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UKCA Product Certifications

Requirements for Market Access

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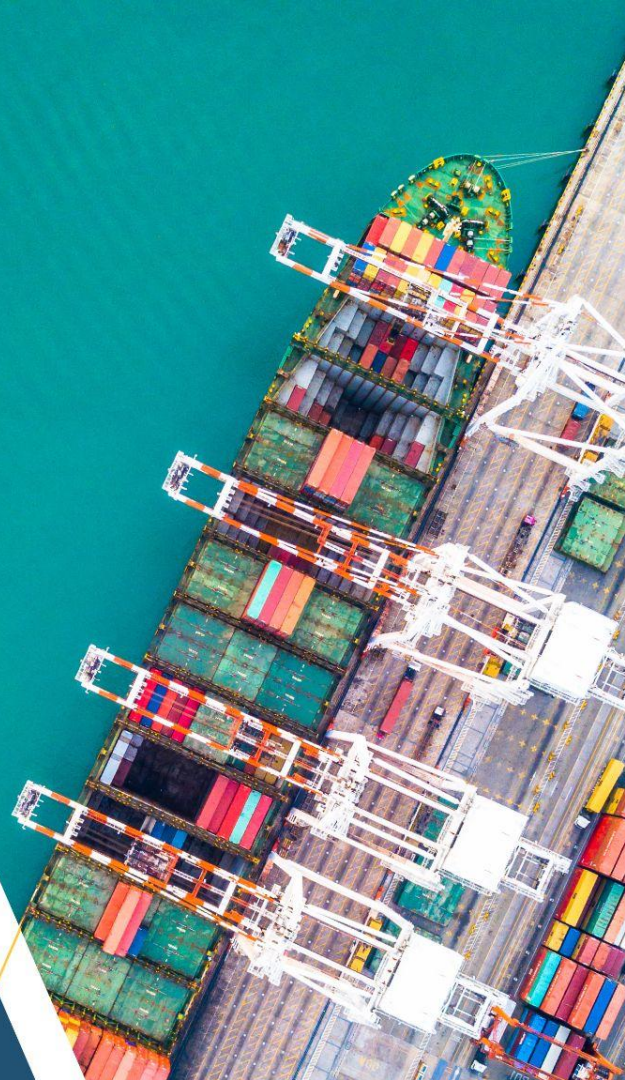


DISCLAIMER

This presentation does not represent legal advice.

It is for reference only and requirements indicated are subject to change. This presentation does not assume to include ALL required activities in order to place products on the market in the United Kingdom or Great Britain - it is intended to provide a high-level overview of the requirements as they are understood as of October 2022.

For the most current information provided by authorities on the requirements for market access using the UKCA or UKNI schemes in the United Kingdom or Great Britain, please refer to:

https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-great-britain

https://www.gov.uk/guidance/using-the-ukca-marking

https://www.gov.uk/guidance/ukca-marking-roles-and-responsibilities

https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-northern-ireland

Past and future webinars:

https://www.gov.uk/guidance/webinars-for-using-the-ukca-marking-and-placing-goods-on-the-market-in-great-britain-and-northern-ireland

Product Compliance Requirements

European Union

To support a single market of goods for trade across the European Union, the 27 Member States of the EU utilize a common approach for managing technical requirements for products on the market

EU member states

Non-EU countries participating in the EU single market through the EEA or other agreements

European Union Market Access

“Conformité Européenne”

The letters ‘CE’ appear on many products traded on the extended Single Market in the European Economic Area (EEA). **They signify that products sold in the EEA have been assessed to meet high safety, health, and environmental protection requirements.**

The product’s “manufacturer” (whose name is on the product) bears the sole responsibility for declaring conformity with all requirements

“manufacturer” ≠ “assembler” or “designer”

By affixing the CE marking to a product, a manufacturer declares that the product meets all the legal requirements for that product and can be sold throughout the EEA, regardless of where the product is manufactured

The EU “Blue Guide” (most current version - 2022) outlines many other aspects of selling products in the EU that are subject to the CE marking Directives.

The Blue Guide also gives specifics around the format of the DoC, CE-marking, placing products on the market, etc.

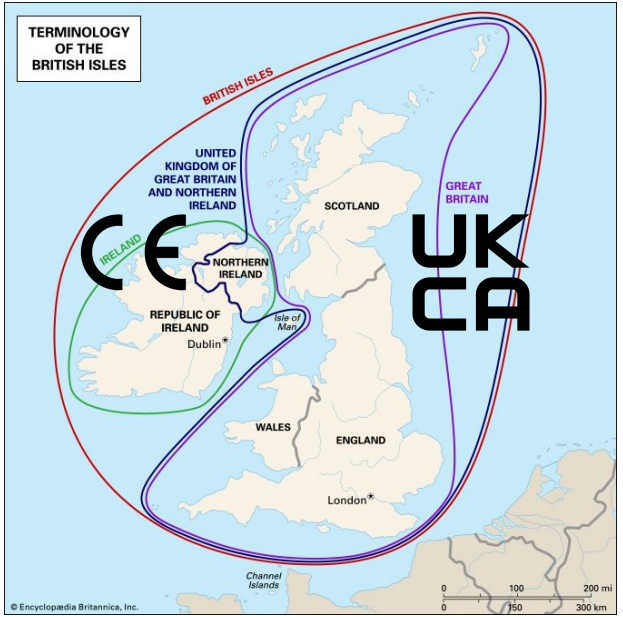
Link to download the Blue Guide in multiple languages: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2022:247:TOC

https://europa.eu/youreurope/business/product-requirements/labels-markings/ce-marking/index_en.htm

UK Product Legislation

Selling products in the UK after EU-Exit (“Brexit”)

- As of January 2021, the UK transition period for their exit from the EU is no longer in effect
- Great Britain (England, Scotland and Wales) ceased utilizing the CE-mark to demonstrate product conformity to regulations and have developed a new “UKCA” certification
  - Although Northern Ireland is part of the United Kingdom, there is a separate Brexit agreement in place which includes NI aligning with the EU product regulations, including utilization of the CE
- **Throughout 2021-2022 both the CE and the UKCA are recognized as compliant** for most of the regulations, but as of January 2023 **only** the UKCA will demonstrate conformity to UK requirements in Great Britain
  - There may be additional requirements for Northern Ireland



https://www.gov.uk/guidance/using-the-ukca-marking

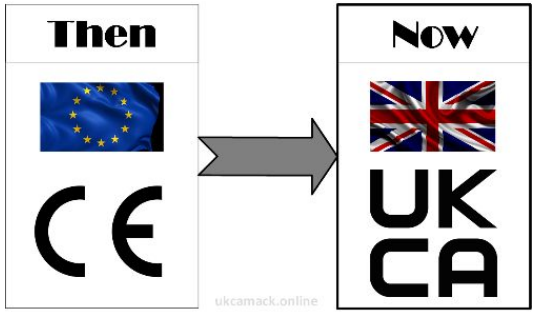
UK Product Legislation

UKCA vs. CE

The UKCA marking applies to most goods previously subject to the CE marking. It also applies to aerosol products that previously required the ‘reverse epsilon’ marking.

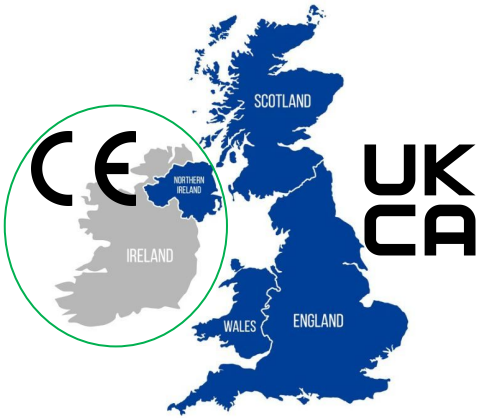
The technical requirements (‘essential requirements’) you must meet – and the conformity assessment processes and standards that can be used to demonstrate conformity – are largely the same as they were for the CE marking.

