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The UKCA Mark & CE Marking

Changes to product compliance, certification, testing and market access

February 2021 v1.5

Contents

Introduction

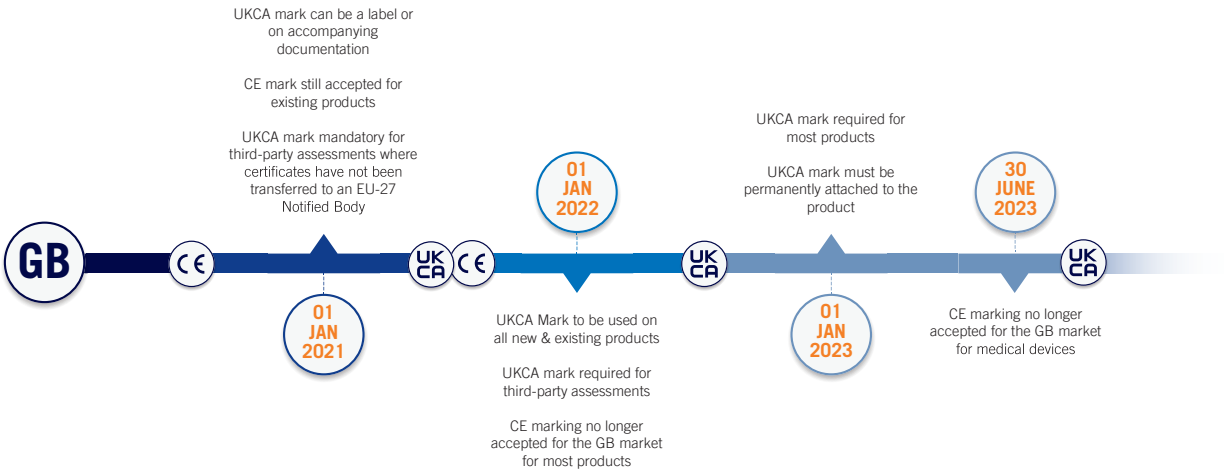
The UKCA (United Kingdom Conformity Assessed) mark is the new product marking scheme to replace CE marking for the GB market (England, Wales and Scotland) that came into force from 1st January 2021 for most products.

The Ireland/Northern Ireland Protocol means that products placed on the Northern Ireland market will continue to meet relevant EU rules including CE marking.

The Headlines

- The UKCA mark came into effect on 1st January 2021
- The principle of self-certification and third-party assessments established under EU legislation is unchanged
- CE marking will continue to be accepted in GB until 31st December 2021 for most products, assuming that GB and EU rules remain the same
- There is no mutual recognition of marks between the UK and EU
- From 1st January 2021, third-party assessments from EU appointed Notified Bodies located in the UK are no longer be accepted in the EU, and certificates issued by those bodies ceased to be valid
- Existing UK based Notified Bodies have ceased to operate and automatically became UK Approved Bodies with the same scope. They will perform the same activities but under the UK Regulations
- CE marking continues to be the product marking scheme for Northern Ireland where the product is placed on the market using self-certification
- To place a product onto the Northern Ireland market that requires the use of third-party approval, either an EU-27 Notified Body can be used and the CE mark applied, or both the CE and UK(NI) mark applied when a UK Approved Body is used

