Placing products for use at work on the GB market: a product safety guide

Introduction

GB businesses wishing to supply goods on the GB market following the departure of the UK from the single European market must meet the amended GB rules for product conformity, and in most cases show this by the new UKCA marking. The main amending legal instrument is the Product Safety and Metrology etc (Amendment etc.)(EU Exit) Regulations 2019, which seek to provide continuity and maintain high standards for safety. This guide describes the common requirements for industrial products that must be met, primarily from a product safety perspective. However, other non-safety product legislation (e.g. environmental) which often impose similar duties on the various economic operators may also apply to a product and must also be met in full for product compliance.

This guide does not cover placing of workplace goods on the marketplace in Northern Ireland or goods from Northern Ireland being placed on the GB market as part of unfettered access. Information on this can be found at GOV.UKWhilst the above amending product safety Regulations make changes, (e.g.; UKCA instead of CE marking, designated standards instead of harmonised standards and UK Conformity Assessment Bodies instead of European Notified Bodies), they also permit continued access to the GB market for goods complying with European single market rules until 31st December 2021 (CE marking etc), and maintain alignment in the main safety requirements (essential requirements, technical files, information for users, third party verification in specified instances). All UK regulations can be freely obtained as PDFs files from http://www.legislation.gov.uk/

Placing industrial products on the GB market

UK product legislation is concerned with: the health and safety of people (and in many cases domestic animals), as well as the safety of property; the protection of the environment; correct product function; and other matters of public interest protection. Although this guide mentions some other legislation (e.g. on electromagnetic compatibility) its emphasis is on industrial products and the risk to health and safety, by design and construction.

New products may not be placed on the GB market unless they fully meet the requirements of all product legislation relevant to the product. UKCA marking (and CE marking up to 31st December 2021), which is a sign of compliance, is required in most cases, as well as product labelling indicating the relevant economic operator(s). Manufacturers may only affix the UKCA marking when all of the requirements of all UK product supply legislation applicable to the product have been met.

Where UKCA/CE marking is not required by any product legislation applicable to the product it must not be affixed (e.g. industrial scaffolding towers): in these cases manufacturers must

meet any other applicable National requirements for the product. In the case of articles for use at work the obligations of Section 6 of the Health and Safety at Work etc Act 1974 must be met when it is made available on the GB market (the relevant part of the Health and Safety at Work (Northern Ireland) Order 1978 as amended also covers placing articles for use at work on the Northern Ireland market).

Where articles are not primarily intended for use at work, and other more specific product legislation does not apply, the General Product Safety Regulations 2005 apply to the placing and making available of products on the UK market.

British, European and International Standards, including those designated by the Secretary of State (these if followed in full may give a presumption of conformity) can assist in helping meet the obligations for safety and an absence of risk to health, so far as reasonably practicable.

It is the responsibility of economic operators, but particularly the manufacturer, to establish which, and all, legislation is applicable to their product, and apply it/ensure it has been applied before making a product available for the first time on the GB market. Enforcement of any non-compliance will be subject to the provisions made in UK legislation which appoint market surveillance authorities. Market surveillance authorities have general obligations to deal with non-compliance, taking account of the principle of proportionality, and in particular where products present risk.

Compliant products accompanied by appropriate 'Information for Use', and in many cases Declarations (of Conformity, Incorporation or Performance) in English have a presumption of access to the UK market. However, this 'presumption' is rebuttable by the authorities on presentation of suitable evidence.

Importers, if you place goods on the GB marketplace for the first time from outside GB you have specific duties as described by specific product legislation.

As an importer, you'll need to make sure that from 1 January 2021:-

- Goods are labelled with your company's details, including your company's name and a contact address (until January 2023 you can provide these details on the accompanying documentation rather than on the good itself. This could be on a separate document or within other documents such as product manuals, as long as it is easily available to market surveillance authorities when requested).

- The correct conformity assessment procedures have been carried out and that goods have the correct conformity markings

- The manufacturer has drawn up the correct technical documentation and complied with their labelling requirements

- You maintain a copy of the declaration of conformity for a period of 10 years

- Goods conform with the relevant essential requirements

You must to comply with the above immediately for goods placed on the GB market from 1 January 2021, for both CE and UKCA marked goods.

