

Placing products on the single European market: a product safety guide for the UK

Introduction

UK businesses wishing to supply goods into the single European market, comprising the EU and EEA member states, and Switzerland, must meet EU single market rules for product conformity and in many cases show this by CE marking. 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 may also apply to a particular product and must also be met in full for product compliance (eg environmental provisions). Furthermore, this guide is not a substitute for the provisions of the relevant European legislation or other detailed guidance such as the EU Blue Guide or the RAPEX guidelines.

Key examples of relevant European product legislation and topic guidance are listed. All are freely available using the legislation's reference via the Commission's europa.eu website.

Placing industrial products on the single European market

European 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 (eg on electromagnetic compatibility), its emphasis is on the health and safety of industrial products by design and construction.

New products may not be placed on the single European market unless they fully meet the requirements of all product legislation relevant to the product. CE marking, which is a sign of compliance for many goods regulated under the New Approach, is required in most cases, as well as product labelling indicating the relevant economic operator(s). Manufacturers may only affix the CE marking when all of the requirements of all CE marking legislation applicable to the product have been met. Where CE marking is not required by any product legislation applicable to the product it must not be affixed (eg industrial scaffolding towers): in these cases, manufacturers must meet all applicable national requirements for the particular product for the market(s) it is made available, and recognised standards may assist in helping meet these.

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 single European market. Enforcement of any non-compliance will be subject to the national provisions of each member state of the market on which a product is made available. National market surveillance authorities have general obligations, which are summarised by European Regulation 765/2008 on market surveillance, to deal with non-compliance, taking account of the principle of proportionality, in particular where products present risk.

Compliant products accompanied by appropriate 'Information for Use', and in many cases EC Declarations (of Conformity, Incorporation or Performance) in the language of the market for which they are intended, then have a right of free movement within the single European market, without further barrier to trade.

Manufacturers, importers (who place goods on the single European market for the first time from a third country) and distributors who subsequently make goods available (which have already been placed on the market by manufacturers or importers), are collectively known as economic operators and have specific duties as described by the specific product legislation. With the recent alignment of much European product legislation to the New Legislative Framework (NLF) these duties are common for much product legislation, as too are the definitions of terms like manufacturer, importer, distributor, placing and making available on the market, and many others (see EC Decision 768/2008 for further details of these obligations and definitions).

Certain legislation, like the Machinery Directive 2006/42/EC, have yet to be fully 'aligned' according to the NLF, but expect to be on revision in the next few years. A number of specific guides have been published by the European Commission on the application of certain legislation like that for lifts, machinery, pressure, ATEX and electrical equipment, and electro-magnetic compatibility. These freely available guides explain further the specific application of the legislation they cover, in particular the safety objectives or essential requirements that such products must meet by design and construction, and the procedures concerning third party verification when required for specific products.

CE marking

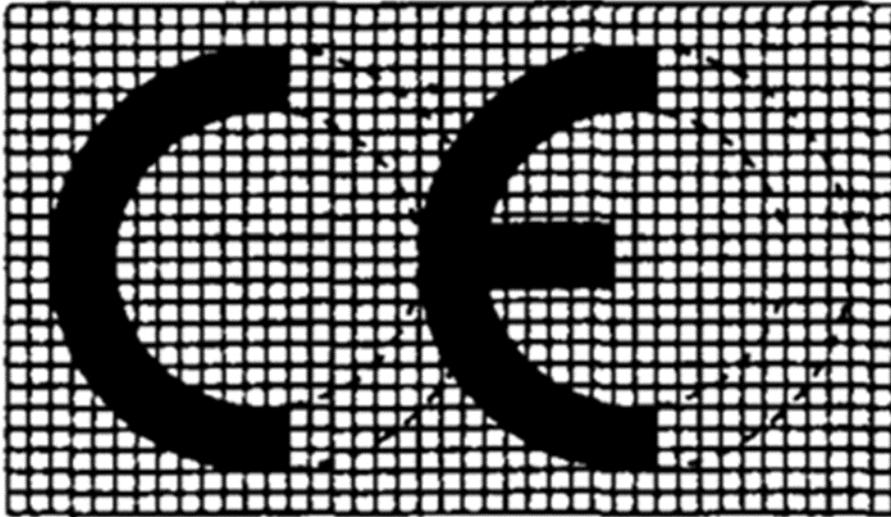
Most new products placed on the European market and regulated by the New Approach must be CE marked. This will include products which are "new" to the single European market, that is second-hand products from outside Europe and which are put into service or placed on the market in Europe for the first time, some existing products which are so substantially modified as to be considered "new", and users who make certain products (eg machinery) for their own use.

