices.

1.4.2.1 Fixed Guards

- Fixed guards only able to be opened or removed with tools.
- Their fixing system must remain attached to the guards or machinery when the guards are removed.
- Where possible must be incapable of remaining in place without their fixings.

Essential Health & Safety Requirements – 1.4 The Required Characteristics of Guards & Protective Devices cont.…

1.4.2.2 Interlocking Moveable Guards

Interlocking Moveable Guards must:

- As far as possible remain attached to the machine when open.
- Designed so as to be adjusted only by means of intentional action.

Interlocking moveable guards must be associated with an interlocking device that;

- prevents hazardous functions until they are closed and
- gives a stop command when they are not closed

Essential Health & Safety Requirements – 1.4 The Required Characteristics of Guards & Protective Devices cont.…

1.4.2.2 Interlocking Moveable Guards

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
- Keeps the guard closed and locked until the risk of injury from the hazardous machinery functions has ceased.

Interlocking movable guards must be designed in such a way that the absence or failure of one of their components prevents starting or stops the hazardous machinery functions.

Essential Health & Safety Requirements – 1.5 Risks Due To Other Hazards

This section looks at other relevant issues not included in the previous parts, and lists 16 topics which may need addressing, such as;

- Supply voltage
- Fire,
- Explosion risks
- Vibration
- Radiation
- Emissions of hazardous materials
- Risk of being trapped in a machine
- Risk of slipping, tripping falling
- Lightning
- Etc.

Essential Health & Safety Requirements – 1.6 Maintenance

This section defines what is required when designing a machine to enable it to be maintained safely. It includes;

- Access to operating positions and servicing points
- Isolation of energy sources**
- Operator intervention
- Cleaning of internal parts

** Isolators must be clearly identified. They must be capable of being locked if reconnection could endanger persons. Isolators must also be capable of being locked where it is not possible, from any of the points to which the operator has access, to check that the energy is still cut off.

After the energy is cut off, it must be possible to dissipate normally, any energy remaining or stored in the circuits of the machinery without risk to persons.

Essential Health & Safety Requirements – 1.7 Information

This details the requirements for information and warnings and warning devices, marking and instructions. Information and warning on the machines should preferably be provided in the form of readily understandable symbols or pictograms.

Any written or verbal information and warnings must be expressed in English and may be accompanied on request by versions in any other language or languages understood by the operators.

The marking requirement section 1.7.3 details that all machinery must be marked visibly, legibly and indelibly with the following minimum particulars:

- The business name and full address of the manufacturer and, where applicable, the manufacturer's authorised representative
- Designation of the machinery
- The UKCA Marking
- Designation of series or type
- Serial number (if any)
- The year of construction, that is the year in which the manufacturing process is completed

Essential Health & Safety Requirements – Additional groups

Group 2

- Foodstuffs, Cosmetics and Pharmaceutical Machinery.
- Woodworking and Similar Physical Characteristic Machinery.
- Portable Hand-Held and/ or Hand Guided Machinery.
- Pesticides Machinery.

Group 3

- Requirements to offset hazards arising due to mobility of machinery.

Group 4

- Requirements to offset hazards due to lifting operations.

Group 5

- Requirements for machinery intended for underground work.

Group 6

- Concerned with machinery designed to lift people.

UKCA Marking - How to

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UKCA marking – Self Declaration

The circumstances in which you can use self-declaration for UKCA marking are the same as for CE marking. If you were able to self-declare conformity for CE marking, you will be able to do the same for UKCA marking.

Where self-declaration of conformity is permitted in the Regulations, manufacturers placing machinery on the GB market, can affix the UKCA marking on the machinery before placing it on the GB market.

It is possible to affix both the UKCA marking and the CE marking to the same machinery on the basis of self-declaration, where permitted, as long as the EU and GB requirements remain the same.

NOTE:
When selling to the EU or placing on the NI market, then CE marking remains mandatory.