UKCA marking

The UKCA marking will apply to most goods currently subject to the CE marking.
From 1 January 2021 the technical requirements ('essential requirements') you must meet – and the conformity assessment processes and standards that can be used to demonstrate conformity – will be largely the same as they are now.
The UKCA marking can be used from 1 January 2021. However, to allow businesses time to adjust to the new requirements, you will still be able to use the CE marking until 31 December 2021. You are encouraged to be ready to use the UKCA marking as soon as possible before this date.
The CE marking will only be valid in Great Britain for areas where GB and EU rules remain the same. If the EU changes its rules and you CE mark your product on the basis of those new rules you will not be able to use the CE marking to sell in Great Britain even before 31 December 2021.

UKCA marking is the responsibility of the person/company who places the product on the GB market for the first time, or in some cases (e.g. machinery) where it may not have been placed on the market, the person who puts it into service for the first time. This duty primarily rests with the manufacturer, aspects of which may be performed by the manufacturer's authorised representative (must be agreed in writing between the parties). But it can also apply to those who import and place products on the GB market for the first time (particularly where goods are not yet compliant, e.g. without UKCA or CE marking, etc), and those who rebrand products made by another to supply under their own brand name.

By affixing UKCA marking you take on responsibility for the conformity of the product. UKCA marking is a visible sign that the product complies with all relevant product supply legislation, and its presence together with the Declaration of Conformity and/or Performance gives the product to which it is affixed a presumption of conformity with relevant product legislation. However, the UK mark is not a quality mark, nor a guarantee that the product actually meets all of the requirements of relevant product law.

UKCA (like CE) marking is the final stage of the conformity assessment process as specified in the relevant legislation for the product. If UKCA marking is required you must:

- use the initials "UKCA" in the prescribed form (see the image below)
- of a minimum size - at least 5mm tall (unless this is not possible for very small products)
- maintaining the proportions shown whatever the size, and
- attach it to the product visibly, legibly and indelibly,
- and where possible position next to the name of the manufacturer, importer etc.

Further information is available at https://www.gov.uk/guidance/using-the-ukca-mark-from-1-january-2021

Conformity assessment

This is the process by which persons can legally place safe and compliant products onto the market (or in some cases, machinery, put into use) for the first time. Conformity assessment is a common feature of the product legislation concerned with safety, and is concerned with:

- assessing the risks presented by a product throughout its lifecycle,
- meeting health, safety and other objectives by design and construction,
- taking account of the current best practice to ensure compliance for that product, known as meeting the 'state of the art',
- in some cases the supply legislation will require the use of third parties, known as 'Conformity Assessment Bodies') to verify compliance,
- collecting and retaining information about the design, testing and construction process and the means by which the product complies with the essential requirements of all relevant product safety legislation in a technical file which in most cases must be kept for at least 10 years after the last product of the product series has been produced,
- declaring the product's conformity with all relevant product safety legislation by means of a document (the Declaration of Conformity), which in many cases must accompany the product down the supply chain to the end user,
- and the preparation and provision of comprehensive product User Instructions, in English.

Depending on the applicable legislation and the nature of the product and risk, conformity assessment ranges from self-assessment of the product to self-assessment with third party type-examination and/or full quality assurance. Full details of the procedures are given, normally within the Schedules, of each piece of applicable legislation. Manufacturers and their authorised representatives need to find out what these procedures are for any of their products destined for the GB market. Information generated and obtained during the conformity assessment procedure must be retained as part of the product's technical file.

Where a third party is required for conformity assessment (e.g. under the Gas Appliances Regulations 2016/426) the economic operator responsible for product compliance must

select an appropriate UK Approved Conformity Assessment Body to assist. However, whilst the Approved Conformity Assessment Body will undertake an assessment of the product and the manufacturer's quality system, and may issue a Type-Examination Certificate, the duty to meet the relevant conformity assessment procedure always remains with the relevant economic operator. It is the economic operator's responsibility to declare the product's conformity with all relevant product legislation and correctly affix UKCA marking, before placing the product on the market.

Manufacturers can choose to use any valid accredited Approved Conformity Assessment Body that is permitted to examine that particular product type. But they are not entitled to 'play off' one Approved Conformity Assessment Body against another. In applying for assessment by an Approved Conformity Assessment Body the applicant must declare that an application for the same product has not been made to another Approved Conformity Assessment Body. Manufacturers are advised to check that the proposed Approved Conformity Assessment Body is valid for the product type and conformity assessment module..