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



Great Britain Market Access

UKCA-Marking Directives and Regulations



Products sold in Great Britain must meet design-related regulations:

- There are multiple UKCA-Marking regulations that, if applicable, **must be met and documented**
- Many products fall into the scope of multiple regulations and must meet the requirements of each one in order to be "compliant", and eligible for the CE or UKCA mark

Aerosols	Construction Products	Ecodesign of energy-related products	Electrical Equipment Safety	Electromagnetic Compatibility (EMC)
Equipment for potentially explosive atmospheres (ATEX)	Explosives for civil use	Gas Appliances	Hot water boilers	Lifts
Machinery	Measuring Instruments	Medical devices	Noise Emission for Outdoor Equipment	Non-automatic weighing instruments
Personal Protective Equipment	Pressure equipment	Pyrotechnics	Radio Equipment	Recreational craft
Restriction of Hazardous Substances (RoHS)	Toys	Simple Pressure Vessels		

Each regulation sets out "essential requirements" that must be met

European Union Legal Instruments
Directives vs. Regulations

Some CE-marking requirements are “Directives” while others are “Regulations”.
Both are legally mandatory, but are implemented differently

- **Regulations** are legal acts that apply immediately and uniformly to all EU countries as soon as they enter into force.
  - They are horizontal requirements that are binding in their entirety in all EU countries
  - The REACH Regulation is an example – it does not require legislation at the Member State level
- **Directives** require EU countries to achieve a certain result but leave them free to choose how to do so.
  - EU countries must incorporate requirements into national law (transpose) in order to achieve the objectives set by the directive, generally within 18-24 months
  - The EU RoHS Directive is an example – while the objectives are set in the EU-level legislation, each Member State must individually incorporate those requirements into national law

More information on the regulations and directives by product groups is on the EC site for manufacturers:
https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en

UKCA Product Legislation

UK Legislation for some EU Directives

EU	UK
ATEX - Equipment for potentially explosive atmospheres 2014/34/EU	Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres Regulations 2016
Ecodesign Directive 2009/125/EC	Ecodesign for Energy-Related Products and Energy Information Regulations 2010
Electromagnetic Compatibility Directive 2014/30/EU	Electromagnetic Compatibility Regulations 2016
Gas appliances 2016/426	Gas Appliances (Enforcement) and Miscellaneous Amendments Regulations 2018
Lifts 2014/33/EU	Lifts Regulations 2016
Low Voltage Directive 2014/35/EU	Electrical Equipment (Safety) Regulations 2016
Machinery Directive 2006/42/EC	Supply of Machinery (Safety) regulations 2008
Measuring Instruments 2014/32/EU	Measuring Instruments Regulations 2016
Non-automatic Weighing Instruments 2014/31/EU	Non-automatic Weighing Instruments Regulations 2016

UKCA Product Legislation

UK Legislation for some EU Directives

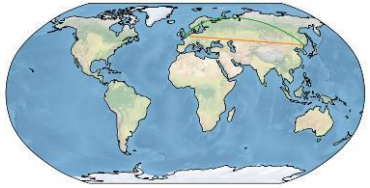
EU	UK
Outdoor Noise Directive 2000/14/EC	Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001
Personal protective equipment 2016/425	Personal Protective Equipment (Enforcement) Regulations 2018
Pressure equipment 2014/68/EU	Pressure Equipment (Safety) Regulations 2016
Pyrotechnic Articles 2013/29/EU	Pyrotechnic Articles (Safety) Regulations 2015
Radio Equipment Directive 2014/53/EU	Radio Equipment Regulations 2017
Recreation craft and personal watercraft 2013/53/EU	Recreational Craft Regulations 2017
Restriction of Hazardous Substances Directive 2011/65/EU	Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment 2012
Simple Pressure Vessels 2014/29/EU	Simple Pressure Vessels (Safety) Regulations 2016
Toy Safety Directive 2009/48/EC	Toy (Safety) Regulations 2011

While this process overview is for the UKCA or CE certification process, many other countries follow a similar approach for their market-access certifications

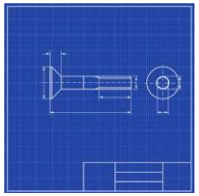
Great Britain Market Access

Obtaining UKCA "Certification"

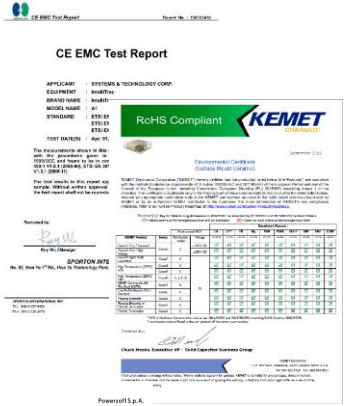
Identify the markets, define applicable directives, regulations and standards and determine whether an independent conformity assessment (by a notified body) is necessary



Design product to technical requirements

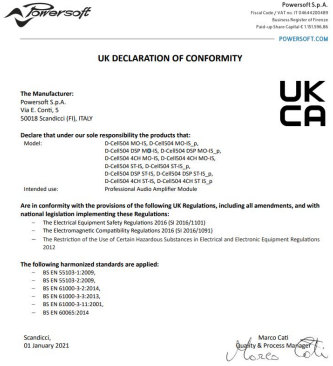


Test the product and check its conformity



Draw up and keep available the required technical documentation including all relevant test reports, supplier RoHS declarations, etc.

Draw up the Declaration of Conformity, Declaration of Performance, and/or Declaration of Incorporation (depends on product and relevant Directives)



Manufacture product and affix the UKCA marking to the product (and packaging if available)

Ensure all other non-UKCA product regulations are met (for example, relevant REACH regulation, Packaging, WEEE, NRMM, Batteries, Biocides, etc.)

Import products. There may be other import/export, label or local language requirements

More details on each step are available in the back-up section

European Union Market Access

Conformity Assessment - Notified Bodies

While **some** directives allow companies to assess their own products, others require the use of a **“Notified Body”**.

A notified body is an organization designated by an EU country to assess the conformity of products before being placed on the market. These bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation when a third party is required

- A Notified Body verifies the compliance of a product by conducting a conformity assessment. It also ensures that the technical documentation sufficiently supports product compliance.
- If the Notified Body is involved in the production control phase, its identification number will follow that CE marking.
- When the Notified Body is convinced of product compliance it issues a certificate of conformity to confirm this. Then the **manufacturer** still must draw up the Declaration of Conformity (DoC) to declare on his sole responsibility conformity to the relevant Directive.
- While a Notified Body is designated by an individual EU Member State, the assessment supporting the CE will be recognized across the European Economic Area.

If a product is in scope of multiple regulations, a Notified Body may be required to provide conformity assessment for SOME regulations, while the manufacturer may self-assess for others

This same approach is used for the UKCA, but Great Britain has a separate set of “Approved Bodies”. The same product, if being both CE and UKCA certified, must be tested separately for each certification.