UKCA marking – UK Approved Body

UK Notified Bodies automatically became UK Approved Bodies from 1 January 2021.

They (where applicable) can carry out conformity assessments for which they have been approved for products to be placed on the GB market.

The Department for Business, Energy and Industrial Strategy (BEIS) Secretary of State has compiled a register of Approved Bodies, with their approved body identification numbers, the activities for which they have been approved, and any restrictions on those activities.

NOTE:
UK Approved Bodies cannot carry out conformity assessments for products to be placed on the EU market.

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UKCA marking – UK Approved Body

On 20th June 2022, the Government announced legislation will be introduced which will allow completed conformity assessment activities carried out under EU requirements (including existing testing, certification, and contractual arrangements relating to the quality control or auditing of existing certificates) undertaken by non-UK conformity assessment bodies (CABs) (accredited by their national accreditation body) for CE certification before 1 January 2023* to be used by manufacturers to declare existing product types as compliant with UKCA.

* On the 14th November 2022, this date was changed to 1 January 2025.

Products must still bear UKCA marking.

For ongoing production, they will need to undergo conformity assessment with a UK Approved Body once any of the relevant CE certification has expired, or after 5 years (31 December 2027), whichever is sooner.

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UKCA marking – UK Approved Body

Where manufacturers are using existing CE certification undertaken before 31 December 2024 as the basis to demonstrate compliance with UKCA for their products, they should include in the UK Declaration of Conformity the list of relevant UK designated standards and equivalent EU harmonised standards that apply to their product, as well as details of the EU CAB (or CAB recognised under an EU Mutual Recognition Agreement) which carried out the conformity assessment procedures.

If conformity assessment procedures have not been completed and a supporting CE certificate issued before 31 December 2024 , these products are considered ‘new’ products.

This also includes where goods are subject to important changes, overhauling its original performance, purpose, or type requiring new certification.

Any ‘new’ good must comply with GB regulatory requirements, including the requirement for conformity assessment by a UK approved body from 1 January 2025.

UKCA marking – Authorised Representative

Manufacturers are able by written mandate to appoint authorised representatives to perform all or part of the obligations and formalities imposed on manufacturers (either as manufacturers or responsible persons) by the Regulations.

Mandated authorised representatives for the GB market can be based in GB or Northern Ireland but cannot be based outside the UK.

A manufacturer can only mandate an authorised representative established in the UK, under the 2008 Regulations as they apply in GB.

NOTE:
No GB-based authorised representatives are recognised under EU law. This means GB-based authorised representatives cannot carry out tasks on the manufacturer's behalf for machinery being placed on the Northern Ireland or EEA markets. Therefore, a GB manufacturer selling machinery to the EEA or placing on the NI market, who wishes to appoint an authorised representative to carry out tasks for them in respect of that machinery, must appoint an authorised representative based in Northern Ireland or the EEA.

UKCA Marking - Legislation

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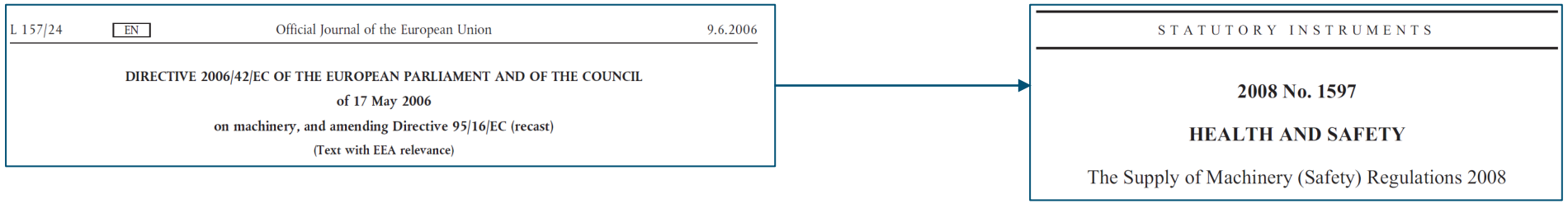
Current EU & UK Legislation

New Approach directives stipulating Essential Requirements are transposed into national legislation.