If an Approved Conformity Assessment Body issues a Type-Examination Certificate for a product submitted to them for conformity assessment this must be retained by the economic operator and included in the technical file. There is sometimes confusion as to what the Type-examination certificate means. It is a document indicating that in the Approved Conformity Assessment Bodies' judgement the product meets the requirements of particular product legislation. It is not a Declaration of Conformity, although details of any Approved Conformity Assessment Body issuing such a certificate should be included on the Declaration of Conformity, as too the Type-examination reference number.

Type-examination certificates normally have to be renewed after 5 years even if no changes have been made to the product. Where changes are made to a product for which a Type-Examination certificate has been issued the manufacturer is obliged to inform the Approved Conformity Assessment Body of those changes in case re-assessment is required, which may give rise to a new Type-examination Certificate if the product is found in conformity.

Where the use of an Approved Conformity Assessment Body is not required for conformity assessment this is often referred to as 'self-certification'. This applies to many products that are not considered of high or special risk, or to all products in scope of certain legislation , e.g. the Electrical Equipment Safety Regulations 2016. However, there is nothing to stop an economic operator approaching an Approved Conformity Assessment Body, or another organisation, to assist with his product assessment, but if an Approved Conformity Assessment Body is used when not required by the legislation then it is only as a 'consultant' and no Type-Examination Certificate must be issued and the number of the Approved Conformity Assessment Body must not be quoted on the Declaration of Conformity. This option is at the economic operator 's own election and cost, and does not relieve the economic operator of his fundamental duty to declare conformity of, and take responsibility for, the product.

Approved Conformity Assessment Bodies

They provide an independent assessment of a product against all of the essential requirements of specific applicable legislation, and the standards used in the design, for which as an Approved Conformity Assessment Body they are competent and appointed to undertake. Approved Conformity Assessment Bodies will charge the economic operator, normally the manufacturer (but can include other economic operators who have to take on the manufacturer's duties) for this service. For some products this may effectively be compulsory because of the conformity assessment provisions of the relevant product legislation (particularly where there is no designated standard for the product, or the product cannot meet a relevant designated standard).

In some cases an example of the product will be submitted to the Approved Conformity Assessment Body for type-examination, along with a copy of the technical file, which must include the Instructions for Use. In other cases, determined or permitted by the legislation applicable to the product, alterative procedures may be followed. For example, some product legislation permits a fill quality assurance conformity assessment route where an Approved Conformity assessment Body must assess and audit the full quality assurance system for the design and manufacturing processes.

If the Approved Conformity Assessment Body accepts from the evidence placed before it that the product is compliant with the relevant legislation and if relevant standards to which conformity is declared, (and where relevant, that the manufacturing and quality system meets acceptable minimum standards for product assurance), they will then issue the manufacturer (or an economic operator taking on the manufacturer's duties) with a Type-Examination Certificate. This should retained, along with other relevant documentation (e.g. on the quality assurance system) as part the technical file and record of compliance assessment, and the manufacturer should quote on the Declaration of Conformity the Approved Bodies' title, address and identity code. This information on the Declaration of Conformity will enable purchasers and market surveillance authorities to make enquiries on the validity of the Approved Conformity Assessment Body used, and in the case of market surveillance authorities, facilitate enquires into the validity of the Approved Conformity Assessment Body's assessment of the product.

Where an Approved Conformity Assessment Body has undertaken Type-examination a copy of the technical file will have to be provided to the Approved Conformity Assessment Body, , as well as the manufacturer (or other economic operator if relevant), must keep this for a significant period (i

In circumstances where following assessment an Approved Conformity Assessment Body has not issued a Type-Examination Certificate the Approved Conformity Assessment Body is under a duty to communicate its decision and reasons to the applicant and share information with the other Approved Conformity Assessment Bodies and the Secretary of State.

Conformity Assessment Bodies can only act within their areas of competence, that is for the particular legislation and particular modules for conformity assessment for which they have been accredited. UKAS will continue as the UK's appointed national accreditation body. Its role in accrediting UK approved bodies will be the same as its current role for UK-based notified bodies. UK-based notified bodies who become approved bodies will keep the same 4-digit identification number as they have now.