Placing Products on the GB Market



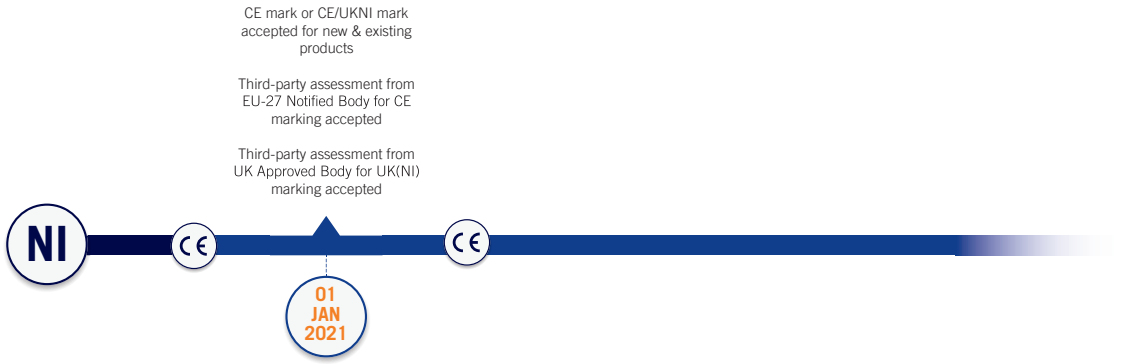
Special rules apply for some products. The timelines shown are simplified and do not show these special rules.

- The UKCA mark can be used to demonstrate conformity with UK Regulations for products placed on the GB market from 1st January 2021.
- To allow businesses time to adjust to the new requirements, CE marking can continue to be used until 31st December 2021 for most products assuming that GB and EU rules remain the same.
- The UKCA mark should be used immediately from 1st January 2021 if **ALL** of the following apply:
  - The product is intended for the GB market
  - It is covered by legislation which requires the UKCA marking
  - It requires mandatory third-party conformity assessment
  - A third-party assessment has been carried out by an EU appointed Notified Body located in the UK and the files have not been transferred to an EU-27 Notified Body

Note that this does not apply to existing stock, for example if goods were fully manufactured and ready to be placed on the market before 1st January 2021. In these cases, a product can still be sold in GB.

- From 1st January 2022, all products placed on the GB market are required to be UKCA marked unless special arrangements, such as those for medical devices, are in place
- CE marking for medical devices will continue to be recognised in Great Britain until 30 June 2023 assuming that GB and EU rules remain the same.
- Products that are currently CE marked on the basis of an EU Notified Body assessment are, from 1st January 2022, required to be assessed by a UK Approved Body for GB market access
- For businesses based in Northern Ireland, qualifying Northern Ireland goods can be placed on the GB market with an EU conformity assessment marking, such as the CE marking, after 31st December 2021.

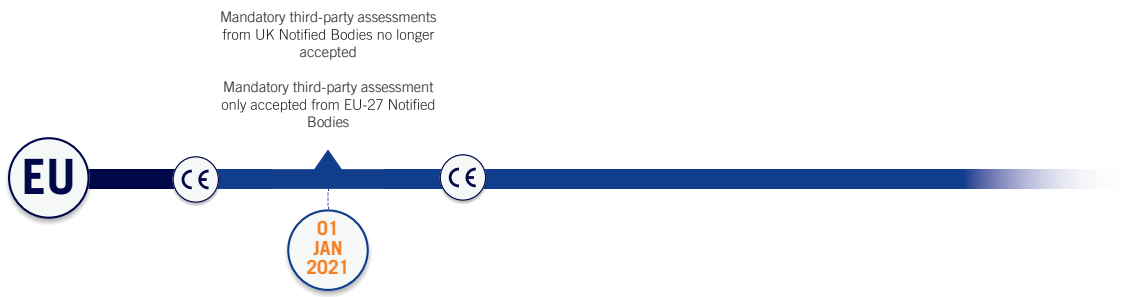
Placing Products on the NI Market



Special rules apply for some products. The timelines shown are simplified and do not show these special rules.

- New and existing products that are CE marked can be placed onto the NI market without any changes
- The UKCA mark is not recognised in Northern Ireland
- Products that require third-party assessment can be placed onto the Northern Ireland market using either an EU-27 Notified Body and affixed with the CE mark or a UK Approved Body and affixed with both the CE and UK(NI) marks
- Existing third-party assessment from an EU-27 Notified Body continues to be accepted for the Northern Ireland market

Placing Products on the EU Market



Special rules apply for some products. The timelines shown are simplified and do not show these special rules.