In the UK, this has been achieved through **Statutory Instruments** for many years, and published as Regulations.

For example, EU Machinery directive 2006/42/EC was transposed into the 2008 UK Supply of Machinery (Safety) Regulations by the Statutory Instrument SI 1597/2008.


L 157/24 EN Official Journal of the European Union 9.6.2006

DIRECTIVE 2006/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 17 May 2006
on machinery, and amending Directive 95/16/EC (recast)
(Text with EEA relevance)

STATUTORY INSTRUMENTS

2008 No. 1597

HEALTH AND SAFETY

The Supply of Machinery (Safety) Regulations 2008

UK Regulations under amendment as a result of EU Exit

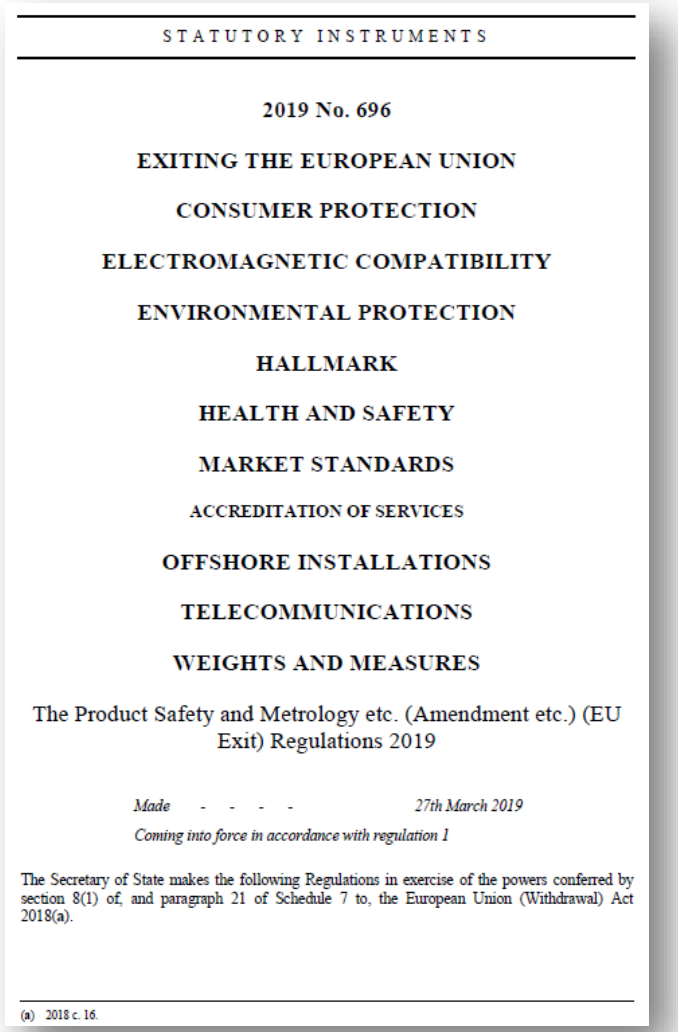
(a) Aerosol Dispensers Regulations 2009/ 2824
(b) Cosmetics (EU Regulation) 1223/2009 & Cosmetic Product Enforcement Regulations 2013 (2013/1478)
(c) Electrical Equipment (Safety) Regulations 2016/1101
(d) Electromagnetic compatibility Regulations 2016/1091
(e) Equipment for use in potentially explosive atmospheres Regulations GB 2016/1107 and Equipment for use in potentially explosive atmospheres Regulations NI 2017/90
(f) Explosives Regulations 2014/1638
(g) Gas Appliances (Enforcement) Regs 2018/389 & Gas Appliances (EU Reg) 2016/426
(h) Identification and Traceability of Explosives Regulations (NI) 2013/449
(i) Lifting Operations and Lifting Equipment Regulations 1998/2307
(j) Lifts Regulations 2016/1093
(k) Making Available on the Market & Supervisions of Transfers of Explosives (NI) 2016/366
(l) Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001/1701
(m) Offshore Installations (Offshore Safety Directive) (Safety Case etc) 2015/398
& Offshore Installations (Safety Case) Regulations 2005/3117
(n) Personal Protective Equipment (Enforcement) Regulations 2018/390 & PPE (EU Regulation) 2016/425
(o) Pressure Equipment (Safety) Regulations 2016/1105
(p) Pyrotechnic Articles (Safety) Regulations 2015/1553
(q) Radio Equipment Regulations 2017/1206
(r) Recreational Craft Regulations 2017/737
(s) Simple Pressure Vessels (Safety) Regulations 2016/1092
(t) Supply of Machinery (Safety) Regulations 2008/1597
(u) Toys (Safety) Regulations 2011/1881
(v) Measuring Container Bottles (EEC Requirements) Regulations 1977/932
(w) Measuring Instruments (EEC Requirements) Regulations 1988
(x) Measuring Instruments Regulations 2016/1153
(y) Non-automatic weighing instruments Regulations 2016/1152
(z) Weights & Measures (Intoxicating Liquor) Order 1988/2039
(aa) Weights & Measures (Packaged Goods) Regulations 2006/659
(bb) Weights and Measures (Revocations) Regulations 2015/356