CE marking is the responsibility of the person/company who places the product on the single European market for the first time, or in some cases (eg 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 single market for the first time (particularly where goods are not yet compliant, eg without CE marking, etc), and those who rebrand products made by another to supply under their own brand name.

By affixing CE marking you take on responsibility for the conformity of the product. CE marking is a visible sign that the product complies with all relevant product supply requirements, 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 CE mark is not a quality mark, nor a guarantee that the product actually meets all of the requirements of relevant EU product safety law.

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

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



Conformity assessment

This is the process by which persons can legally place safe and compliant products onto the single 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 who have been notified by an EU member state to the EU Commission (usually referred to as 'Notified 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 directives 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 the language of the end user.

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 by a conformity assessment body and/or full assessment by a third party conformity assessment body (quality assurance). Full details of the procedures are given, normally within the Annexes, 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 single 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 (eg under the Gas Appliances Regulation 2016/426/EU) the economic operator responsible for product compliance must select an appropriate EU Notified Body to assist. However, whilst the Notified Body will undertake an assessment of the product and the manufacturer's quality system, and may issue an EU 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 CE marking, before placing the product on the market.

Although most larger member states have several Notified Bodies within their territory, and manufacturers will often for convenience use one of their national Notified Bodies, they can choose to use any valid accredited Notified Body in any member state that is permitted to examine that particular product type. But they are not entitled to 'play off' one Notified Body against another. In applying for assessment by a Notified Body the applicant must declare that an application for the same product has not been made to another Notified Body. Manufacturers are advised to check that the proposed Notified Body is valid for the product type and conformity assessment module (see below for details on NANDO website).

If a Notified Body issues an EU 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 EU Type-examination certificate means. It is a document indicating that in the Notified Bodies' judgement the product meets the requirements of particular product legislation. It is not a Declaration of Conformity, although details of any Notified Body issuing such a certificate should be included on the Declaration of Conformity, as well as the Type-examination reference number.

EU 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 Notified 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 a Notified 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, eg the Low Voltage Directive 2014/35/EU. However, there is nothing to stop an economic operator approaching a Notified Body, or another organisation, to assist with his product assessment, but if a Notified 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 Notified 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.

EU Notified Bodies

They provide an independent assessment of a product against all of the relevant essential requirements of specific applicable legislation, and the standards used in the design, for which as Notified Body they are competent and appointed to undertake. Notified Bodies, which are subject to accreditation, must be appointed by a member state of the EU. They 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 harmonised standard for the product, or the product cannot meet a relevant harmonised standard).

In some cases, an example of the product will be submitted to the Notified Body for EU 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, alternative procedures may be followed. For example, some Directives/Regulations permit a full quality assurance conformity assessment route where a Notified Body must assess and audit the full quality assurance system for the design and manufacturing processes.

If the Notified 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 an EU Type-Examination Certificate. This should be retained, along with other relevant documentation (eg 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 Notified Bodies' title, address and 4-digit code. This information on the Declaration of Conformity will enable purchasers and market surveillance authorities to make enquiries on the validity of the Notified Body used, and in the case of market surveillance authorities, facilitate enquires into the validity of the Notified Body's assessment of the product.

Where a Notified Body undertakes a type-examination, a copy of the technical file will have to be provided to the Notified Body, and the Notified Body, as well as the manufacturer (or other economic operator if relevant), must keep this for a significant period (eg in the case of the Machinery Directive, for 15 years from the date of issue of the Type-examination certificate).

In circumstances where, following assessment, a Notified Body has not issued a Type-Examination Certificate the Notified Body is under a duty to communicate its decision and reasons to the applicant and share information with the appointing member state and other Notified Bodies. There are committees of EU Notified Bodies to facilitate such communication, both 'horizontal' (cross-cutting issues) and 'vertical' (sectorial issues).

Some aspects of product safety legislation are unclear or ambiguous, and the European Commission via the relevant advisory committee may approve a ruling drawn up by a committee of EU Notified Bodies, known as Recommendations for Use (RfU). These seek to aid consistency in the assessment and decision taking of Notified Bodies, especially where the matters of concern are not currently addressed by standards. Notified Bodies must take into account any relevant RfUs in making their assessment of submitted products. RfUs are published by the Commission on the Europa website against the relevant legislation

Notified 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. For an organisation to act as a Notified Body it must be appointed and accredited according to EC Regulation 765/2008 by the member state in which it is located.