Great Britain Market Access

Conformity Assessment - Approved Bodies

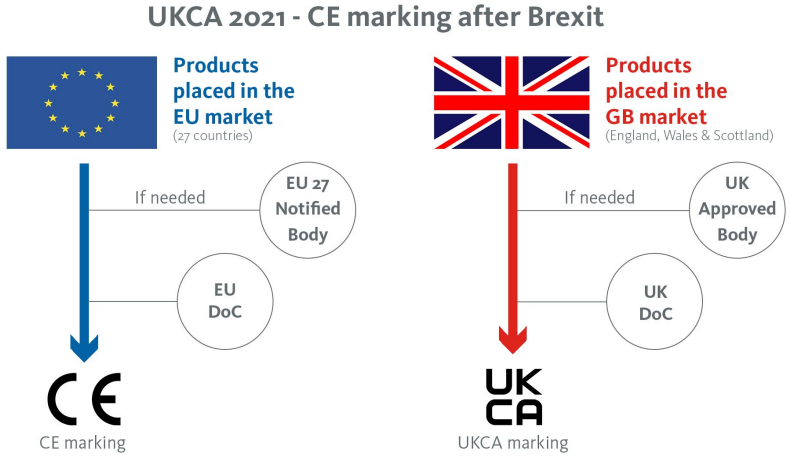
Just as in the EU, **some** product regulations require the use of an appointed third-party to conduct the conformity assessment for the product.

- The term for these third-parties operating in this capacity is "Approved Bodies" in the UK while the EU term is "Notified Bodies"

https://www.gov.uk/uk-market-conformity-assessment-bodies

UK Approved Body No. 2636

Products being certified for both CE and UKCA, and which are in scope of directives/regulations that mandate the use of appointed third-parties (either "Notified Bodies" or "Approved Bodies") will need to be assessed twice – once in the EU and once in the UK



European Market Access

Conformity Assessment - Approved and Notified Bodies

This step is not obligatory for all products. Check if your product has to be tested by a 3rd party:

- UK: https://www.gov.uk/guidance/uk-conformity-assessment
  (Annex 2 lists the legislation that is covered by this requirement)
- EU: https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en
  (check the appropriate product type)

Bodies approved by the UK and/or EU Member States can be found online:

- UK: https://www.gov.uk/uk-market-conformity-assessment-bodies
- EU: https://ec.europa.eu/growth/tools-databases/nando/

- If your product doesn't need to be verified by an independent body, then it is up to you to check that it complies with the technical requirements. This includes estimating and documenting the possible risks when using your product. It may or may not involve the use of a third-party test agency (not operating as an “Approved” or “Notified Body”) or your own in-house accredited test labs
- If you need to involve a notified body, the label marking must be accompanied by the identification number of the notified body.

UKCA Mark

UK Declaration of Conformity (DoC)

The Declarations for UKCA are similar, but not exactly the same, as the CE declarations

- The UK uses the term “designated” standards rather than “harmonised” standards
- UK legislation must be referenced, not EU regulations
- BS standards must be used instead of EN standards. Guidance from the government states:
  - “On 1 January 2021 the UK standards will be the same in substance and with the same reference as the standards used in the EU. However, they will use the prefix ‘BS’ to indicate that they are standards adopted by the British Standards Institution as the UK’s national standards body”

HARMAN
A SAMSUNG COMPANY

UKCA-DECLARATION OF CONFORMITY (DoC)

Document No. 60003-20210211

We

Company Name:	Harman Professional, Inc.
Post Address:	8500 Balboa Blvd.
Postcode and City:	Northridge, CA 91329 USA
Telephone number:	+1 (818) 841-4600
E-Mail address:	HProTechSupportEMEA@harman.com

declare that the DoC is issued under our sole responsibility and belongs to the following product:

Apparatus Model/Product:	*MAC ULTRA PERFORMANCE, MAC ULTRA PERFORMANCE WHITE MAC ULTRA WASH, MAC ULTRA WASH WHITE*
Type:	*Stage luminaire*

Object of the declaration:

Stage and studio moving head fixture with high power LED light source and DMX/Ethernet interface for automated control. Includes the variants Performance having framing/profile effects and the basic Wash type, both with color choices of the outer enclosure.

The object of the declaration described above is in conformity with the relevant legislation of United Kingdom:

UK SI 2016 No. 1101	The Electrical Equipment (Safety) Regulations 2016
UK SI 2016 No. 1091	Electromagnetic Compatibility Regulations 2016
UK SI 2012 No. 3032	Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (RoHS2)

The following BSI standards and technical specifications have been applied:

BS EN IEC 60598-2-17:2018	Luminaires - Part 2: Particular requirements - Section 17: Luminaires for stage lighting, television film and photographic studios (outdoor and indoor)
BS EN 62471:2008	Photo-biological safety of lamps and lamp systems
BS EN 62493:2015	Assessment of lighting equipment related to human exposure to electromagnetic fields
BS EN 55015:2013+A1:2015	Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment
BS EN 55032: 2012	Electromagnetic compatibility of multimedia equipment – Emission requirements, Class B

Page 1 of 2

UK Guidance: Using the UKCA Marking

UKCA Mark

UK Declaration of Conformity (DoC)

The UK DoC is a document which must be drawn up for most products lawfully bearing a UKCA marking. The UK recommends that manufacturers have a separate UK DoC from their EU DoC, however the information required is largely the same. It can vary based on the applicable legislation but generally should include:

- Name and business address of manufacturer or authorised representative
- The product's serial number, model or type identification
- A statement that you take full responsibility for the product's compliance
- The details of the approved body which carried out the conformity assessment procedure *(if applicable)*
- The relevant UK legislation with which the product complies
- UK designated standards (rather than EU standards)
- Your name and signature
- The date the declaration was issued

Where several pieces of legislation apply to a product, the manufacturer has to provide a **single declaration of conformity.**

The DoC must be made available to the surveillance authority upon request**. Some legislation, like that relating to machinery or products with wireless functions, requires products to be accompanied by the DoC**

There are different requirements for the "Declaration of Performance" outlined in the Construction Products Regulation. It's possible for a product to require both a DoC and a DoP

https://www.gov.uk/guidance/using-the-ukca-marking#technical-documentation

Great Britain Market Access

UKCA-Marking the Product

Once the necessary steps have been successfully completed, the logo can be affixed on the product.

- Principles of affixing the marking are the same as for the CE mark:
  - The UKCA marking must be affixed visibly, legibly and indelibly to the product or to its data plate
    - » Where this is not possible or not warranted on account of the nature of the product, it must be affixed to the packaging and the accompanying document
  - The marking may not be affixed until the conformity assessment procedure has been completed
  - The marking cannot be placed on products unless there is a specific requirement to do so in the legislation

https://www.gov.uk/guidance/using-the-ukca-marking

UPDATE

From the UKCA site:

The rules on affixing the UKCA marking are currently the same as for affixing the CE marking, but we intend to introduce legislation to extend the period for which the UKCA marking can be affixed on a sticky label or accompanying document (see below).

UKCA labelling easement until 31 December 2025

The government intends to introduce legislation so that the UKCA marking can be placed on a label affixed to the product or on a document accompanying the product until 11pm on 31 December 2025. This will apply for most products requiring UKCA marking unless there are special rules in place for your specific product area.