Those highlighted in red are most relevant to machinery

EU directives, UK Regulations and UK Statutory Instruments – some examples

EU Equipment directive	Topic	UK Regulation	UK SI
2006/42/EC	Machinery	Supply of Machinery (Safety) Regulations 2011	SI 2008/1597
2014/30/EU	EMC	Electromagnetic Compatibility Regulations 2016	SI 2016/1091
2014/35/EU	LVD	The Electrical Equipment (Safety) Regulations 1994.	SI 2016/1101
2014/53/EU	RED	Radio Equipment Regulations 2017	SI 2017/1206
2014/68/EU	PED	Pressure Equipment (Safety) Regulations 2016	SI 2016/1105
2001/95/EC	General product safety	The General Product Safety Regulations 2005	SI 2005/1803
2014/33/EU	Lifts	Lift regulations 2016	SI 2016/1093
2014/29/EU	Pressure Vessels	Simple pressure vessels (safety) regulations	SI 2016/1092
214/34/EU	ATEX	BIS Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 1996	SI 1996/192

Supply of Machinery (Safety) Regulations 2008



STATUTORY INSTRUMENTS

2019 No. 696

EXITING THE EUROPEAN UNION

CONSUMER PROTECTION

ELECTROMAGNETIC COMPATIBILITY

ENVIRONMENTAL PROTECTION

HALLMARK

HEALTH AND SAFETY

MARKET STANDARDS

ACCREDITATION OF SERVICES

OFFSHORE INSTALLATIONS

TELECOMMUNICATIONS

WEIGHTS AND MEASURES

The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019

Made - - - - 27th March 2019

Coming into force in accordance with regulation 1

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(a).

(a) 2018 c. 16.

Following Brexit, the UK Secretary of State introduced;

The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 No.696

This Statutory Instrument (SI) outlines the changes made to the Supply of Machinery (Safety) Regulations 2008 S.I. 2008/1597; relevant amending instruments are S.I. 2011/1043, S.I. 2011/2157 are amended in accordance with paragraphs 2 to 34.

Supply of Machinery (Safety) Regulations 2008

They were made under section 2(2) of the European Communities Act 1972 and are accordingly saved by virtue of section 2(2)(a) of the European Union (Withdrawal) Act 2018.

This details the changes to be made for the application of the UKCA mark in place of the CE mark on machinery and to;

- Ensure no reduction in safety of products, accuracy or protection of consumers as a result of EU exit
- Maintain requirements for product safety by retaining the appropriate EU obligations in UK law
- To fix EU references that will no longer be appropriate in the UK (such as EEA, directive etc)

What‘s changed with machinery requirements in the UK?

