

## Latest information about the UKCA mark

The UK government released numerous updates to the information about the UK domestic regime for manufactured goods, this information has been published on the UK government's website (links provided below) over the course of 2020 to 2022, this document summarises the latest position.

In summary, any manufactured goods that are being placed on the market in Great Britain (England, Wales and Scotland), and that are currently subject to the European Union CE marking, are required to carry the UKCA mark from the 1<sup>st</sup> January 2025. There are different requirements for manufactured goods that are being placed on the market in Northern Ireland<sup>1</sup>.

Until the 31<sup>st</sup> December 2024 CE marked goods will continue to be accepted, but there are limitations to this, as outlined below.

## Eurofins CML and the UKCA mark

Eurofins CML became a UK Approved Body on the 1<sup>st</sup> January 2021. From this date, Eurofins CML has been issuing the UKCA equivalent services to those currently provided as a Notified Body for the ATEX Directive. In addition to the certification of products for use in explosive atmospheres, Eurofins CML is also a UK Approved Body for the following:

- Radio Equipment
- Machinery
- PPE (respiratory and hearing, footwear and garment)
- (Expected summer 2023) Medical Devices

CML B.V., our Dutch Notified Body, continues to provide services as a Notified Body for the ATEX Directive within the EU.

For Eurofins CML (UK Notified Body) certificate holders, read the following section, for CML B.V. certificate holders, read the subsequent section. If you are unsure what type of certification you hold, please contact us.

The following explains how these proposed changes are to be interpreted as impacting products that fall under the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016 and are intended to be placed on the UK market.

*This is intended as a supplement to the existing guidance published by the UK government which can be found in the following links:*

- *News story on GOV.UK [here](#)*
- *Updated UK guidance on [Using the UKCA marking](#)*
- *and [Placing manufactured goods on the market in GB](#).*

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<sup>1</sup> Different requirements exist for Northern Ireland, they have not been included in this document but can be found at <https://www.gov.uk/government/publications/moving-goods-under-the-northern-ireland-protocol>

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## **EU-Type Examination certificates (Directive 2014/34/EU Module B, Annex III)**

### **Products currently certified under an EU-Type Examination certificate**

Any product that currently has certification with an EU-Type Examination certificate against the Directive 2014/34/EU (often referred to as ATEX certification) will not require a UK Type Examination certificate against the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016 (often referred to as UKEX certification) until the 31<sup>st</sup> of December 2027.

### **Products certified under a new EU-Type Examination certificate between now and the 31<sup>st</sup> of December 2024**

Any product that undergoes conformity assessment activity and receives certification with an EU-Type Examination certificate against the Directive 2014/34/EU (often referred to as ATEX certification) before the end of 2024 will not require a UK Type Examination certificate against the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016 (often referred to as UKEX certification) until the 31<sup>st</sup> of December 2027.

### **Products certified under a new EU-Type Examination certificate after the 31<sup>st</sup> of December 2024**

Any product that undergoes conformity assessment activity and receives new certification with an EU-Type Examination certificate against the Directive 2014/34/EU (often referred to as ATEX certification) after the end of 2024 will require a UK Type Examination certificate against the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016 (often referred to as UKEX certification).

### **Updates to products certified under an EU-Type Examination certificate after the 31<sup>st</sup> of December 2024**

Any product that undergoes conformity assessment activity and requires an update to the EU-Type Examination certificate against the Directive 2014/34/EU (often referred to as ATEX certification) after the end of 2024 may require a UK-Type Examination certificate against the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016<sup>2</sup> (often referred to as UKEX certification). This subject requires clarification as the current guidance states “if the product has been subject to important changes, substantially changing its original performance, purpose, or type, it will be considered as a ‘new’ product”. What is deemed to be a substantial change will be subjective. It is likely that any changes that require re-evaluation and/or re-testing by a Notified Body will be determined to be substantial changes, however, further clarification on this point will be required. It is possible that the amended legislation will clarify this<sup>3</sup>.

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<sup>2</sup> The UK legislation is UKSI 2016:1107 (as amended by UKSI 2019:696) – Schedule 3A, Part 1. This legislation is comparable with the European Union Directive 2014/34/EU(ATEX).

<sup>3</sup> This document will be updated when further information is made available.

## **Quality Assurance Notifications (QAN) (Directive 2014/34/EU Modules C1, D, E, Annexes IV, VI and VII)**

### **Manufacturers currently holding a Quality Assurance Notifications (QAN) issued by an EU Notified Body**

Any manufacturer that currently has a Quality Assurance Notification (QAN) issued by an EU Notified Body against the Directive 2014/34/EU (may be referred to as an EU QAN) will not require a separate Quality Assurance Notification issued by a UK Approved Body against the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016 (may be referred to as an UK QAN) until it expires after the 31<sup>st</sup> of December 2024. They can therefore use the EU QAN as the basis of their UKCA marking until that EU QAN expires (after the 31<sup>st</sup> of December 2024).