There are different rules for:

- medical devices
- construction products
- cableways
- transportable pressure equipment
- unmanned aircraft systems
- rail products
- marine equipment

European Market Access

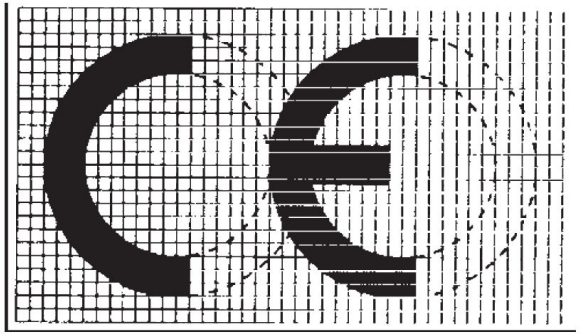
UKCA- or CE-Marking the Product

- The marking can take different forms (e.g. color, solid/hollow) as long as it remains visible, legible and respects its proportions
- Each mark should always be **at least 5mm high** unless otherwise specified in the legislation.
- The official CE mark comprises the letters C and E, with their shapes based on a series of circles.
  - There should be a specific amount of space between the letters

ANNEX II

CE marking

1. The CE marking shall consist of the initials 'CE' taking the following form:



2. If the CE marking is reduced or enlarged, the proportions given in the graduated drawing in paragraph 1 shall be respected.

3. Where specific legislation does not impose specific dimensions, the CE marking shall be at least 5 mm high.

Artwork is available for download:

https://www.gov.uk/guidance/using-the-ukca-marking#technical-documentation

https://single-market-economy.ec.europa.eu/single-market/ce-marking_en

UK CA

European Market Access

Traceability Requirements - Manufacturer Address

Although these requirements are outlined in the EU Blue Guide, UK authorities have indicated the same requirements

- Section 4.2.2 of the Blue Guide includes provisions for “traceability” of the product. Under this requirement, manufacturers must indicate the following on the product label:
  - Their name
  - Registered trade name or registered trademark
  - The address at which they can be contacted (a single point) by market surveillance authorities
- This information must be affixed to the product
  - In some cases, the address may be moved from the product if it is not possible to label the product under reasonable technical or economic conditions, generally based on the size of the product
  - Esthetic reasons are NOT acceptable reasons for not affixing this information to the product
- Manufacturers must also ensure that their products bear a type, batch, serial or model number or other element allowing their identification

Per the Blue Guide, while a website can be additional information, it is not enough as an address. Normally an address consists of a street and number and the postal code and town

European Market Access

Traceability Requirements - Importer Address

The manufacturer's name and address is required to be on the product, regardless of the country of origin. However, to facilitate contact with local representatives in the case of questions or issues, section 4.2.2 of the **Blue Guide** also requires that, when importing a product to the EU market from a third country (including the UK), the manufacturer must ALSO include the name and address of the importer on the product label

4.2.2.2. *The requirement to indicate name and address for importers*

Importers must also indicate the following elements: their (1) name, registered trade name or registered trade mark and (2) the address at which they can be contacted on the product, or, where that is not possible, on its packaging or in a document accompanying the product. The provision refers to an address at which they can be contacted, in particular by market surveillance authorities. This is not necessarily the address where the importer is actually established but can for example be the one of the customer services.

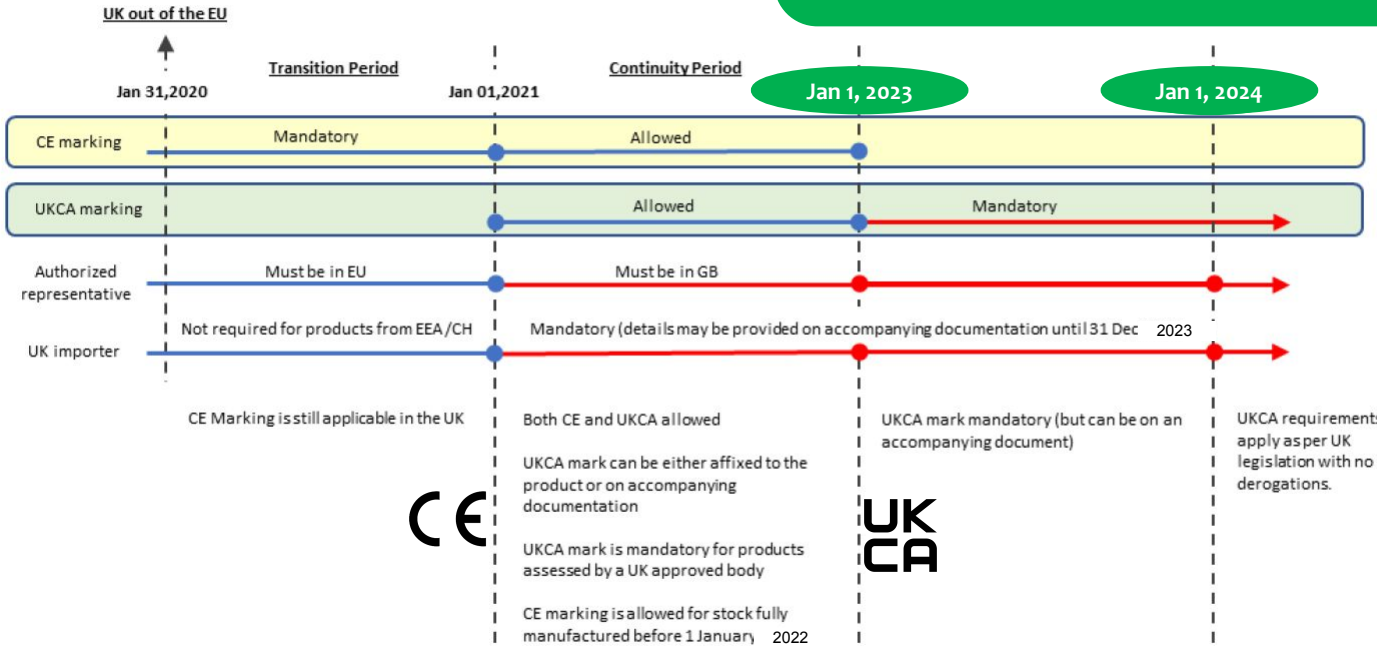
As a rule, the identification and the address of importer must be indicated on the product. Only where it is not possible, the identification and address of the importer may be indicated on the packaging and / or in a document accompanying the product. This may be the case when the importer would have to open the packaging to put his name and address. The additional information from the importer shall not hide the information put on the product by the manufacturer.

A website address may be given in addition to, but not instead of a postal address. Normally an address consists of a street and number or post-box and number and the postal code and town, but some countries might deviate from this model. Also, it is useful to include an email address and/or phone number to facilitate swift contacts with the relevant authorities.

Although these requirements are outlined in the EU Blue Guide, UK authorities have indicated the same requirements

UK Product Conformity Timeline

In August 2021, the UK announced a 12-month extension to these dates. You can continue to use the CE marking for goods placed on the market in Great Britain until 1 January 2023. The UKCA marking must be used for placing goods on the market in Great Britain from 1 January 2023.