Schedule 12 of SI 2019/696 amends SI 2008/1597 Supply of Machinery (Safety) Regulations

First important thing to say:

The EHSRs from the Machinery directive are still enshrined in the UK Supply of Machinery (Safety) Regulations and these are not changing at all

Some key phrases or words that have changed

- The directive now referred to as These Regulations
- Notified Body referred to in UK as Authorised Body
- Harmonised standard referred to in UK as Designated Standard
- EEA state referred to in UK as the United Kingdom
- CE marking referred to in the UK as UKCA marking

UK SI 2019/696 – amending SI relating to EU Exit

A “designated standard” means a technical specification which is;

- adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory
- designated by the Secretary of State by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.

For the purposes of this regulation a “recognised standardisation body” means any one of the following organisations;

- the European Committee for Standardisation (CEN)
- the European Committee for Electrotechnical Standardisation (Cenelec)
- the European Telecommunications Standards Institute (ETSI)
- the British Standards Institution (BSI)

References to standards for machinery in support of the Supply of Machinery (Safety) Regulations 2008 (S.I. 2008/1597)

Designated standards are prefixed “BS”, “EN”, “EN ISO” or “EN IEC”.

The “EN” prefix indicates that the standard has been adopted by a European standardising body.

For UKCA marking, where the designated standard specified in the notice of publication is prefixed “EN” it is acceptable to reference this version in technical documentation, or a version of the same standard with a national prefix.

It is worth noting that the BEIS (UK Govt. Dept. for Business, Energy and Industry Strategy) issued the **References to standards for machinery in support of the Supply of Machinery (Safety) Regulations 2008 (S.I. 2008/1597) on 1st January 2021**

UKCA marking process

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Marking Process Overview - 6 Step Process

1. Legal Framework
2. Define Requirements
3. Select Conformity Assessment Procedure
4. Conformity Validation
5. Technical File
6. Affix UKCA Mark

This is the overall UKCA marking procedure in general

- Each step contains a number of internal procedures and tasks to be carried out in order to complete the step
- The steps do not necessarily need to be completed in the order shown and some steps may be active at the same time
- The exception to this is Step 6 which cannot be under any circumstances undertaken until all other steps are completed

UKCA Marking Process - Legal Framework

For products defined as machinery to have free access to the UK it must meet the Supply of Machinery Safety Regulations SI 2008/1597as amended SI 2019/696

Machinery can be affected by other product regulations, e.g.

- The Electrical Equipment (Safety) Regulations 1994 SI 2016/1101
- Electromagnetic Compatibility Regulations 2016 SI 2016/1091

NOTE:

These three regulations are those which typically apply for UKCA marking of machinery, BUT there are machines where other product regulations may also apply.

UKCA Marking Process - Define Requirements

Requirements are established through a number of different routes:

1. Essential Requirements from each applicable regulation – UK regulations, lay down minimum safety & health requirements
   - The regulations themselves must be reviewed to see if the machine falls under the regulation by consulting their definitions, exclusions, etc.

2. Risk assessment – In order to identify applicable EHSR's, it's necessary to conduct a risk assessment

3. Designated standards, non-designated standards, technical specifications: Many suggest that an evaluation of the risks of the product and a match between the risks analyses, and risks covered by the standards, is completed
   - The fact that designated standards are chosen to address machinery risks does not mean that a risk assessment is not necessary

UKCA Marking Process - Select Conformity Assessment Procedure

For all products that require UKCA marking, the manufacturer must follow an approved procedure for assessing conformity with the applicable regulations

There are numerous possible procedures (called Conformity Assessment Procedures) to follow when assessing a certain product

The individual regulations state which of the procedures must / can be used for a specific product in scope