- For products using self-certification, no action is required
- For products having third-party assessment by an EU-27 Notified Body, no action is required
- Where a product has third-party assessment from an EU appointed Notified Body located in the UK, the files should have been transferred to an EU-27 Notified Body before 1st January 2021 or a new assessment completed by an EU-27 Notified Body

How we can help you?

Eurofins E&E UK, as well as the wider Eurofins group, can help ensure that your products can continue to have unhindered market access to the GB, NI and EU markets.

Watch our UKCA Webinar

Our UKCA webinar contains a range of information regarding these changes and how they may affect your use of compliance marking on your products as well as the route to market that you use.

Click here to view the latest version of this recording.

Get in touch and let us know how we can help

We would be happy to answer any questions around compliance for both new and existing products so please get in touch.

You can contact any of our team by email at UKCA@eurofins.com or click here to use our contact form.

You can also use the live chat on any of our websites as well as calling any of our locations across the UK. Contact details can be found on the last page of this document.

The UKCA Mark

What is the UKCA Mark?

The UKCA (UK Conformity Assessed) mark is the new UK product mark that is required for certain products being placed on the market in Great Britain (England, Wales and Scotland). It covers most products that previously required the CE mark.

The UKCA mark is not recognised outside of Great Britain and products will still need to bear a CE mark to be sold in the EU.

CE marking will continue to be accepted in Northern Ireland under the Ireland/Northern Ireland Protocol.

What does a UKCA mark show?

By affixing a UKCA mark to a product and placing it onto the GB market, the manufacturer is stating that the product meets the UK Regulations as defined in the relevant Statutory Instruments (SIs).

When does the UKCA mark come into force?

The UKCA mark came into force at 11pm UK time on the 31st December 2020 which marked the end of the transition or implementation period.

However, to allow manufacturers time to adjust, CE marking will continue to be accepted until 31st December 2021 in most cases, assuming that GB and EU rules remain the same.

What is the legislation that implements the UKCA mark?

For most products, the UKCA mark is defined in UK Statutory Instrument 2019 No.696 (The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019) and any subsequent amendments.

There are exceptions for automotive, medical and marine products where specific requirements are in place.

The technical and administrative aspects of the UK and EU requirements will be the same, however, it is possible that they will diverge in the future.

Details of the current legislation can be found in the references section on page 14.

The UKCA Mark

Are there different timescales for medical devices?

Yes. CE marking for medical devices will continue to be recognised in Great Britain until 30th June 2023 assuming that GB and EU rules remain the same.

What products is the UKCA mark applicable to?

The UKCA mark is applicable to the same products that would be been subject to CE marking and to aerosol products.

See “Product areas covered by the UKCA marking” on page 14.

Can I use self-certification as the basis for affixing the UKCA mark or do I need to use a third-party assessment body?

The principle of self-certification and third-party assessments established under EU legislation is unchanged in UK Regulations so if self-certification was used for the basis of CE marking, it can also be used for the UKCA mark.

FAQ

CE Marking

Do I need to make any changes to my current CE marking regime for the EU market?

Where CE marking is currently applied by following the self-certification route, no changes will be required.

Where a product has third-party assessment from an EU appointed Notified Body located in the UK, the files should have been transferred to an EU-27 Notified Body before 1st January 2021 or a new assessment completed by an EU-27 Notified Body.

If I have CE marking now, is it still valid after the 1st January 2021?

Yes, any testing and self-certifications are still valid after the 1st January 2021. Products that carry the CE mark will continue to be accepted in the EU as well as in the UK until 31st December 2021 in most cases.

Can I use the CE mark alongside the UK(NI) mark for products placed onto the EU-27 market?

No, the CE/UK(NI) marking route can only be used for products placed onto the Northern Ireland market where third-party assessment has been used.

The UK(NI) mark is not accepted within the EU or GB markets.

Product Marking & Labelling

Does the UKCA mark need to be on the product or can it be on a label or accompanying documentation?

Until 31st December 2022, for most products (not including those covered by special rules), there is an option to affix the UKCA mark on a label attached to the product or onto accompanying documentation.