Each European Notified Body has its own unique 4 digit identification number. The NANDO website <http://ec.europa.eu/growth/tools-databases/nando/> publishes list of Notified Bodies by: 4-digit number, member state and legislation, and includes details of the areas of competence (which legislation and in some cases which conformity assessment procedures) for which they currently are permitted to act as a conformity assessment body.

Essential requirements

All product legislation requires conformity with essential requirements, sometimes known as safety objectives. These requirements are usually listed in Annex I of the legislation and tailored to the specific characteristics of the product types in scope for the objectives of the legislation. Standards,

especially those harmonised to the legislation (see later), often assist in describing or 'benchmarking' the 'state of the art' for products in scope. 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', although they can choose to go beyond these minimums if they wish.

In the main, essential requirements set objectives to be reached rather 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, which they must show through technical documentation/file 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. Further discussion of this concept in the context of the Machinery Directive's Essential Health and Safety Requirements (EHSRs) as listed at Annex I of 2006/42/EC may be found at paragraph 161 of the European Commission Guide to the Machinery Directive.

Some product legislation (eg the Machinery Directive 2006/42/EC) indicates the order of preference in which risks must be managed, following long standing principles of:

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

Where a hazard can be avoided or reduced 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 (eg 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 (eg 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.

Some "total" product safety legislation has a comprehensive list of essential requirements dealing with all aspects of health and safety (eg the EHSRs for machinery), whereas other product legislation only covers a restricted range of issues (eg the essential requirements of the EMC Directive only deal with issues of electromagnetic compatibility). Note that although the objectives of Annex I of the Low Voltage Directive (2014/35/EU) principally concern electrical matters it is nevertheless a 'total' safety Directive even though non-electrical hazards are not further detailed (however many standards supporting LVD 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 Directives will apply, and the designer and manufacturer must take account of and simultaneously meet the requirements of both Directives' essential requirements. However, for 'total safety Directives' that cover all risks, only one can be applied to any product. But this situation is covered, for example medical devices which are also machines. Although medical machinery is out of the scope of the Machinery Directive, the EHSRs of the Machinery Directive are 'called up' by the Medical Devices Directive and Regulations, in so far as those EHSRs are relevant to that medical device. Similarly, the essential requirements of the Low Voltage Directive are brought into the Machinery Directive via EHSR 1.5.1, so any Standard developed for the Low Voltage Directive may be support the design of machinery, especially the electrical system.

Standards and their use

The use of Standards in complying with European product safety legislation is not compulsory, but they can be very useful when designing products, and may simplify the conformity assessment process. Some European standards (those which are harmonised) 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" or "EN", sometimes by both)
- National standards (eg British Standards prefixed by "BS", German by "DIN", etc)
- 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 declared 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 (eg under the Construction Products Regulation (EU/305/2011) products covered by its harmonised standards must meet certain minimum requirements of those standards concerning the Declaration of Performance). Manufacturers who declare compliance with a standard effectively bind themselves and their product to the requirements of the standard.

The British Standards Institute (BSI) is the UK's National Standards Body, and publishes in English all National, 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). 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.

In the field of European product safety transposed harmonised standards are a group of standards with special status. Their status is confirmed by their listing in the Official Journal of the European Union (OJEU), although usually an indication of the status of any particular standard is given in the standard, and any limits on its coverage, at Annex Z. Although their use remains voluntary, if a transposed harmonised standard is followed in full by a product designer it can confer a presumption of conformity with one or more essential (health and safety) requirements, provided the product is within scope of the standard and the standard supports the relevant product safety legislation – and without qualification, eg as detailed by Annex Z, and fundamentally by any modification to the listing in the OJEU (usually a complete de-listing or restriction of an existing standard's presumption of conformity following due process and publication of a Commission Decision in the OJEU).

This means in effect that by following the requirements of a currently transposed harmonised standard a designer knows that his product will comply with the 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 check the listing in the OJEU against the relevant legislation).

In the machinery sector, standards dealing with a particular type of product are often referred to as "C" standards (eg BS EN 1493 Vehicle Lifts). Those dealing with common safety issues (eg BS EN 574 Two-hand control devices) are often referred to as "B" standards, and those dealing with the fundamental principles for safety (eg BS EN ISO 12100 Safety of machinery - General principles for design - Risk assessment and risk reduction) as "A" standards.

