UL Solutions

U.K. and European Market Access for PPE Products

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Introduction

On 1 Jan. 2020, the U.K. officially exited the European Union (EU). That was the start of the implementation period (IP) to allow both the EU and the U.K. to establish the processes to handle the changes for customs, immigration, etc. The implementation period ended 31 Dec. 2020. The transition period began 1 Jan. 2021, and has been extended for personal protective equipment (PPE) untl 1 Jan. 2025.

The process will depend upon where the end products are being sold, either into the U.K. or into EU and if they are already covered by European conformity assessment documentation. The simplified diagram here shows the overall process for U.K. Conformity Assessed (UKCA) and CE markings.

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U.K. market access

During the transition period, i.e., before 1 Jan. 2025, existing products can continue to use the previously generated CE marking to show compliance with U.K. regulations. If the product is not covered by an EU CE marking process before 1 Jan. 2025, compliance for the U.K. market will subsequently need to be addressed via a new U.K. Approved Body. From the end of 2024, all U.K. compliance will be covered by a UKCA marking.

Looking to the future, you will need to use the new UKCA marking immediately after 31 Dec. 2024 if all of the following apply. If your product:

- Does not currently carry the CE marking.
- Is for the market in Great Britain.
- Is covered by legislation which requires the UKCA marking (which includes PPE).
- Requires mandatory third-party conformity assessment.

This does not apply to existing stock; for example, if your good was fully manufactured and ready to place on the market before 1 Jan. 2025. In these cases, your goods can still be sold in Great Britain with a CE marking even if covered by a certificate of conformity issued by a U.K. body.

From 1 Jan. 2025, CE marking will not be recognised in Great Britain for PPE and the UKCA marking must be applied.

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What is the UKCA marking?

To replace CE marking the U.K. introduced their own regulatory marking, the UKCA marking.[1]

This marking will be required on products subject to the U.K. equivalent legislation to all the EU directives that required CE marking, including the PPE regulation. So, if you are already CE marking products, you will now need to add the UKCA marking. For products sold in both the U.K. and EU, you will need both markings.

As with CE marking, the UKCA marking will need to be a minimum of 5 millimetres (mm) high and included on both the device label and packaging, although an additional transition period allowing markings to be on the documentation and not the product would appear to be applicable for PPE (see When to use the UKCA marking). It will need to be supported by a Declaration of Conformity (DoC). Also, for relevant products, the label will need to display the manufacturer's name and address (no change from EU requirements), as well as display the U.K. importer (not the EU importer) on the label and/or packaging.

1. Image files can be found on the U.K. site here.

What format is the DoC for the UKCA marking?

The DoC to support UKCA marking will follow the format of the EU directive. The main changes will be to:

- Replace the references to the EU Directives with the equivalent U.K. statutory instrument (regulation).
- Replace, where applicable, the standards with the U.K. versions.
- Remove or, where applicable, replace references to a Notified Body with a reference to a U.K. Approved Body.

When do I need to start UKCA marking?

The U.K. has adopted a limited time period (Transition Period) to allow manufacturers to transition to UKCA marking and the U.K.'s regulatory scheme for PPE. In November 2022, the U.K. announced that this limited time period will extend through to the end of 2024 for most legislation (and that includes the U.K. equivalents of the PPE Regulation (PPER).

Until the end of December 2024, you can choose to continue CE marking or use the UKCA marking to support shipment and sales in the U.K. In addition, for many products (excluding medical devices and some other categories), there is an additional three-year transition period which allows the UKCA marking to be placed in a document accompanying the product rather than on the product itself. Device labelling will be mandatory after 31 Dec. 2027.

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What are the new directives for UKCA marking?

The U.K. transposed the EU directives into U.K. law when the directives were introduced. For now, the core requirements will remain the same as the corresponding EU directives. Changes have been and will continue to be made to update references from EU to U.K., Notified Body to Approved Body, harmonised standard to designated standard, etc.

The U.K.'s equivalent to the EU PPER is:

- Statutory Instrument 2019 No. 676 Product Safety and Metrology, etc. (Amendment, etc.) (EU Exit) Regulations 2019

What standards are used for UKCA marking?

The U.K. will list the designated standards for the directives – the location of that list is here. The U.K. did explain that the U.K. standards will be the same in substance and with the same reference as the standards used in the EU.