Essential requirements

All product legislation requires conformity with essential requirements, sometimes known as safety objectives. These requirements are listed in a Schedule of the legislation and tailored to the specific characteristics of the product types in scope for the objectives of the legislation. Standards, especially those 'designated' for the legislation (see later), often assist in describing or 'benchmarking' the 'state of the art' for products in scope. While designers and manufacturers must meet the common minimum requirement of all the relevant essential requirements when placing their products on the market, to the 'state of the art', they can choose to go beyond these minimums if they wish.

In the main, essential requirements set objectives to be reached rather than specifying the precise method of compliance. This allows designers and manufacturers to choose the most appropriate ways to meet those objectives for their particular product to the 'state of the art', which they must show through a technical file/documentation for the product.

Where a corresponding hazard/feature exists for the product the objectives of all relevant essential requirements must be met, in so far as the product is used under the conditions foreseen by the manufacturer, who must also take account of foreseeable abnormal situations. While each essential requirement is mandatory, taking account of the 'state of the art', it may not be possible to meet the objectives set by them. In these cases the product must, as far as possible, be designed and constructed with the purpose of approaching their objectives. Although the precise means by which an objective is met is left to the product designer/manufacturer, over time the possibilities and standards for meeting those objectives may change as the 'state of the art' for compliance improves.

The notion of the 'state of the art' is not defined, however it includes both a technical and economic aspect. It is a dynamic concept reflecting what can be done at reasonable cost using generally available technology at the time. But it is not an excuse for the lowest common achievable safety level, nor necessarily what all manufacturers of a particular product currently do for safety. The state of the art can change over time as new technologies appear, especially as new/improved methods of safety evolve, such that what was previously the state of the art may some years later no longer be so. F

Some product legislation, e.g. the Supply of Machinery (Safety) Regulations, indicate the order of preference in which risks must be managed, following long standing principles of:

- firstly, risk avoidance, by design
- secondly, protection against risks that cannot be eliminated
- thirdly, warning of any residual risks that remain

Where a hazard can be avoided by design that method should be employed in first preference when meeting any applicable essential requirements. But in many cases hazards persist, perhaps because they are a fundamental part of the product (e.g. the blade of a circular saw), and so physical methods of protection must be employed to meet the objectives of the essential requirement. However, it is not always possible to protect against all risks (e.g. part of the blade of a circular saw necessarily remains unguarded) and manufacturers will have to warn users of any residual risks. The job of the product designer is to consider all relevant essential requirements and seek the best methods of meeting their objectives, to the state of the art, taking account of the fundamental hierarchy of safety outlined above. Standards for specific classes of products can help here (see below).

Some "total" product safety legislation have a comprehensive list of essential requirements dealing with all aspects of health and safety (e.g. the EHSRs for machinery), whereas other product legislation only covers a restricted range of issues (e.g. the essential requirements of the EMC Regulations only deal with issues of electromagnetic compatibility). Note that although the objectives of the Electrical Equipment Safety Regulations 2016 (EESR16) principally concern electrical matters it is nevertheless a ‘total’ safety regulation even though non-electrical hazards are not further detailed (however many standards supporting EESR16 include requirements for non-electrical hazards that are expressed by the equipment they cover).

Essential requirements from more than one piece of product legislation may apply to a particular product. For example, most machinery is electrically powered so both the machinery and EMC Regulations will apply, and the designer and manufacturer must take account of and simultaneously meet the requirements of both Regulations’ essential requirements. However, for ‘total safety Regulations’ that cover all risks only one can be applied to any product. This situation is covered; for example, medical devices which are also machines. Although medical machinery is excluded from the scope of the Supply of Machinery (Safety) Regulations, the EHSRs of the machinery Regulations are ‘called up’ by the Medical Devices Regulations, in so far as those EHSRs are relevant to that medical device. Similarly the essential requirements of the Electrical Equipment Safety Regulations 2016 (EESR16) are brought into the Supply of Machinery (Safety) Regulations via EHSR 1.5.1, so any Standard developed for the EESR16 may support the design of machinery, especially the electrical system.