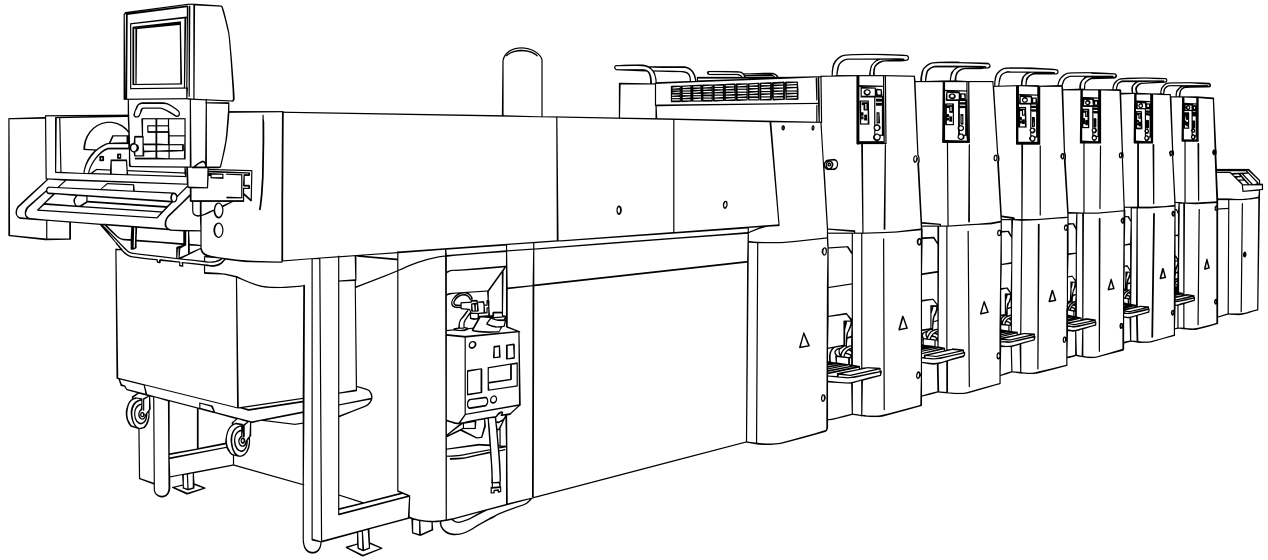
Some refer to only a few of these procedures, other regulations refer to all of them

Some require involvement of an Approved Body

UKCA Marking Process - Select Conformity Assessment Procedure

The Supply of Machinery (Safety) Regulations refers to different types of procedures for example:

- Production Control / Internal Checks
- Type-examination
- Full quality assurance



Which one to use depends on the machine type to assess:

- Is the machine listed in annex IV of the regulations?
- Is a type-C standard followed under the design and construction?
- Does the type-C standard fully cover all aspects of the machine?

UKCA Marking Process - Conformity Validation

In order for the product to comply with the requirements of applicable regulations and as part of the UKCA marking process, the product must fulfil the essential requirements laid out in each regulation.

This is completed by ensuring that all defined requirements applicable to the product are met. In practice, this means validation in accordance with

- the Essential Requirements identified,
- the Risk Assessment completed and
- the standards used

Some parts of the validation process must be documented by practical tests. Other parts can be proved by calculation or inspection

Much of the validation can be done alongside the construction process

All results must be documented and stored in the Technical File

UKCA Marking Process - Technical File

The manufacturer or their representative is obligated to prepare a technical file (TF) for the machine. The TF is intended to demonstrate compliance with the relevant safety & health requirements of all applicable regulations.

The TF must be stored for at least 10 years (for series-produced machines, after the last product has been manufactured)

The TF (or parts thereof) shall be handed over to competent national authorities upon request (i.e., The Health and Safety Executive, Trading Standards in the UK)

The UKCA TF must be drawn up in English

UKCA Marking Process - Technical File

Technical File Contents (minimum requirement)

- Copy of the Risk Assessments
- Mechanical and electrical drawings of the overall machine
- Control circuits drawings
- Calculations, test results etc. required to check conformity
- Conformity of machinery with essential requirements
- List of requirements of regulations, standards & technical specifications used
- Description of methods to eliminate hazards
- Copy of the instructions of the machine
- Copy of the Declaration of Conformity
- ….