What about Notified Bodies for U.K.?

Under the U.K. regulations, a U.K. Approved Body will have the equivalent role for the U.K. statutory instruments as the EU Notified Bodies have for the EU directives. Requirements for using an Approved Body will follow the EU directives, i.e., mandatory for Category 2 and 3 PPE under the scope of the PPER.

The current list of U.K. Notified Bodies will be designated as Approved Bodies prior to January 2021. As noted in the earlier sections, unless a trade agreement is established between the EU and U.K., the U.K. Approved Bodies will cease to be Notified Bodies for EU CE marking. The formal location for the listing of Approved Bodies is here.

Summary of impact to manufacturers selling into U.K.

- Labels need to include the importer on either product labelling or packaging. This may now mean a different importer for CE marking if the previous importer was in the U.K. and the addition of the name/address of a U.K. importer if shipping to the U.K.
- As of 1 Jan. 2025, the UKCA marking will need to be added to the product label and packaging if shipping to the U.K.
- A new DoC for UKCA marking will be required for devices that are UKCA marked. This will require updated links in user documentation as to the location of the UKCA DoC if not shipped with the product.
- EU Notified Body Certificates issued by a U.K. Notified Body will no longer be valid for CE marking. If your EU (CE marking) certificate was from a U.K. Notified Body refer to Transfer of CE marking for your options.

European market access

From 1 Jan. 2021 any mandatory third-party conformity assessment for the EU market will need to be carried out by an EU Notified Body. The UKCA marking will not be recognised on the EU market. Products currently requiring a CE marking will still need a CE marking for sale in the EU from 1 Jan. 2021.

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What is the impact of Brexit on CE marking?

For the sale of goods into the EU, CE marking and the PPE Regulation (PPER) will remain unaffected by Brexit and manufacturers shall continue to use the CE marking on their product, issue Declarations of Conformity, and label the device and packaging with the appropriate names and addresses of the manufacturer, importer, etc.

However, at the end of the implementation period, U.K. Notified Bodies will lose their status as EU Notified Bodies and will be removed from the Commission's information system on notified organisations (New Approach Notified and Designated Organisations (NANDO) database17). As such, U.K. bodies will not be in a position to perform conformity assessment tasks pursuant to EU product legislation after 1 Jan. 2021.

Products placed on the EU market after 1 Jan. 2021 will require a certificate delivered by an EU Notified Body. It will therefore be necessary for producers to either apply for a new certificate issued by an EU Notified Body or arrange for a transfer of the file and the corresponding certificate from the U.K. Notified Body to an EU Notified Body, which would then take over the responsibility for that certificate.

Transfer of CE marking from U.K. Notified Body

The transfer of certificates from a U.K. Notified Body to an EU Notified Body needs to take place before the end of the implementation period, based on a contractual arrangement between the manufacturer, the U.K. Notified Body, and the EU Notified Body.

When a certificate has been transferred, both the EU Declaration of Conformity (drawn up by the manufacturer) and the Notified Body Certificate must be updated accordingly. These documents will need to mention that the certificate is now under the responsibility of an EU Notified Body and indicate both the old U.K.and the new EU Notified Body's details/identification numbers. If the above-mentioned product documentation is in order, there is no need to change the Notified Body number for products already placed on the EU or the U.K. market. This also applies to products manufactured before the transfer of certificate has taken place and are yet to be placed on the EU or the U.K. markets. However, products manufactured after the transfer of the certificate has taken place should be marked with the new EU Notified Body number.
It will not be possible to continue to use the U.K. Notified Body number.

UL Solutions has established a separate legal entity under UL International (Netherlands) B.V. to act as an EU Notified Body and is currently able to issue certificates under its notification number 2821.

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Northern Ireland

Northern Ireland has a set of different rules for marking that are also subject to change.
These currently include the following provisions:

- Labels need to include the importer on either product labelling or packaging. This may now mean a different importer for CE marking if the previous importer was in the U.K. and the addition of the name/address of a U.K. importer if shipping to the U.K.
- Products placed on the market in Northern Ireland have to comply with the applicable EU legislation.
- A product manufactured in Northern Ireland and shipped to the EU is not an imported product for the purpose of labelling and identification of economic operators/responsible persons.
- A product shipped from Great Britain to Northern Ireland is an imported product.
- Importers, authorised representatives and other responsible persons may be established in Northern Ireland.
- Certificates issued by a Notified Body in Great Britain are not valid in Northern Ireland. A Notified Body in Northern Ireland, however, can continue to certify products in certain circumstances.