Standards and their use

The use of Standards in complying with product supply legislation is not compulsory, but they can be very useful when designing products, and may simplify the conformity assessment process. Some standards (those which are designated) have a special legal

status and define minimum acceptable levels for health and safety by supporting the essential requirements of the legislation they support. For products in scope if followed in full they can provide a ‘presumption of conformity’ with the relevant legislation's essential requirements, potentially reducing the burden of demonstrating product conformity (through the technical file).

Standards may deal with broad general principles, aspects of safety common to many products, or be product specific, and can exist at many levels and include:

- International standards (prefixed by "ISO", “IEC” or "EN")
- National standards (e.g. British Standards)
- industrial/sector
- even in-house

Standards have been defined as "an agreed, repeatable way of doing something" (BSI). Normally they are published documents containing technical information to guide or define practice in a consistent way, and are usually used by designers and manufacturers of products. They are also used by customers when specifying products, and authorities when checking product compliance, particularly where the use of a standard is listed in the Declaration of Conformity or the technical file.

Normally the use of standards is voluntary and they do not impose legal responsibilities. However, in some cases legislation may ‘call-up’ a specific standard effectively giving it legal force (e.g. under the Construction Products Regulations products covered by its designated standards must meet certain minimum requirements of those standards concerning the Declaration of Performance), or their use by a manufacturer may be declared, effectively binding them and their product, to the requirements of the quoted standard.

The British Standards Institute (BSI) is the UK's National Standards Body, and publishes in English all British, European and many International standards. In many cases standards are double prefixed "BS EN" which means this is the UK version in English of a European standard (in some cases the prefix may be "BS EN ISO" where an international standard has been adopted by Europe as a European standard, and the published by BSI). The UK, through BSI as a member of CEN, CENELEC, ISO and IEC, continues to contribute to the preparation of International and European standards, as well as British Standards in areas where there are none at, or proposed at, European or International level.

Although the use of almost all standards remains voluntary (the Construction Products Regulations may be an exception where a product is in scope of a relevant standard), if a designated standard is followed in full by a product designer it can confer presumption of conformity with one or more essential requirements, provided the product is within scope of the standard and the standard supports the relevant product safety legislation - without qualification.This means in effect that by following the requirements of a currently designated standard a designer knows that his product will comply with the relevant parts of the legislation applying to his product. The use of such standards can save designers

much time in assessing risks and adopting strategies for safety, particularly where the standard deals with all essential requirements relating to a particular product.

Standards are subject to review and revision, and normally the presumption of conformity they can provide is only valid for the latest version of the standard (manufacturers should regularly check the listing made by the Secretary of State for the relevant legislation).

In many cases designated standards define the state of the art for either a product or safety feature.
Although the use of any standard by a designer or manufacturer is voluntary where compliance with any standard is declared without qualification on the Declaration of Conformity for the product, that manufacturer is bound to fully meet all requirements of those quoted standards for his product.

Standards are not usually applied retrospectively to products first placed on the market before the standard was published, and may only define the 'state of the art' at the time they were developed and published. Standards are therefore subject to periodic review), and so their provisions may change over time. Standards should normally be referenced to a dated version. Where a standard is referenced undated, for example on a Declaration of Conformity or in a technical file, the market surveillance authorities can assume that the manufacturer is referring to the latest version of that standard prevailing at the time the product was placed on the market. Designers and manufacturers should therefore keep aware of the current status of standards relevant to their product, and ensure that product documentation is similarly kept under review and updated as necessary.

Technical files

Manufacturers of new products subject to product safety legislation must collect and be able to assemble comprehensive information covering the design, construction, conformity assessment and use of the product to demonstrate how their product complies with all applicable product legislation. This is known as a technical file or technical documentation. It should be in English and kept available for at least the time period specified in the relevant product legislation (e.g. for machinery this means for at least 10 years since last production of the product range).

A technical file must be complied for each product you as a manufacturer or importer placed on the market (or one file for a series of identical products) as required by the relevant product safety legislation. It should demonstrate with appropriately detailed documentation, calculations and drawings, how the product complies with all relevant product legislation, and so is safe and compliant during all phases of its life. Systematically assembling the technical file may also help you when undertaking the conformity assessment process for a particular product. If you have to submit your product for Type-examination, a copy of the technical file must be provided to the Approved Body at the same time.