Regulations have similar requirements but they might differ slightly, all relevant regulations need to be checked individuall y

UKCA Marking Process - Affix UKCA Mark - Declaration of Conformity

“The manufacturer, or the authorised representative established within the UK, must draw up and sign a UK declaration of conformity as part of the conformity assessment procedure.”

The Declaration of Conformity (DoC) is the document where the manufacturer takes on the responsibility that his product fully complies with all applicable regulations

In order to justify this compliance the manufacturer can list the designated standards used to gain the presumption of conformity

In the absence of designated standards, the manufacturer might list other technical documents used to achieve conformity

UKCA Marking Process - Affix UKCA Mark - Declaration of Conformity

Only one DoC is needed for the product. In the case of two or more applicable regulations, the DoC will indicate compliance for all those applicable.

The manufacturer must store the DoC as a part of the TF and save it for 10 years

Must be delivered with the machine

Usually a DoC concerns one single product but it could also address a product portfolio

Pre- or post-dating the DoC is prohibited

UKCA Marking Process - Who should keep the documentation

The declaration of conformity and the technical documentation must be kept and be available for inspection by UK based enforcement bodies (including HSE, trading standards etc.) by:

- the manufacturer, if they are in the UK
- their authorised representative**
- if neither of the above, the importer i.e., the first one bringing goods from outside the UK and placing them on the market in Great Britain

** If you need to (or choose to) use an authorised representative or responsible person, they will need to be based in the UK for products being placed on the GB market.

Distributors must also act with care to ensure that they supply only equipment for which the manufacturers and importers have carried out their duties as above. They should verify that the equipment :

- bears the UKCA mark
- is accompanied by the required documents
- the labelling requirements have been complied with
- the label identifies the importer
- that instructions and safety information are provided in English

UKCA – useful references

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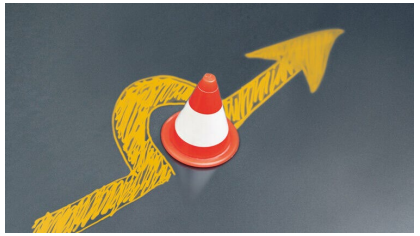
Pilz International Compliance Services

UKCA

- Assistance with your compliance requirements from initial design to final build: risk assessments, safety validations, EHSR checks, TF construction, DRA, FAT, SAT etc…….
- Authorised Representative for both UKCA and CE
- International Compliance services for USA, Canada, Brasil etc.
- Global business with global locations for ease of support with OEM‘s
- Services include AGV and Robotics certification