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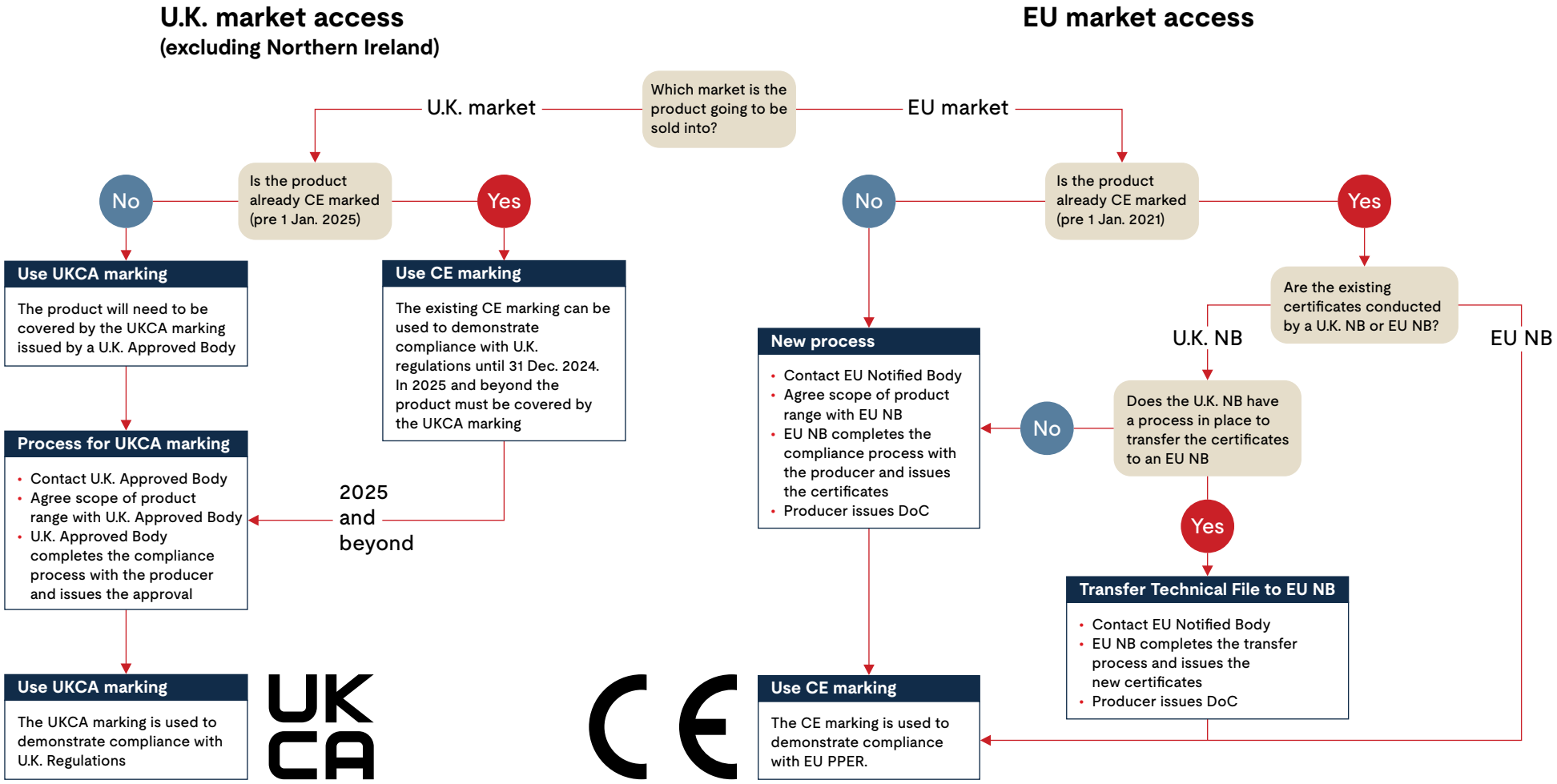
Simplified flowchart showing process for UKCA and CE markings



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