The content depends on the relevant product safety legislation applicable to the product, but generally should include:

- information concerning the products design assessment and construction, including which essential requirements are relevant, and how these essential requirements have been met (which may include references to technical standards applied),
- the conformity assessment procedure applied to the product,
- a copy of the Declaration of Conformity and Declaration of Performance (if relevant), and any other Declarations of Conformity or Incorporation relevant to the product or its subassemblies/component parts)
- a copy of the User Instructions,
- details of relevant research and test reports,
- and where a series of products are made, details of the quality systems to assure the safety of those products with the original specification (and any changes made).

Normally the technical file does not have to be permanently available in material form provided it is capable of being assembled and made available in a reasonable period of time. But you must be able to provide the technical file/documentation to any appointed market surveillance authority (MSA) on a duly reasoned request and within a reasonable time scale (which for material that should exist prior to the product being placed on the market means days/1-2 weeks, not months). A failure to do so may give sufficient grounds for the MSA to doubt the conformity of the product in question with essential requirements and so prevent its placing on the market. The technical file should be available from a UK address even where the manufacturer is not UK based (e.g. under the Supply of Machinery (Safety) Regulations the address from where the technical file may be obtained must be included on the Declaration of Conformity)

Purchasers are not entitled to see a products' technical file, but they should be provided with User Instructions, including information on noise and vibration levels (if relevant), and for safe installation, some of which is needed in sales literature to help product selection.

Instructions

New products must be accompanied by information, most often in the form of an Instruction Manual. All product safety legislation requires information to be made available to end users to enable the safe use of products. Others, such as installers, may also need information to enable the product to be safely installed before use. User instructions should be comprehensive, easy to understand, and in English (except certain parts for specialist maintenance activity where this will not be undertaken by the user). Other information provided on the product such as warnings, which may be given in pictorial form, should be explained in the user instructions. User instructions essential for health and safety should be provided in a printed form. A copy of the original Instruction Manual should be included as part of the technical file for a product.

The precise contents of information to be provided with a product depends on the relevant product legislation, but can be summarised as sufficient detail about the product regarding:

- intended use, and ways the product should not be used
- the manner of installation
- correct use to ensure health and safety, and
- safe maintenance, including cleaning, unblocking, and any inspection and testing

Some legislation specifies the content of Instructions for users and others such as installers in significant detail. For example, the Supply of Machinery (Safety) Regulations, where essential health and safety requirement (EHSR) 1.7 specifies detailed information requirements for all types of products covered, and EHSRs 2.1.2, 2.2.1.1, 2.2.2.2, 3.6, & 4.4 supplement this for specific types of machinery (e.g. cleaning instructions for machinery processing foodstuffs to avoid cross contamination in the processed product). Others such as the Electrical Equipment Safety Regulations 2016 are less specific, although, where possible key information is required on the electrical component itself so it can be used safely in the manner intended.

Instructions should cover not only intended use of a product, but take account of reasonably foreseeable misuse, warning of ways the product should not be used. Where the product is intended to be used by non-professionals instructions should be worded and laid out taking account of the level of general education and understanding that can be expected of such users. Short quick start guides may be a useful additional approach.

In some cases the results of product testing should be provided in the User Instructions. For all machinery information on airborne noise emissions must be provided, and in the case of hand-held and hand-guided machinery, information concerning vibrations transmitted must also be provided. Where machinery is likely to emit non-ionising radiation information concerning the radiation emitted for the operator and exposed persons should be provided. Sales literature describing the performance characteristics of machinery must contain the same information on emissions as is contained in the instructions.

Where the on-going safety of a product depends on it remaining within certain parameters (e.g. below a certain force limit for a powered door/gate, the stopping time of a braking system, trip current of electrical equipment), this information should be specified within the maintenance, inspection or examination/testing sections of the instructions.

In the case of partly completed machinery (PCM, as defined by the Supply of Machinery (Safety) Regulations) assembly instructions must be provided instead. Assembly instructions must contain a description of the conditions which must be met with a view to the correct incorporation of the partly completed machinery into the final machinery, so as not to compromise safety and health (e.g. relevant data on safety performance/reliability so the required safety performance of the machinery is achieved when the PCM is incorporated).

Instructions, and warnings given on products must be in English. Where pictorial warnings are given on the product these, along with the meanings of any warning devices, should be explained in the Instruction Manual.

