

UKEX Update

June 2022

(Revision 2 – 04/07/2022 – Updated following UK Approved Body meeting and clarification provided by BEIS – change to highlighted text)

On the 20th of June 2022 the UK government announced changes to legislation that they intend to implement to simplify the requirements for manufacturers placing product on to the UK market.

The main changes as presented by the UK government department for Business, Energy and Industrial Strategy (BEIS) will be:

To reduce re-testing costs for UKCA certification, by allowing conformity assessment activities for CE marking completed by 31 December 2022 to be used by manufactures as the basis for UKCA marking. This will reduce the immediate costs faced by manufacturers and will be valid until the expiry of their certificate or for 5 years (31 December 2027), whichever is sooner. This will reduce duplication and costs for businesses and by extension, consumers.

To make clear there is no need to re-test existing imported stock, as these products will be considered already placed on the market in Great Britain (GB). This will prevent the costly and unnecessary re-labelling of existing stock for businesses.

To make clear that spare parts that repair, replace, or maintain goods already on the GB market can meet the same requirements that were in place at the time the original product or system was placed on the GB market. This will allow products and goods requiring spare parts to continue to be maintained.

To continue to allow businesses to affix the UKCA marking, and to include importer information for products from EEA countries (and in some cases Switzerland), on an accompanying document or label until 31 December 2025. This will allow business to adjust their product design to accommodate marking changes at a convenient and cost-effective time.

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.](#)

For electrical and electronic products that do not fall under these regulations, Eurofins E&E UK will be publishing additional guidance and information.

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 31st of December 2027.

Products certified under a new EU-Type Examination certificate between now and the 31st of December 2022

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 2022 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 31st of December 2027.

Products certified under a new EU-Type Examination certificate after the 31st of December 2022

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 2022 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 31st of December 2022

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 2022 may require a UK-Type Examination certificate against the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016¹ (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 this².

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

¹ 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).

² This document will be updated when further information is made available.

after the 31st of December 2022. They can therefore use the EU QAN as the basis of their UKCA marking until that EU QAN expires (after the 31st of December 2022).

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 31st of December 2022) 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 31st of December 2027.

Products with technical files to be lodged at an EU Notified Body between now and the 31st of December 2022

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 2022. It will not require a separate technical file lodging with a UK Approved Body until the 31st of December 2027 if it is to be placed on the UK market.

Products with technical files to be lodged after the 31st of December 2022

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 2022 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 2022 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 this³.

³ This document will be updated when further information is made available.

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 31st of December 2027.

Products certified under a new Unit Verification or Product Verification certificate issued between now and the 31st of December 2022

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 2022 will not require a separate certificate from a UK Approved Body unless the product is placed on the UK market after the 31st of December 2027.

Products certified under a new Unit Verification or Product Verification certificate issued after the 31st of December 2022

Any product intended to be placed on the UK market that requires a Unit Verification or Product Verification certificate issued after the end of 2022 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 marketing@metlabs.com.