The requirement is that the Economic Operator should take reasonable steps to ensure that the UKCA mark remains in place.

It is mandatory for the UKCA mark to be affixed to most products from 1st January 2023.

Are the product labelling requirements for the UKCA mark different to those for CE marking?

The product labelling requirements for the UKCA mark are currently the same as for the CE mark.

Specific requirements for Radio Equipment

Regulation 14 of the 2017 Regulations requires that where there are restrictions on putting into service or requirements for authorisation of use, a manufacturer must include information on the packaging of the radio equipment to identify this:

- a Pictogram followed by the abbreviation “UK” or “UK(NI)” or
- the words “Restrictions or Requirements in the UK” or “…UK(NI)” as appropriate

The pictogram that should be used is as shown below:

For more information, please see the published document “*Radio Equipment Regulations 2017 Guidance on Regulation 14: Information to be included where there are restrictions on putting into service or requirements for authorisation of use*”

Product Testing

Product Testing

Is Eurofins able to carry out the test/ assessments for the UKCA Mark?

From 1st January 2021 the technical requirements, or the 'essential requirements', as well as the conformity assessment processes and standards that can be used to demonstrate conformity, will be largely the same as they were prior to this date.

Eurofins is able to test products as part of UKCA and CE marking regimes as well as being able to offer services that will allow global product compliance requirements to be met.

For most customers, there should be no change to the process of testing needed to meet the requirements of both UKCA and CE marking.

If I've had my product tested in the UK, will this continue to be accepted in the EU?

Yes, any testing that has been carried out in the UK to demonstrate compliance with the requirements of CE marking will continue to be valid and accepted within the EU after 1st January 2021.

Eurofins' accredited laboratories are assessed against an international standard, ISO17025, meaning that the UK leaving the EU has no impact on accreditation or the laboratory's activities.

What standards will products need to be tested against?

The standards against which a product should be tested are detailed in the appropriate UK Designated Standards list.

A Declaration of Conformity to support the UKCA marking of a product should show UK Designated Standards rather than Harmonised Standards cited in the Official Journal of the European Union (EUOJ)

The current UK Designated Standards list contains the same standards as the EUOJ.

There may be commercial advantages to test to a more expansive version of a standard, such as the IEC version with National Deviations, and where this is the case, local Eurofins technical teams will advise and discuss in detail.

Can standards listed in the UK Designated Standards list be used on the EU DoC or do these need to be changed to the EN version?

No. An EU DoC should reference harmonised standards.

What about IEC, ISO or ETSI standards? Will these be affected?

No. For both UKCA and CE marking there will be no changes to the use of standards such as those published by IEC, ISO or ETSI where these are currently used.

For most testing, there will in reality be no changes to the standards against which a product is tested with ISO, IEC, EN, BS EN, ETSI etc. being applicable as they are now.

Will there be an equivalent to the EUs Official Journal for UKCA?

The Designated Standards lists will be the equivalent to the OJEU listing for the UKCA mark.

The UK Designated Standards can be found here:

www.gov.uk/guidance/designated-standards

Accessing markets

Selling products into the EU

Do I need an Authorised Representative to sell into the EU?

For some products, such as those classed as medical products, there is a requirement to use an authorised representative and this requirement is determined by the relevant Directive.

However, for many manufacturers, using an Importer is a practical route to market and is often chosen where existing distributors are in place and where there is no requirement to do so.

From 16th July 2021 an authorised representative based in the EU or EEA will need to be appointed if goods are sold without using an importer or fulfilment service provider. For example, if they are sold online and shipped directly to the end user.

What happens to distributors after 1st January 2021?

A UK manufacturer who previously used an EU based distributor will need to employ the services of an importer from 1st January 2021. By agreement, this may be the existing distributor that agrees to take on the additional importer responsibilities.

Can I have a different importer for each country?

Yes. The role of an importer is different to that of an authorised representative and there can be as many importers as the manufacturer chooses.

Do an EU importer's details need to appear on the DoC?