Exceptionally, parts of the machinery maintenance instructions intended for use only by specialised maintenance personnel mandated by the manufacturer may be supplied in another language which the specialised maintenance personnel understand. However, the other general parts of the user instructions must be supplied in English.

Declarations

Most new products must be supplied to end users with a certificate called a Declaration of Conformity which must relate to the particular product placed on the market. Products in scope of the Construction Products Regulations and a relevant standard must also be accompanied by a Declaration of Performance. There is also a Declaration of Incorporation, which is only currently relevant for partly completed machinery as defined by the Supply of Machinery (Safety) Regulations.

A Declaration of Conformity, Performance or Incorporation is a formal declaration by a manufacturer, or the manufacturer's representative, that the product to which it applies meets all relevant requirements of all product safety legislation applicable to that product. It is a sign that the particular product has been designed and constructed for compliance with relevant essential requirements, and has been through the appropriate conformity assessment processes. The precise requirements are specified in each piece of product legislation, but essentially Declarations of Conformity should include the following key information:

- the name and address of the organisation taking responsibility for the product
- a description of the product
- list which product safety legislation it complies with
- may include details of relevant standards used
- and be dated, and signed by a representative of the organisation placing it on the market.

Such Declarations are not quality certificates, nor a guarantee for safety. However, when properly drawn up along with UKCA marking on the product, conformity of the product with the product legislation quoted on the Declaration may be presumed by economic operators in the distribution chain and by the end customer, provided there are no obvious or known defects, and permit free movement throughout the GB market . However, this presumption of conformity is rebuttable if it can be shown that the product is not in fact in conformity with all aspects of any applicable product legislation.

Products subject to more than one piece of legislation should normally have a single Declaration of Conformity declaring conformity with all of the relevant product legislation. However, where a product bearing UKCA marking is incorporated in another, such as a

safety interlock in a machine, the Declaration of Conformity for the final product need only declare conformity of the overall final product. In this case the Declaration(s) for any component parts should form part of the technical file for the complete product.

For some new products the full Declaration of Conformity must accompany the product through the supply chain to the end user (e.g. for all products in scope of the Supply of Machinery (Safety) Regulations). This is not required for electrical equipment within scope of the Electrical Equipment Safety Regulations 2016, but key information about the product must be supplied, although often a copy of the Declaration is included in the User Manual. However, under the Electrical Equipment Safety Regulations a Declaration of Conformity must be drawn up by the manufacturer or the manufacturer's authorised representative, and included in the technical documentation. Declarations must also be made available to Importers where they place the product on the market. Some product legislation permits the use of a 'simplified Declaration', e.g. the Radio Equipment Regulations, where the simplified version must accompany the product to the end user.

Declarations must also, on request, be made available by any economic operator to any market surveillance authority (MSA). MSAs must presume that products with correct UKCA marking, and accompanied by suitable Declaration(s) comply with the provisions of the legislation mentioned on them, and so not restrict their free movement, unless they have evidence to the contrary (for example by examining or testing the product).

A Declaration of Incorporation may only be issued when placing partly completed machinery (PCMs) on the market. PCMs are drive systems and other assemblies that are:

- almost machinery,
- cannot in themselves perform a specific application, and
- are only intended to be incorporated into or assembled with other partly completed machinery or equipment, so forming machinery that is not excluded from the Supply of Machinery (Safety) Regulations 2008.

This is essentially because partly completed machinery is not in a final state that will allow it to operate and it needs to be incorporated with other parts so it can work as part of the final machine. In its partly completed state it may be not be able to fully conform to all of the essential health and safety requirements of the Supply of Machinery (Safety) Regulations. The interface where partly completed machinery will be combined with other parts will therefore require assessment and protection when the final machine is assembled.

PCMs must not be UKCA marked under the Supply of Machinery (Safety) Regulations, as they are only intended for incorporation to form machinery to which UKCA marking will be later applied. However, PCMs may need to bear UKCA marking under other legislation (e.g. the Radio Equipment Regulations) if other product safety legislation applies alongside the Supply of Machinery (Safety) Regulations. Hence the importance of the separate

Declarations of Conformity and of Incorporation to clearly indicate on what basis UK marking is applied to PCMs.