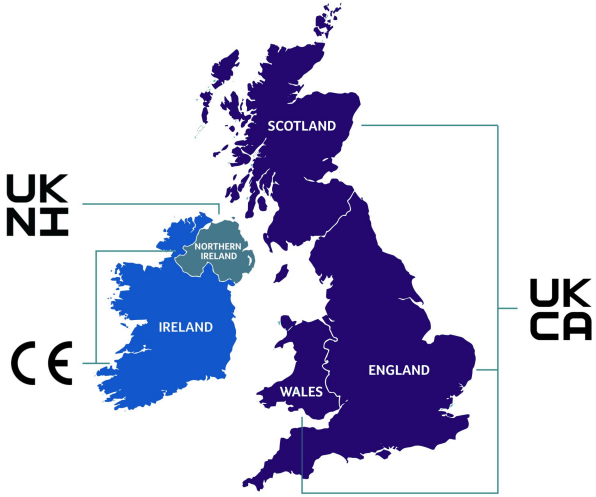


NOTE: The CE marking will only be valid in GB for areas where GB and EU rules remain the same. If the EU changes its rules and you CE mark your product based on those new rules you will not be able to use the CE marking to sell in Great Britain even before 31 December 2022

UK Product Legislation
Northern Ireland Protocol

A separate agreement regarding Northern Ireland came into force in January 2021 which aligns NI with all relevant EU product rules

You must show that your products meet the rules by using "conformity markings". The UKNI marking is a new conformity marking for products placed on the market in NI which have undergone **mandatory** third-party conformity assessment by a Notified Body based in the UK



	Type of Good	Marking(s)
Placing goods on the market in Northern Ireland	Manufactured goods being placed on the market in NI using an **EU conformity assessment body**	CE
	Manufactured goods being placed on the market in NI using a **UK-based body**	CE and UKNI
Placing goods on the market in Great Britain	Manufactured goods being placed on the GB market until the end of 2022	UKCA or CE
	Manufactured goods placed on the GB market from 1 Jan 2023	UKCA
Placing qualifying NI goods on the market in GB (unfettered access)	Qualifying NI goods being placed on the GB market under unfettered access (https://www.gov.uk/guidance/unfettered-access-procedure-for-marketing-authorisations-approved-in-northern-ireland)	CE or CE+UKNI
Placing goods on the EU market	Manufactured goods being placed on the EU market	CE

For further information on the general arrangements for placing goods on the NI market:
https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-northern-ireland

European Union Market Access

The UK has similar counterparts to many of these regulations

Manufacturer Obligations

There are MANY additional European Union regulations and Directives that still may be required but are not covered by the CE mark, including: *(not an exhaustive list)*

- Batteries Directive (2006/66/EU)
- Biocidal Products Regulation (EC No 528/2012)
- Classification, Labeling and Packaging (EC No 1272/2008)
- Energy Labelling Regulation (EU 2017/1369)
- General Product Safety Directive (2001/95/EC) – all products that don't have a separate product-specific regulation applied
- Marine Equipment Directive (2014/90/EU)
- Non-Road Mobile Machinery Regulation (EU 2016/1628)
- Ozone Depleting Substances (EC No 1005/2009) – aka "Montreal Protocol" – **all products**
- Packaging Directive (94/62/EC)
- Persistent Organic Pollutants (EC No 850/2004) – aka "Stockholm Convention" – **all products**
- Plastics Directive (EU 2019/904)
- Product Liability Directive (85/384/EEC)
- REACH Regulation (EC No 1907/2006) – applies to ALL products sold in the EU
- Waste Framework Directive (EU 2018/851) – this includes the requirement to report REACH SVHC's into the **"SCiP" Database (all products)**
- WEEE Directive (2012/19/EU) – nearly all products with an "electrical" function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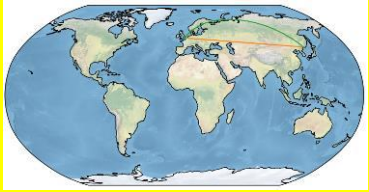
Step 1: Identify the markets, and then the applicable regulations in each market

European Market Access

Obtaining CE or UKCA "Certification"

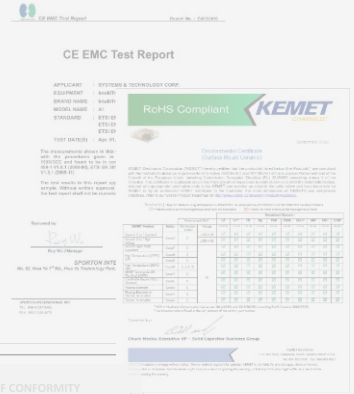
Identify the markets, define applicable directives, regulations and standards and determine whether an independent conformity assessment (by an approved or notified body) is necessary



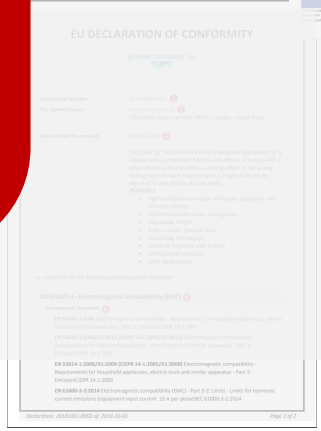
You must first define where the product will be sold so that the correct regulations and standards required for legal sale may be identified

Within the UK and EU, **this includes conducting a risk assessment for the product** and determining whether the product is in the scope of any UK or EU product regulations, and then understanding the requirements of those regulations

Import products. There may be other import/export, label or local language requirements



Draw up and keep available the required technical documentation including all relevant test reports, supplier RoHS declarations, etc.



Draw up the Declaration of Conformity, Declaration of Performance, and/or Declaration of Incorporation (depends on product and relevant Directives)

UK Product Regulations
Essential Requirements

Electrical Equipment Safety Regulations

Each regulation that's aligned with the EU "New Legislative Framework" provides a set of **"essential requirements"** that must be met:

- The manufacturer undertakes a risk assessment to determine which of these requirements will apply to their product, which must be included in the final Technical File
- The "essential requirements" for electrical product safety is shown on the right:

https://www.legislation.gov.uk/uksi/2016/1101/contents

SCHEDULE 1 Regulation 2

Principal elements of the safety objectives for electrical equipment designed for use within certain voltage limits

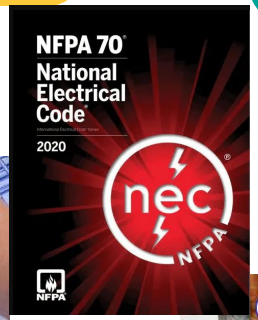
1. General conditions
   - (a) The essential characteristics, the recognition and observance of which will ensure that electrical equipment will be used safely and in applications for which it was made, must be marked on the electrical equipment or, if this is not possible, on an accompanying document.
   - (b) The electrical equipment, together with its component parts, must be made in such a way as to ensure that it can be safely and properly assembled and connected.
   - (c) The electrical equipment must be so designed and manufactured as to ensure that protection against the hazards set out in paragraphs 2 and 3 is assured, providing that the equipment is used in applications for which it was made and is adequately maintained.
2. Protection against hazards arising from the electrical equipment
   - (a) Persons and domestic animals must be adequately protected against the danger of physical injury or other harm which might be caused by direct or indirect contact.
   - (b) Temperatures, arcs or radiation which would cause a danger, must not be produced.
   - (c) Persons, domestic animals and property must be adequately protected against non-electrical dangers caused by the electrical equipment which are revealed by experience.
   - (d) The insulation must be suitable for foreseeable conditions.
3. Protection against hazards which may be caused by external influences on the electrical equipment
   - (a) The electrical equipment must meet the expected mechanical requirements in such a way that persons, domestic animals and property are not endangered.
   - (b) The electrical equipment must be resistant to non-mechanical influences in expected environmental conditions, in such a way that persons, domestic animals and property are not endangered.
   - (c) In foreseeable conditions of overload the electrical equipment must not endanger persons, domestic animals and property.

Standards vs. Regulations

Codes are usually applied where the products are being installed - based on how the product will be USED

A **standard** is a document approved through consensus by a recognized (standardization) body, that provides common rules, guidelines or characteristics for products

Product **regulations** are government rules that are usually applied when the product is imported or placed on the market to be SOLD



Enforcer is **Building Inspector**

Enforcer is Customs or **Market Surveillance**

An "**approval**" is a type of certification by a third-party that is often separate from a regulation. An approval, like a UL listing in the US, can be used to help demonstrate that your product will comply with codes. While every situation is different, they are not USUALLY mandatory in order to sell your product, but may be commercially necessary for customers.