No. The DoC is produced by the manufacturer as a statement that the product meets the essential requirements of the relevant Directive(s) and the appropriate harmonised standards.

The details of the importer, as the person or entity placing the product onto the market must be displayed on the product to allow, for example, market surveillance or regulatory authorities to contact that person.

If an authorised representative is appointed, their details may appear on the DoC in place of those of the manufacturer.

What does an EU importer need to do?

An importer takes on the responsibility of ensuring that the product meets the requirements of the EU markets and therefore would need to undertake the following:

"When importing from non-EU countries, importers must check that products fulfil all EU safety, health and environmental protection requirements before placing them on the market. The importer has to verify that:

- the manufacturer outside the EU has taken the necessary steps to allow the product to be placed on the EU market
- the necessary documentation such as the EU Declaration of Conformity and the technical documentation is available upon request
- contact with the manufacturer is possible at any time"

The administrative and technical requirements for the manufacturer remain the same – they must ensure that they are in compliance with the requirements of any applicable Directives and Legislation under which their products fall.

The importer should affix their details to the product, packaging or accompanying documentation. There are exemptions that state that if the importer has to open the packaging to affix their information, they can put their details on the outside of the packaging or include it with the product.

Accessing markets

Selling products into Northern Ireland (NI)

Is there more than one way of marking a products for the Northern Ireland market?

For products placed onto the NI market after 1st January 2021, the CE mark can continue to be used for both self-certification and for EU-27 Notified Body assessments.

For products that require third-party assessment and where a UK-based Approved Body has been used, the UK(NI) mark will be required alongside a CE mark.

To place products onto the NI market from the GB, an importer or Authorised Representative is required in the same way as placing products onto the EU market.

The UKCA mark has no meaning outside of the GB market. It can appear on products that are being sold globally with no impact upon other certification or approval marks.

The Declaration of Conformity & Technical Files

Can a single Technical File be used for both the UKCA and CE mark?

Yes, the same technical file can be used as part of the process of both CE and UKCA marking.

Essentially the requirements for the technical file are the same for both marks, however, where reference is made to regulations and standards it needs to be ensured that correct references are made.

Who needs to sign the DoC?

The DoC is signed by a person nominated by the company or legal entity who has been delegated with the power to do so on behalf of that company or legal entity.

The signing requirements for the DoC are the same for CE marking and the UKCA mark.

If a standard that I've declared compliance against changes, do I need to re-test my product?

Standards forming the basis of product testing are continually changing and typically every 3-4 years they will be amended and then periodically be re-issued.

The practical changes to standards vary significantly in degree and applicability; for example one change may be concerned with the set-up of one particular type of product within the scope of a standard, whereas another may be a change to a test frequency range which affects all products covered by the standard.

Changes to standards don't automatically mean that a product needs to be fully re-tested; in some cases partial re-testing may adequate and in others no additional testing at all.

The key points are

(a) the changes to the standard and
(b) how they apply to the product in question

The best way to deal with such changes is by using a gap analysis and documenting the actions taken as a result in the Technical File and updating the DoC.

FAQ

The Declaration of Conformity & Technical Files

Out of date standards are the most common reason that a DoC becomes invalid.

The Compliance Support services from Eurofins E&E can assist with performing gap analyses and advise of the suitability of DoCs and other administrative requirements.

Contact us for more information.

Is a separate DoC required for the UKCA and CE marks?

Yes. The GB and EU/NI markets require their own DoC. Although the actual type of information required for each is the same, there are some specific naming conventions and other differences that need to be reflected in them. These are particularly in relation to legislation and standards.

The differences are:

	UKCA	CE
Title	Declaration of Conformity	EU Declaration of Conformity
Legislation	Applicable UK legislation	Applicable EU Directives
Standards	UK Designated Standards	EU Harmonised Standards

The list of UK Designated Standards can be found here:

www.gov.uk/guidance/designated-standards

Other Certification Marks & Schemes

I have a CB certificate. Does the implementation of the UKCA mark affect this?