European standards typically follow a similar style and format and knowing something of the structure can help reading and understanding them. The following is typical of a CEN machine specific "C" standard supporting the Machinery Directive as published by BSI:

- the European standard (EN) will be inside a BSI "wrapper" with a National forward. Inside that will be an unaltered copy of the EN as published by CEN or CENELEC (some EN standards are similarly based on international ISO or IEC standards, so there is also a European or 'EN' wrapper around the ISO/IEC),

- the front page of the standard describes the status and origin of the EN,
- the Scope of a standard is fundamental as here the products to which the standard applies, and in some cases does not apply, are detailed,
- a section listing other Standards referenced within. These are of two types: "normative" references which form a legal part of the Standard, and "informative" references which are for information and do not form part of the Standard,
- a section Defining terms used in the standard, and sometimes the products,
- a Hazard Analysis section,
- a section listing the Safety Requirements for each hazard,
- a section indicating measures for product Verification against the requirements,
- a section outlining what the Instructions for Use should contain,
- and it may be accompanied by a number of Annexes. These may be Normative (which directly support the Safety Requirements), or Informative, including
- usually in Annex Z, the origin, status, and extent to which the standard supports product legislation, including which essential requirements, and so for which it may give a presumption of conformity (if listed without qualification in the OJEU).

In many cases transposed harmonised standards define the state of the art for either a product or safety feature. For example:

BS EN ISO 13857 Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs which was prepared under a mandate given to CEN by the European Commission and the European Free Trade Association (more information on the process of developing standards is available). This standard provides one means of conforming to Essential Requirements of the New Approach Directive 2006/42/EC on machinery, by defining the safe minimum distances through different sized holes in guards to prevent access to dangerous parts.

Nevertheless, the use of even this standard remains voluntary, fundamental as it is for defining safety distances. All a product designer /manufacturer has to do is meet the objectives of the essential requirements of the relevant product legislation and show this in his technical file. The standard shows one way this can be done, and if followed gives a presumption of conformity.

However, in certain circumstances, and where justified, even fundamental standards such as this need not be followed, provided the designer and manufacturer can show compliance with the essential requirements in their technical file by another equally effective method so the level of risk reduction is at least as good as if the standard had been used. For example, the physical nature of a product may ergonomically constrain access to dangerous parts even though the safety distance is less than that defined in BS EN ISO 13857, and so it may be justified in particular circumstances to not follow the standard in full.

The use of any standard by a designer or manufacturer is voluntary. But 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 standards for his product.

Standards are not usually applied retrospectively to products first placed on the market before the standard is published and may only define the 'state of the art' at the time they were developed and published. European standards, like most others, are therefore subject to periodic review (normally the process starts 5 years after the date of publishing by CEN etc), 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 Documentation

Manufacturers of new products subject to European 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 documentation or a technical file in some cases. It should be in one or more of the official Community languages and kept available for at least the time period specified in the relevant product legislation (eg for machinery this means for at least 10 years since last production of the product range).

The technical documentation must be compiled for each product that a manufacturer or importer places on the single European market (or one file for a series of identical products) as required by the relevant European 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

manufacturers when undertaking the conformity assessment process for a particular product. If a product is submitted for type-examination, a copy of the technical documentation must be provided to the Notified 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 documentation does not have to be permanently available in material form, nor located within the territory of the EU/EEA/Switzerland, provided it is capable of being assembled and made available in a reasonable period of time. But manufacturers must be able to provide the technical documentation to any European market surveillance authority (MSA) on a duly reasoned request and within a reasonable timescale (which for material that should exist prior to the product being placed on the market means days/1 to 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 an EU address even where the manufacturer is not EU based (eg under the Machinery Directive 2006/42/EC the address from where the technical file may be obtained must be included on the Declaration of Conformity).

End users are not entitled to see a product's technical documentation, but they should be provided with User Instructions, including information on noise and vibration levels (if relevant), and for safe installation, some of which may be 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 European product safety legislation require 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 a language easily understood by the end user (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 safety should normally be provided in a printed form.

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 Machinery Directive, where essential health and safety requirement (EHSR) 1.7 specifies detailed information requirements for all types of products covered, and EHSRs 2.1.2 etc supplement this for specific types of machinery (eg cleaning instructions for machinery processing foodstuffs to avoid cross contamination in the processed product). Others, such as the Low Voltage Directive, 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 (eg 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 Article 2g of the Machinery Directive 2006/42/EC) 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 (eg 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 the official Community language or languages of the member state(s) in which the product is first placed on the market and/or first put into service. This may require dedicated language versions for each member state the product is marketed in, or, as is often seen, multi-language instructions / warnings including all languages of all the members states on which the product is placed on the market. 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 the one official Community language which the specialised maintenance personnel understand. However, the other general parts of the user instructions must be supplied in the language of the end user.

A copy of the original Instruction Manual should be included as part of the technical documentation/file for a product, along with any translations made into other Community languages.