European Market Access
"Designated" and "Harmonised" Standards

UK: https://www.gov.uk/guidance/designated-standards
EU: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en

European standards organizations (CEN, CENELEC or ETSI) develop standards to support the "essential requirements" in the legislation

Manufacturers or conformity assessment bodies can use these standards to demonstrate that products comply with relevant EU and UK legislation.

The references of harmonized (EU) standards must be published in the Official Journal of the European Union in order to provide a "**presumption of conformity**" to the essential requirements of the regulation

In the UK, the standard is recognized by government when it is published on GOV.UK. The UK National Standards Body is BSI

The use of these standards is voluntary but usually provides the easiest path to demonstrate compliance to the regulation

Manufacturers are free to choose another technical solution to demonstrate compliance with the mandatory legal requirements outlined in the legislation that applies to the product but may be required to demonstrate how their solution meets requirements, whereas a "harmonised" or "designated" standard is already accepted by authorities

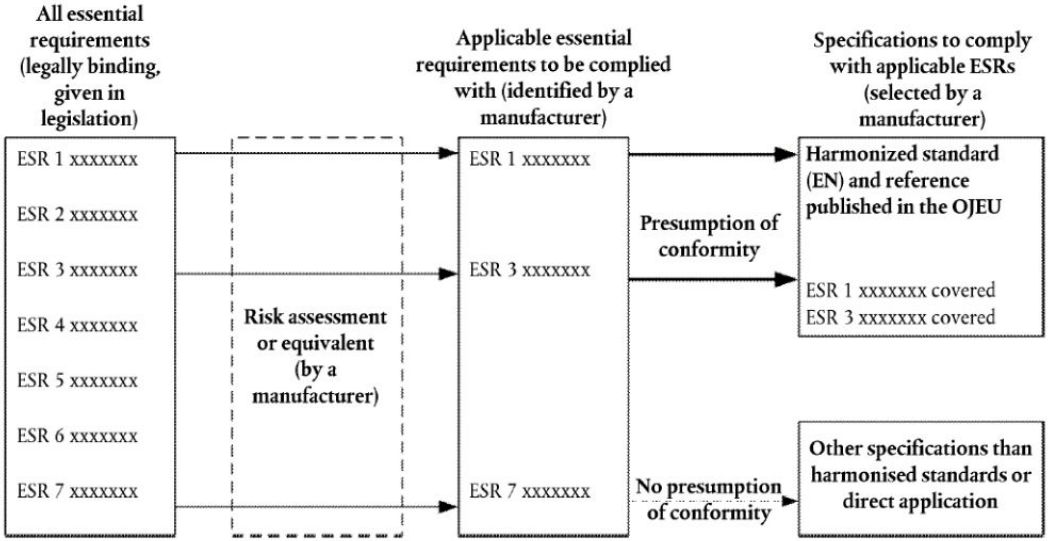
For many "horizontal" Directives, (meaning the Directive itself is not product-specific) standards are often specific by product.

For example, under the EMC Directive, there are over 150 different harmonized standards that have been published in the EU Official Journal. There may be multiple standards that are required to demonstrate compliance – one standard may describe immunity requirements, while another describes emission requirements

Standards can be used to demonstrate conformity to the requirements of the regulation

European Market Access
“Designated” and “Harmonised” Standards

The role of harmonised or designated standards in complying with applicable essential requirements identified by a manufacturer — a generic philosophy for cases where a **manufacturer needs to identify applicable essential requirements** from the legislation through a risk assessment process:



The risk assessment and identification of, and strategy for, meeting essential requirements, must be kept as part of the product “technical file”

EU Low Voltage Directive
Harmonised Standards Published in Official Journal (12/2021)

Reference number of the standard (C)	Title of the standard (D)	Date of start of presumption of conformity (1)	Date of withdrawal from OJ (end of presumption of conformity) (6)
EN 60335-1:2012, EN 60335-1:2012/AC:2014, EN 60335-1:2012/A11:2014	Household and similar electrical appliances - Safety - Part 1: General requirements	20/04/2016	27/05/2021
EN 60335-1:2012, EN 60335-1:2012/AC:2014, EN 60335-1:2012/A11:2014, EN 60335-1:2012/A13:2017	Household and similar electrical appliances - Safety - Part 1: General requirements	27/11/2019	03/02/2022
EN 60335-1:2012, EN 60335-1:2012/AC:2014, EN 60335-1:2012/A11:2014, EN 60335-1:2012/A13:2017, EN 60335-1:2012/A1:2019, EN 60335-1:2012/A14:2019, EN 60335-1:2012/A2:2019	Household and similar electrical appliances - Safety - Part 1: General requirements	03/08/2020	21/06/2023
EN 60335-1:2012, EN 60335-1:2012/AC:2014, EN 60335-1:2012/A11:2014, EN 60335-1:2012/A13:2017, EN 60335-1:2012/A1:2019, EN 60335-1:2012/A14:2019, EN 60335-1:2012/A2:2019, EN 60335-1:2012/A15:2021	Household and similar electrical appliances - Safety - Part 1: General requirements	21/12/2021	

This version of 60335-1 was "withdrawn" in 2021. Any products that were certified using this version of the standard no longer benefit from the "Presumption of Conformity" and the CE certification is no longer valid.

These two versions of 60335-1 will be "withdrawn" in 2022 and 2023; after that date, any products that were certified using these versions of the standard will no longer benefit from the "Presumption of Conformity" and the CE certifications will no longer be valid.

When standards are set to be withdrawn, the products certified using those version must be reassessed to see if they still meet the Essential Requirements.
This assessment should be added to the technical file as justification for not re-testing the product

This version of the standard was published in the OJ in 2021 and doesn't currently have an "end date", so should be the version used to "certify" new products. Products certified to previous versions should be reassessed against the new version

https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en

Step 2: Design the product to meet the identified technical requirements

European Market Access

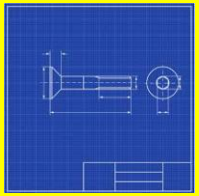
Obtaining CE or UKCA "Certification"

Identify the markets, define applicable directive(s) and standards and determine whether an independent conformity assessment (by a notified body) is necessary

Import products. There may be other import/export, label or local language requirements

Ensure all other non-CE product regulations are met (for example, REACH regulation, Packaging, WEEE, NRMM, Batteries, Biocides, etc.)

Design product to technical requirements

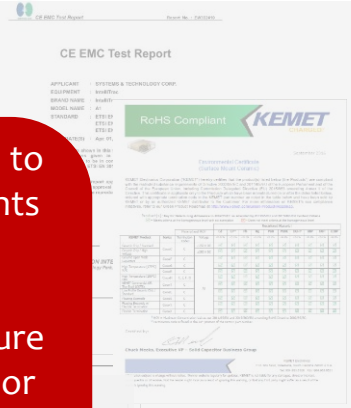


(and packaging if available)

The product must be designed to meet the technical requirements required by the standards.

These may be intended to ensure product safety, performance, or lessen environmental and health impact (for example, restricting the use of Pb-solder in the design of circuit boards for the product)

Test the product and check its conformity



Draw up and keep available the required technical documentation including all relevant test reports, supplier RoHS declarations, etc.