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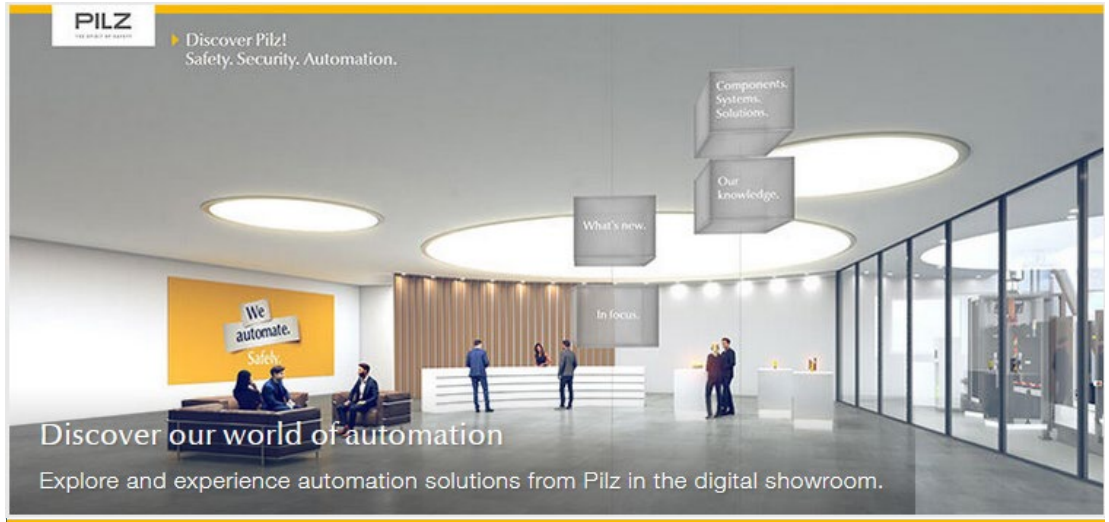
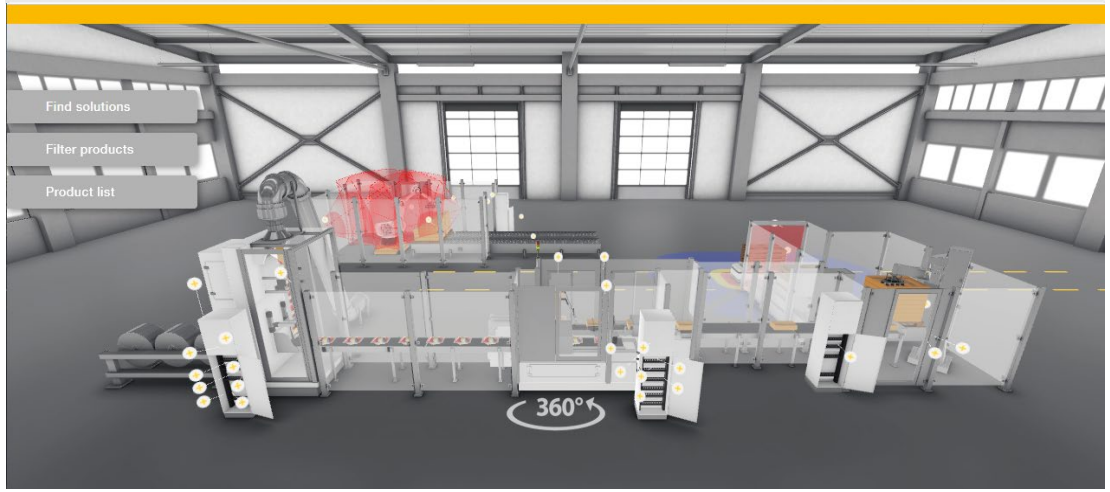
Stay up to date with the Pilz website and webinar channel





Catch Up on Previous Machinery Safety Webinars

Pilz UK has a dedicated webinar channel which plays host to a collection of previously broadcast Machinery Safety presentations

The channel gives you the opportunity to brush up on your machinery safety knowledge in your own time or revisit previously watched webinars to be reminded of key standards and technologies.

The list of recordings include:

- ISO 13855 – Keeping your distance safely
- A look into PUWER regulations
- Safe human-robot collaboration
- Safe operating mode selection
- ……

Useful references in relation to the UKCA marking requirements in the UK?

- For guidance on using the UKCA marking visit: https://www.gov.uk/guidance/using-the-ukca-marking#how-to-use-the-ukca-marking
- For guidance on placing goods on the GB market visit: https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-great-britain
- For guidance on designated standards visit: https://www.gov.uk/guidance/designated-standards-new-or-amended-notices-of-publication
- Guide to the Supply of Machinery (Safety) Regulations visit: https://www.gov.uk/government/publications/supply-of-machinery-safety-regulations-2008
- The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 contents visit: https://www.legislation.gov.uk/uksi/2019/696/contents
- BEIS date revision statement 14-11-2022 visit: Businesses to be given UK product marking flexibility - GOV.UK (www.gov.uk)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