No. The UK is a recognised country for issuing and accepting IECEE and IECEx CB reports and certificates. This is not affected by the implementation of the UKCA mark or by BREXIT.

Can a CB certificate obtained from a UK test laboratory be used in the EU?

Yes. The CB Scheme is independent of any changes to the relationship between the UK and the EU.

I have an NRTL mark. Is this affected by BREXIT?

No. NRTL marks, such as the MET Mark, are unaffected by BREXIT and independent from the relationship between the UK and the EU in the same way as the CB Scheme.

Is the UKCA mark accepted for compliance for other markets?

At this time, the UKCA has no acceptance outside of the GB market.

FAQ

Notified Bodies & Approved Bodies

What happens to UK Notified Bodies after 1st January 2021?

From the 1st January 2021, UK Notified Bodies ceased to be recognised by the EU. They automatically became UK Approved Bodies with the same number and scope as they previously had. They are no longer be able to carry out third-party conformity assessment for products placed onto the EU market.

Is the CE mark still valid when affixed via third-part assessment from a UK Notified Body?

From the 1st January 2021, a third-party assessment through a UK Notified Body is no longer recognised in the EU. Existing files should have been to be transferred to an EU-27 Notified Body before this date.

Can I CE mark my products for the GB market using an existing EU-27 Notified Body assessment after the 1st January 2021?

Until the 1st January 2022, third-party assessment from an existing EU-27 Notified Body will be accepted for the GB market. After this date, only third-party assessments from a UK Approved Body will be accepted.

Does the number of my UK Approved Body need to appear on the product as it does now for my EU Notified Body?

Yes, this will mirror existing EU Directive requirements.

Using the UKCA Mark

Placing the UKCA marking

In most cases, the UKCA marking should be applied to the product itself or to the packaging. In some cases, it may be placed on the manuals or on other supporting literature. This will vary depending on the specific regulations that apply to the product.

The following general rules apply:

- UKCA markings must only be placed on a product by the manufacturer or authorised representative (where allowed for in the relevant legislation)
- The UKCA mark signifies conformity with the relevant UK legislation
- No marking or sign that may misconstrue the meaning or form of the UKCA mark should be used
- The UKCA mark cannot be placed on products unless there is a specific requirement to do so in the legislation

Rules for using the UKCA image

You must make sure that:

- if you reduce or enlarge the size of your marking, the letters forming the UKCA marking must be in proportion to the version set out below
- the UKCA marking is at least 5mm in height – unless a different minimum dimension is specified in the relevant legislation
- the UKCA marking is easily visible, legible and from 1st January 2023 it must be permanently attached

References

Product areas covered by the UKCA marking

- Toy safety
- Recreational craft and personal watercraft
- Simple pressure vessels
- Electromagnetic compatibility
- Non-automatic weighing instruments
- Measuring instruments
- Lifts
- ATEX
- Radio equipment
- Pressure equipment
- Personal protective equipment
- Gas appliances
- Machinery
- Outdoor noise
- Ecodesign
- Aerosols
- Low voltage electrical equipment
- Restriction of hazardous substances

Products covered by the UKCA marking but have some special rules:

- Medical devices
- Rail interoperability
- Construction products
- Civil explosives

References

UK Government Information

Using the UKCA mark from 1 January 2021

https://www.gov.uk/guidance/using-the-ukca-mark-from-1-january-2021

Placing manufactured goods on the market in Great Britain from 1 January 2021

https://www.gov.uk/guidance/placing-manufactured-goods-on-the-market-in-great-britain-from-1-january-2021

Placing manufactured goods on the EU market from 1 January 2021

https://www.gov.uk/guidance/placing-manufactured-goods-on-the-eu-market-from-1-january-2021

Moving goods under the Northern Ireland Protocol

https://www.gov.uk/government/publications/moving-goods-under-the-northern-ireland-protocol/moving-goods-under-the-northern-ireland-protocol-introduction