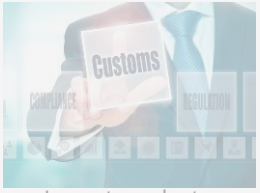
Draw up the Declaration of Conformity, Declaration of Performance, and/or Declaration of Incorporation (depends on product and relevant Directives)

Step 3: Conduct required testing using accredited test labs and/or 3rd parties as required

European Market Access

Obtaining CE or UKCA "Certification"

Identify the markets, define applicable directive(s) and standards and determine whether an independent conformity asses a notified body) is nece



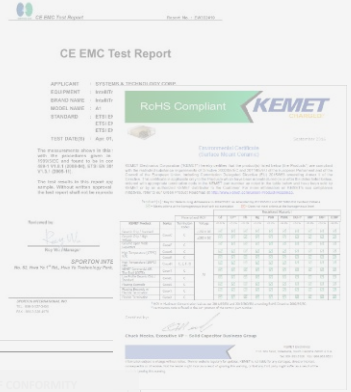
Import products. There may be other import/export, label or local language requirements

Each regulation will outline the conformity process required for that particular regulation.

In some cases the manufacturer may do this testing themselves. In others, it may require the use of an "Approved" or "Notified" Body (third party) to perform this testing

Test the product and check its conformity

e product and affix the CE marking to the product (and packaging if available)



Draw up and keep available the required technical documentation including all relevant test reports, supplier RoHS declarations, etc.

Draw up the Declaration of Conformity, Declaration of Performance, and/or Declaration of Incorporation (depends on product and relevant Directives)

Step 4: Compile all required technical documentation per the regulations

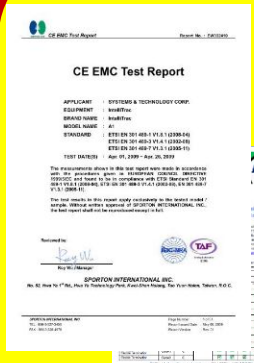
European Market Access

Obtaining CE or UKCA "Certification"

Identify the markets, define applicable directive(s) and standards and determine whether an independent conformity assessment (by a notified body) is necessary

Design product to technical requirements

Test the product and check its conformity



Draw up and keep available the required technical documentation including all relevant test reports, supplier RoHS declarations, etc.

After all of the design and test requirements for each applicable Directive and regulation have been met, the manufacturer must draw up technical documentation, and keep this on-hand for 10 years past the life of the product

Authorities may, under certain circumstances, ask to review the technical file

Import products. There may be other import/export, label or local language requirements

(and packaging if available)

Performance, and/or Declaration of Incorporation (depends on product and relevant Directives)

European Market Access

The manufacturer must keep the technical documentation for 10 years from the date of placing the product on the market

Technical Documentation

Once all of the design and testing requirements have been met, a technical file and product dossier must be compiled


Technical Documentation

The manufacturer shall establish the technical documentation. The documentation shall:

- Include an adequate analysis and **assessment of the risk**(s)
- Specify the applicable requirements
- Wherever applicable, contain at least the following elements:
  - a general description of the product,
  - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
  - descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,
  - a list of the designated (UK) or harmonised (EU) standards and/or other relevant technical specifications the references of which have been published on GOV.UK or in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those standards have not been applied
  - results of design calculations made, examinations carried out, etc., and
  - test reports

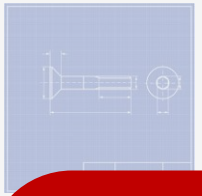
Step 5: Draw up the appropriate Declaration(s) to state compliance

European Market Access

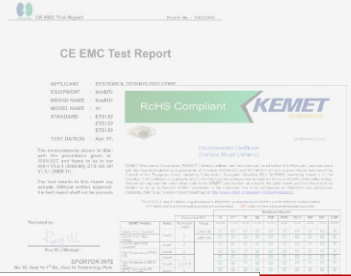
Obtaining CE or UKCA "Certification"

Identify the markets, define applicable directive(s) and standards and determine whether an independent conformity assessment (by a notified body) is necessary

Design product to technical requirements



Test the product and check its conformity

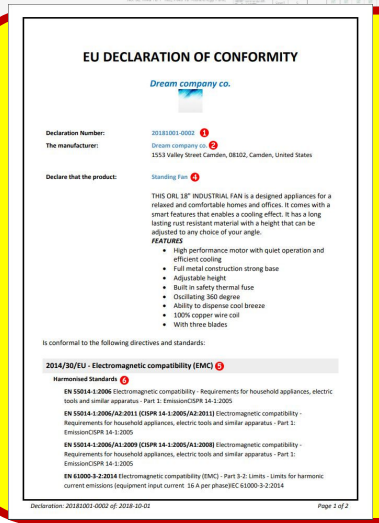


Draw up and keep available the required technical documentation including all relevant test reports, supplier RoHS declarations, etc.

Import products. There may be other import/export, label or local language requirements

Because compliance with the UKCA or CE-marking regulations is "self-declared", the manufacturer is required to write up a **declaration.**

There are three different versions of this "declaration" depending on the product and which regulations apply



EU DECLARATION OF CONFORMITY

Dream company co.

Declaration Number: 20181001-0002 (1)

The manufacturer: Dream company co. (2)
1553 Valley Street Camden, 08102, Camden, United States

Declare that the product: Standing Fan (3)

THIS ORL 18" INDUSTRIAL FAN is a designed appliances for a relaxed and comfortable homes and offices. It comes with a smart features that enables a cooling effect. It has a long lasting rust resistant material with a height that can be adjusted to any choice of your angle.

FEATURES

- High performance motor with quiet operation and efficient cooling
- Full metal construction strong base
- Adjustable height
- Built in safety thermal fuse
- Oscillating 360 degree
- Ability to dispense cool breeze
- 100% copper wire coil
- With three blades

Is conformal to the following directives and standards:

2014/30/EU - Electromagnetic compatibility (EMC) (5)

Harmonised Standards (4)

EN 55014-1:2006 Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: EmissionCISPR 14-1:2005

EN 55014-1:2006/A2:2011 (CISPR 14-1:2005/A2:2011) Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: EmissionCISPR 14-1:2005

EN 55014-1:2006/A1:2009 (CISPR 14-1:2005/A1:2008) Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: EmissionCISPR 14-1:2005

EN 61000-3-2:2014 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current 16 A per phase)IEC 61000-3-2:2014

Declaration: 20181001-0002 of: 2018-10-01 *Page 1 of 2*

Draw up the Declaration of Conformity, Declaration of Performance, and/or Declaration of Incorporation (depends on product and relevant Directives)

European Union CE Mark

Declaration of Conformity and the Blue Guide

The EU **Declaration of Conformity** is the document that states that the product satisfies all requirements of the applicable legislation. Legislation imposes an obligation on the **manufacturer to draw up and sign an EU declaration of conformity** before placing a product on the market.

The "**manufacturer**" is responsible for the generation, accuracy and maintenance of the Declaration (even when an Approved/Notified Body has been used) and is responsible for supplying hard copies and translations. Declaration types:

- Declaration of Conformity (DoC): A single Declaration should be used for declaring conformity with all relevant Directives
- Declaration of Performance (DoP): This is only applicable for products falling under the scope of the *Construction Products Regulation (CPR)*
- Declaration of Incorporation (DoI): This is only applicable for "partially-finished" machinery subject to the *Machinery Directive*

https://europa.eu/youreurope/business/product-requirements/compliance/technical-documentation-conformity/index_en.htm

The EU "Blue Guide" (most current version - 2022) outlines many other aspects of selling products in the EU that are subject to the CE marking Directives.

The Blue Guide also gives specifics around the format of the DoC, CE-marking, placing products on the market, etc.

Link to download the Blue Guide in multiple languages: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2022:247:TOC

EU DoC Example

EU DECLARATION OF CONFORMITY

Dream company co.