An EU QAN typically has a 3 year validity and would be considered to have expired after this 3 year validity period ends, it would then be reissued following reassessment.

Once an EU QAN has expired (after the 31<sup>st</sup> of December 2024) it can no longer be used as the basis of the UKCA marking and a separate UK QAN will be required.

Where the EU QAN is used as the basis for the UKCA marking, and there is no UK QAN issued by a UK Approved Body currently in place, no number is to be marked adjacent to the UKCA marking on the product until that EU QAN expires. After expiration of the EU QAN, a UK QAN will be required from a UK Approved Body and their Approved Body number will be applied adjacent to the UKCA marking.

## **Technical File submissions (Directive 2014/34/EU Module A, Annex VIII)**

### **Products currently with technical files lodged at an EU Notified Body**

Any product that falls under the requirements of Module A of Directive 2014/34/EU and currently has its technical file lodged with an EU Notified Body will not require a separate technical file lodging with a UK Approved Body until the 31<sup>st</sup> of December 2027.

### **Products with technical files to be lodged at an EU Notified Body between now and the 31<sup>st</sup> of December 2024**

Any product that falls under the requirements of Module A of Directive 2014/34/EU and has a technical file to be lodged can do so with an EU Notified Body until the end of 2024. It will not require a separate technical file lodging with a UK Approved Body until the 31<sup>st</sup> of December 2027 if it is to be placed on the UK market.

### **Products with technical files to be lodged after the 31<sup>st</sup> of December 2024**

Any product that falls under the requirements of Module A of Directive 2014/34/EU and has a technical file to be lodged after the end of 2024 will require a separate technical file lodging with a UK Approved Body if it is to be placed on the UK market.

## Updates to products with technical files lodged at an EU Notified Body

Any technical files lodged at an EU Notified Body that require an update due to changes to the product after the end of 2024 may result in there being a need for the manufacturer to lodge a separate technical file with a UK Approved Body. This subject requires clarification as the current guidance is not clear how it impacts technical files. It currently states “if the product has been subject to important changes, substantially changing its original performance, purpose, or type, it will be considered as a ‘new’ product”. Whether this applies to technical files that are lodged with Notified Bodies is not clear. Also, what is deemed to be a substantial change will be subjective. It is likely that any changes that affect the existing compliance and would require re-evaluation and/or re-testing will be determined to be substantial changes, however, further clarification on this point will be required. It is possible that the amended legislation will clarify this<sup>4</sup>.

## Unit Verification and Product Verification (Directive 2014/34/EU Modules F and G, Annex V and IX)

### Products currently certified under Unit Verification or Product Verification certificate

Any product that currently has a Unit Verification or Product Verification certificate against the Directive 2014/34/EU (often referred to as ATEX certification) will not require a separate certificate from a UK Approved Body unless the product is placed on the UK market after the 31<sup>st</sup> of December 2027.

### Products certified under a new Unit Verification or Product Verification certificate issued between now and the 31<sup>st</sup> of December 2024

Any product that undergoes conformity assessment activities and receives a Unit Verification or Product Verification certificate against the Directive 2014/34/EU (often referred to as ATEX certification) before the end of 2024 will not require a separate certificate from a UK Approved Body unless the product is placed on the UK market after the 31<sup>st</sup> of December 2027.

### Products certified under a new Unit Verification or Product Verification certificate issued after the 31<sup>st</sup> of December 2024

Any product intended to be placed on the UK market that requires a Unit Verification or Product Verification certificate issued after the end of 2024 will require that Unit Verification or Product Verification certificate to be issued by a UK Approved Body.

If you have any questions or would like any further information, please contact us at [sales@cmlcx.com](mailto:sales@cmlcx.com).

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<sup>4</sup> This document will be updated when further information is made available.

## Declaration of Conformity

A Declaration of Conformity will be required for UKCA marked products. However, the Declaration of Conformity for UKCA differs to the EU Declaration of Conformity in the following ways:

- "EU" is removed from the title, so "Declaration of Conformity" only.
- Any references to Union harmonisation legislation is replaced with the UK statutory requirements. So, for ATEX, "Directive 2014/34/EU" is to be replaced with "SI 2016 No. 1107".
- Any reference to "harmonised" standards is to be reworded to reference "designated" standards.
- Any reference to "notified" bodies is to be reworded to reference "approved" bodies.
- Any UK Notified Body 4-digit numbers will remain the same when they become a UK Approved Body. So, for example, Eurofins CML is currently 2503, this will remain the same after the 1<sup>st</sup> January 2021 when Eurofins CML becomes a UK Approved Body.

If you have any questions or would like any further information, please contact us at [sales@cmlex.com](mailto:sales@cmlex.com).