Product safety and metrology from 1 January 2021: Great Britain

https://www.gov.uk/guidance/product-safety-and-metrology-from-1-january-2021-great-britain

EU & UK Legislation

EU LEGISLATION	UK LEGISLATION
Toy Safety - Directive 2009/48/EC	Toys (Safety) Regulations 2011
Recreational craft and personal watercraft - Directive 2013/53/EU	Recreational Craft Regulations 2017
Simple Pressure Vessels - Directive 2014/29/EU	Simple Pressure Vessels (Safety) Regulations 2016
Electromagnetic Compatibility - Directive 2014/30/EU	Electromagnetic Compatibility Regulations 2016
Low Voltage Directive 2014/35	Electrical Equipment (Safety) Regulations 2016
Non-automatic Weighing Instruments - Directive 2014/31/EU	Non-automatic Weighing Instruments Regulations 2016
Measuring Instruments - Directive 2014/32/EU	Measuring Instruments Regulations 2016
Lifts - Directive 2014/33/EU	Lifts Regulations 2016
ATEX - Directive 2014/34/EU	Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres Regulations 2016
Radio equipment - Directive 2014/53/EU	Radio Equipment Regulations 2017
Pressure equipment - Directive 2014/68/EU	Pressure Equipment (Safety) Regulations 2016
Personal protective equipment - Regulation (EU) 2016/425	Personal Protective Equipment Regulations (Regulation (EU) 2016/425 as brought into UK law and amended)
Gas appliances - Regulation (EU) 2016/426	Gas Appliances (Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019)
Machinery Directive 2006/42/EC	Supply of Machinery (Safety) Regulations 2008
Outdoor Noise Directive 2000/14/EC	Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001
Directive 92/42/EEC hot-water boilers AND Eco design Directive 2009/125/EC	The Eco design for Energy-Related Products and Energy Information (Amendment) (EU Exit) Regulations 2019
Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) - Directive 2011/65/EU	The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012
Directive 2013/29/EU - Pyrotechnic Articles	The Pyrotechnic Articles (Safety) Regulations 2015

How Eurofins E&E can help you now and in the future

Whether you need help with determining the best route to compliance for a new product or maintaining the compliance of existing products, we can help.

You may have questions about what you need to do ensure that your products will be compliant for the EU as well as for the GB and NI markets, both in terms of technical and administrative compliance or you may be looking further afield, exploring new opportunities and markets.

Whatever stage you're at, Eurofins E&E can help you deliver compliant products to market, on-time and on budget.

Compliance Support

Our latest service, Compliance Support, is a go-to resource for all aspects of product compliance including:

- Compliance reviews & gap analysis
- Documentation reviews including Technical Files & Declarations of Conformity (DoC)
- Compliance roadmaps for new & existing products
- Testing & certification planning which can reduce the costs of product testing
- Standards, Legislation & Directive watching services to keep you up to date with any changes that can affect on-going compliance
- Access to the global Eurofins E&E network as well as services from the wider Eurofins group outside of E&E

This service can become an extension of your existing compliance team or can become your go-to resource for all of your product compliance needs.

Global Market Access

If you're looking further afield, our Global Market Access team can help you develop and implement a plan to access markets around the world, quickly and cost-effectively.

The GMA team can guide you through the regulatory landscape, ensuring your products are compliant both for the technical and administrative requirements for global markets, significantly reducing the costs and time needed to get the correct approvals for global markets.

UK Approved Body Services

Eurofins E&E can issue UK Type Examination certificates through its Approved Bodies for the following UK regulations:

- Electromagnetic Compatibility Regulations 2016 (Eurofins York, Eurofins Hursley)
- Radio Equipment Regulations 2017 (Eurofins MET via UK-US MRA)
- Equipment and Protective Systems Intended for use in Potentially Explosive Atmospheres Regulations 2016 (Eurofins CML)

Do you have any questions?

You can email UKCA@eurofins.com or just call us on **0330 430 3456**.

If you have an existing relationship with one of our locations, please call them directly and your account manager will be happy to help.

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Your partner for product compliance.

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