Declaration Number: 20181001-0002 1

The manufacturer: Dream company co. 2
1553 Valley Street Camden, 08102, Camden, United States

Declare that the product: Standing Fan 4

THIS ORL 18" INDUSTRIAL FAN is a designed appliances for a relaxed and comfortable homes and offices. It comes with a smart features that enables a cooling effect. It has a long lasting rust resistant material with a height that can be adjusted to any choice of your angle.

FEATURES

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Is conformal to the following directives and standards:

2014/30/EU - Electromagnetic compatibility (EMC) 5

Harmonised Standards 6

EN 55014-1:2006 Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: EmissionCISPR 14-1:2005

EN 55014-1:2006/A2:2011 (CISPR 14-1:2005/A2:2011) Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: EmissionCISPR 14-1:2005

EN 55014-1:2006/A1:2009 (CISPR 14-1:2005/A1:2008) Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: EmissionCISPR 14-1:2005

EN 61000-3-2:2014 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current 16 A per phase)IEC 61000-3-2:2014

EN 61000-3-3:2013 Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current <= 16 A per phase and not subject to conditional connectionIEC 61000-3-3:2013

Additional Information 8

Additional information here...

Notified Body 7

Number: 01234567890
Name: Notified BODY 001
Activity: Revision of an existent certificate
Certificate: 99999999

2014/35/EU - Low voltage (LVD)

Harmonised Standards

EN 60335-1:2012 Household and similar electrical appliances - Safety - Part 1: General requirementsIEC 60335-1:2010 (Modified)

EN 60335-1:2012/AC:2014 Household and similar electrical appliances - Safety - Part 1: General requirementsIEC 60335-1:2010 (Modified)

EN 60335-1:2012/A11:2014 Household and similar electrical appliances - Safety - Part 1: General requirementsIEC 60335-1:2010 (Modified)

EN 60335-2-80:2003 +6Household and similar electrical appliances - Safety - Part 2-80: Particular requirements for fansIEC 60335-2-80:2002

EN 60335-2-80:2003/A2:2009 (IEC 60335-2-80:2002/A2:2008) +6Household and similar electrical appliances - Safety - Part 2-80: Particular requirements for fansIEC 60335-2-80:2002

EN 60335-2-80:2003/A1:2004 (IEC 60335-2-80:2002/A1:2004) +6Household and similar electrical appliances - Safety - Part 2-80: Particular requirements for fansIEC 60335-2-80:2002

EN 62233:2008 Measurement methods for electromagnetic fields of household appliances and similar apparatus with regard to human exposureIEC 62233:2005 (Modified)

EN 62233:2008/AC:2008 Measurement methods for electromagnetic fields of household appliances and similar apparatus with regard to human exposureIEC 62233:2005 (Modified)

2011/65/EU - Restriction of the use of certain hazardous substances (RoHS)

Harmonised Standards

EN 50581:2012 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

This declaration of conformity is issued under the exclusive responsibility of the manufacturer 3

Los Angeles, 2018-10-01 9

Dream company co.
10 *John Smith*
CEO

APPROVED

Unofficial Example Source: https://ce-marking.help/example-of-declaration-of-conformity

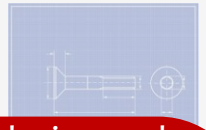
Step 6: Affix UKCA or CE (and any other required markings) to products and/or packaging

European Market Access

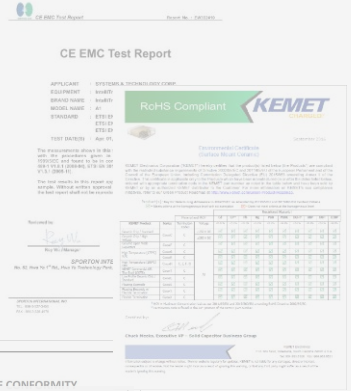
Obtaining CE or UKCA "Certification"

Identify the markets, define applicable directive(s) and standards and determine whether an independent conformity assessment (by a notified body) is necessary

Design product to technical requirements



Test the product and check its conformity



Draw up and keep available the required technical documentation including all relevant test reports, supplier RoHS declarations, etc.

Draw up the Declaration of Conformity, Declaration of Performance, and/or Declaration of Incorporation (depends on product and relevant Directives)

Import p
There ma
import/expor
language re

Once all technical design and testing requirements have been met, the technical file has been compiled, and the Declaration has been created, the manufacturer may then UKCA- or CE-mark the product.

It is also recommended to add the UKCA or CE mark to the packaging if possible to facilitate easier customs entry

UK CA CE

Manufacture product and affix the UKCA or CE marking and other information to the product (and packaging if available). If importing from a third country, the importer address within GB or EU must also be listed

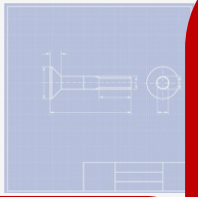
Step 7: Complete conformity requirements for other (non-UKCA or CE) regulations

European Market Access

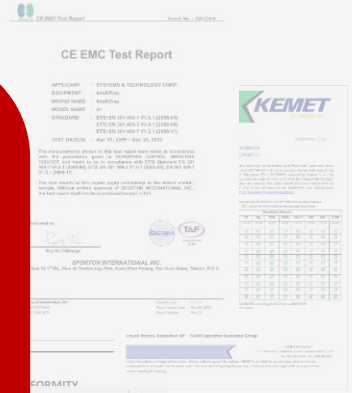
Obtaining CE or UKCA "Certification"

Identify the markets, define applicable directive(s) and standards and determine whether an independent conformity assessment (by a notified body) is necessary

Design product to technical requirements



Test the product and check



Draw up and keep available the required technical documentation including all relevant test reports, supplier RoHS declarations, etc.

Draw up the Declaration of Conformity, Declaration of Performance, and/or Declaration of Incorporation (depends on product and relevant Directives)

Import products. There may be other import/export, label or local language requirements

Ensure all other product regulations are met (for example, REACH regulation, Packaging, WEEE, NRMM, Batteries, Biocides, etc.)

In addition to the UKCA- and CE-mark regulations, there are many other product regulations. However, these are not tied to the UKCA- or CE-mark and if the product only falls into the scope of these requirements (for example, REACH) but not any of the CE-mark regulations, the product must still comply with REACH but should NOT be CE-marked

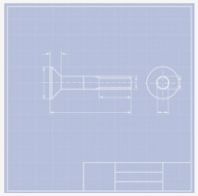
Step 8: Place product on the market for sale

European Market Access

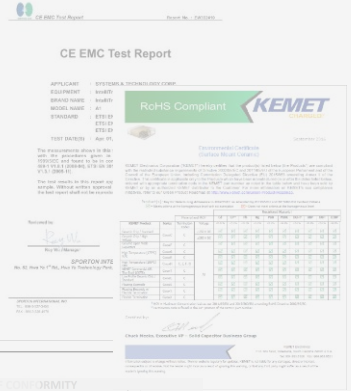
Obtaining CE or UKCA "Certification"

Identify the markets, define applicable directive(s) and standards and determine whether an independent conformity assessment (by a notified body) is necessary

Design product to technical requirements



Test the product and check its conformity



Draw up and keep available the required technical documentation including all relevant test reports, supplier RoHS declarations, etc.

Draw up the Declaration of Conformity, Declaration of Performance, and/or Declaration of Incorporation (depends on product and relevant Directives)

product and affix
g to the product
(and packaging if available)

Import products. There may be other import/export, label or local language requirements

There may be other trade-related requirements that will need to be followed that are separate from the design of the product itself