This special legal status (PCM, as defined) cannot be used as a means of avoiding compliance with the full conformity assessment as required by the Supply of Machinery (Safety) Regulations for complete products (e.g. by leaving off safety items such as guards and saying it is "partly complete"). If a product can operate as a machine it must always be fully protected with all safeguards provided, be UKCA marked and accompanied by a Declaration of Conformity.

In addition to similar particulars as required on a Declaration of Conformity (manufacturer / authorised person details, description etc, date and signature, etc), the Declaration of Incorporation must also clearly state:

- "that the partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the provisions of these Regulations, where appropriate"
- "an undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery."
- "which essential health and safety requirements are applied and fulfilled… and where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant legislation." (Note, there is no requirement for a PCM to fulfil any EHSRs, but it will usually be helpful if those which are relevant to the PCM itself (eg materials used to make the PCM, performance characteristics of any control system in the PCM,) are covered by the technical file for the PCM, and stated on the Declaration of Incorporation – otherwise it may be very difficult for the person incorporating the PCM to meet his conformity assessment obligations under the Supply of Machinery (Safety) Regulations).

Obligations of economic operators to cooperate with market surveillance authorities

Under most product safety legislation the obligations of all economic operators are standardised (an exception is the Supply of Machinery (Safety) Regulations 2008 where there is no concept of distributor, but they are covered by the broad obligations of other legislation such as Section6 of the Health & Safety at Work etc Act 1974 or the General Product Safety Regulations 2005). In them various explicit obligations are laid on manufacturers, importers and distributors (all as defined by the legislation), including:

- for monitoring and investigating compliance, re-testing/examining in certain cases
- keeping records on products and the traceability information,
- Declarations of Conformity,
- information of any reported non-conformity,
- any recalls or other risk information,
- the passing of information up and down the supply chain, and that of

- cooperating fully with requests from any relevant market surveillance authority examining compliance of the product. For example, the failure to present the technical file for products in scope of most product legislation in response to a duly reasoned request from the relevant authorities may give rise to valid grounds for doubting the conformity of the product.

In the case of the Supply of Machinery (Safety) Regulations 2008 essentially only the manufacturer, and any authorised representative, are mentioned as explicit duty holders – however, even under the Supply of Machinery (Safety) Regulations importers and distributors may in certain cases have the manufacturer's obligations for products they place on the market, or put into service for the first time, modify before putting into service, or re-brand and market under own name.

In most cases the person responsible for placing the product on the market for the first time must be established within the UK. In the case of machinery where this is not so, the Declaration of Conformity must state a UK from where the technical file may be obtained (this does not have to be an authorised representative), in addition to the manufacturer, and any authorised representatives', address.

Finally, the UK product supply legislation imposes various legal obligations on economic operators reflecting the requirements of the Market Surveillance Regulation 765/2008. These include enforcement powers for market surveillance authorities to require: Compliance, Withdrawal and/or Recall from the market in appropriate circumstances, as well as full cooperation to evaluate product conformity, suspend goods from free circulation (often in coordination with Customs authorities), and dissuasive penalties through the criminal legal system.

ANNEX Useful reference information

All of the following are amended by the Product Safety and Metrology etc (Amendment etc) (EU Exit) Regulations 2019 to ensure continuity of requirements necessary for the safety of products placed on the UK market:

- Supply of Machinery (Safety) Regulations 2008
- Electrical Equipment (Safety) Regulations 2016
- Lifts Regulations 2016
- Pressure Equipment (Safety) Regulations 2016
- Simple Pressure Vessels (Safety) Regulations 2016
- Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016
- Regulation 2016/425 on PPE and the Personal Protective Equipment (Enforcement) Regulations 2018
- Regulation 2016/426 on Gas Appliances and the Gas Appliances (Enforcement) and Miscellaneous Amendments Regulations 2018
- Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001
- Radio Equipment Regulations 2017
- Electromagnetic Compatibility Regulations 2016
- Pyrotechnic Articles (Safety) Regulations 2015
- Explosives Regulations 2014
- Toys (Safety) Regulations 2011
- Regulation 765/2008 on market surveillance etc
- General Product Safety Regulations 2005
- The Accreditation Regulations 2009

Also, the 2019 amendment Regulations remove the EC reference for Declarations of Conformity from:

- The Lifting Operations and Lifting Equipment Regulations 1998