EU Declarations

Most new products must be supplied to end users with a certificate called an EU Declaration of Conformity which must relate to the particular product placed on the market. Products in scope of the Construction Products Regulation (EU/305/2011) 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 Machinery Directive.

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 Directives 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 single European market.

Such Declarations are not quality certificates, nor a guarantee for safety. However, when properly drawn up along with CE 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 user, provided there are no obvious or known defects, and permit free movement throughout the European single 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 Directive/Regulation should normally have a single Declaration of Conformity declaring conformity with all of the relevant product legislation. However, where a product bearing CE 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 (eg for all products in scope of the Machinery Directive). This is not required for electrical equipment within scope of the Low Voltage Directive (LVD) 2014/35/EU, but key information about the product must be supplied, although often a copy of the Declaration is included in the User Manual. However, under LVD 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, eg the Radio Equipment Directive 2014/53/EU, where it must accompany the product to the end user.

Declarations must also, on request, be made available by any economic operator to any EU market surveillance authority (MSA). MSAs must presume that products with correct CE 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 Directive (see Articles 2g and 1(2) of the Machinery Directive 2006/42/EC)

This is basically 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 not be able to fully conform to all of the essential health and safety requirements of the Machinery Directive. 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 CE marked under the Machinery Directive, as they are only intended for incorporation to form machinery to which CE marking will be later applied. However, PCMs may need to bear CE marking under other legislation (eg the Radio Equipment Directive) where other CE marking legislation applies alongside the Machinery Directive. Hence the importance of the separate Declarations of Conformity and of Incorporation to clearly indicate on what basis CE 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 Machinery Directive for complete products (eg 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 CE 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 the directive, 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 Directives." (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 obligations under conformity assessment).

Obligations of economic operators to cooperate with market surveillance authorities

Under product safety legislation aligned with the NLF (Decision 768/2008) the obligations of all economic operators are standardised between the various legislation. In this legislation various explicit obligations are laid on manufacturers, importers and distributors (all as defined by Decision 768/2008), eg:

- 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 European market surveillance authority examining compliance of the product. For example, the failure to present the technical documentation 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 other cases (eg the Machinery Directive) essentially only the manufacturer, and authorised representative, are mentioned as duty holders – however, even under the Machinery Directive 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 EU/EEA/Switzerland. In the case of machinery where this is not so, the Declaration of Conformity must state a European address 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, most member states have imposed various National legal obligations on economic operators reflecting the requirements of single market product legislation, especially 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 their administrative and/or criminal legal systems.

ANNEX

Useful reference information

European Commission Blue Guide 2016 Edition on the implementation of product rules: <http://ec.europa.eu/DocsRoom/documents/18027/>

All of the following legislation and a number of European Guides for specific topics (eg on lifts, machinery, electrical, radio and pressure equipment, etc) can be found via the Commission webpages at:
https://ec.europa.eu/growth/sectors_en

- Machinery Directive 2006/42/EC & Pesticides Amendment Directive 2009/127/EC
- Agricultural and Forestry Vehicles Regulation 167/2013/EU
- Personal Protective Equipment Regulation 2016/425/EU
- Low Voltage Directive (LVD) 2014/35/EU
- Electromagnetic Compatibility Directive 2014/30/EU
- Radio Equipment Directive 2014/53/EU
- ATEX Directive 2014/34/EU
- Lifts Directive 2014/33/EU
- Pressure Equipment Directive (PED) 2014/68/EU
- Simple Pressure Vessels Directive (SPVD) 2014/29/EU
- Gas Appliances Regulation 2016/426/EU
- Cableways Regulation 2016/424/EU
- Explosives Directive 2014/28/EU
- Pyrotechnic Articles Directive 2013/29/EU
- Medical Devices Regulation EU/2017/745
- Construction Products Regulation 305/2011/EU
- Noise emissions by equipment for use outdoors Directive 2000/14/EC
- Emission of gaseous and particulate pollutants by non-road mobile machinery Regulation 2016/1628/EU

- Restriction of the use of certain hazardous substances in electrical and electronic equipment Directive 2011/65/EU
- Eco-design for Energy Related Products Directive 2009/125/EC
- Toys Safety Directive 2009/48/EC
- General Product Safety Directive (GPSD) 2001/95/EC
- Decision 768/2008/EC on common framework for the Marketing of Products
- Regulation on Accreditation and Market Surveillance (RAMS) 765/2008/EC

Lists of Harmonised Standards as published in the Official Journal of the EU are available at: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en

NANDO database of Notified Bodies <http://ec.europa.eu/growth/tools-databases/nando/>