CE Marking Changes: Post-Brexit Rules & Regulations

A SERCK INFO GUIDE TO THE RULES & REGULATIONS AFFECTING HEAT EXCHANGER AND PRESSURE VESSEL MANUFACTURE IN THE UK POST-BREXIT

Pressure Directives: A time of change for UK Industrial Infrastructure

Beginning on the 1st January 2021 with the exit of the UK from the European Community, the rules on CE marking of Simple Pressure Vessels, Pressure Equipment and Machinery have changed. The UKCA conformance assessment marking came into effect for England, Scotland and Wales (but not Northern Ireland, which is to continue following the EU system).

With many complexities in store for UK manufacturers - and those who depend on them - who will now need to ensure they are able to conform to the UKCA regulations, as well as needing to continue to meet CE standards for equipment being exported, we tapped our internal experts to bring you this guide to help make sense of it all.

This guidance has been pulled together as a collation of available literature on the subject, including existing pressure directive regulations and publications outlining Brexit transition information published by both the UK and European governments.

With the wide range of information available - some of it incomplete or unconfirmed at the time of writing (Spring 2021) - we've done our best to provide a useful and concise overview as a starting point for you to consider as you plan future projects.

This guide is for information only. You should of course independently ensure any products or projects meet all requirements. But we do hope it gives you a helpful place to start.

Products placed on the market in Great Britain that are covered by relevant UK product regulatory requirements need to bear the UKCA marking from the beginning of 2021

The UKCA regulations cover new build or substantially modified equipment placed in service after 1st January 2021. Heat exchangers to Directive 2014/68/EU and heat exchangers fitted with equipment covered by the Supply of Machinery (Safety) Regulations 2008 are the basis of this review, simple pressure vessels to Directive 2014/29/EU are excluded from it. This means that anything operating at above 0.5 bar(g) has to be assessed under the rules and currently will fall into Sound Engineering Practice or Categories I to IV depending on the hazard classification of what is inside the unit and its internal capacity. This also extends to externally heated equipment where heating or boiling takes place at above 110°C. The position of repairs to equipment is covered later in the document.

Products placed on the market in Great Britain that are covered by relevant UK product regulatory requirements need to bear the UKCA marking from the beginning of 2021; the UKCA marking has replaced the CE marking. The existing CE marking system can still be followed by UK companies in the heat exchanger, pressure vessel and machinery industries until 31st December 2021 however the position of the Notified Bodies, if required to provide oversight, has also changed. From 1 January 2022, the CE marking will not be recognised in Great Britain for areas covered by this guidance and the UKCA marking. However, a product bearing the CE marking would still be valid for sale in the UK so long as it was also UKCA marked and complied

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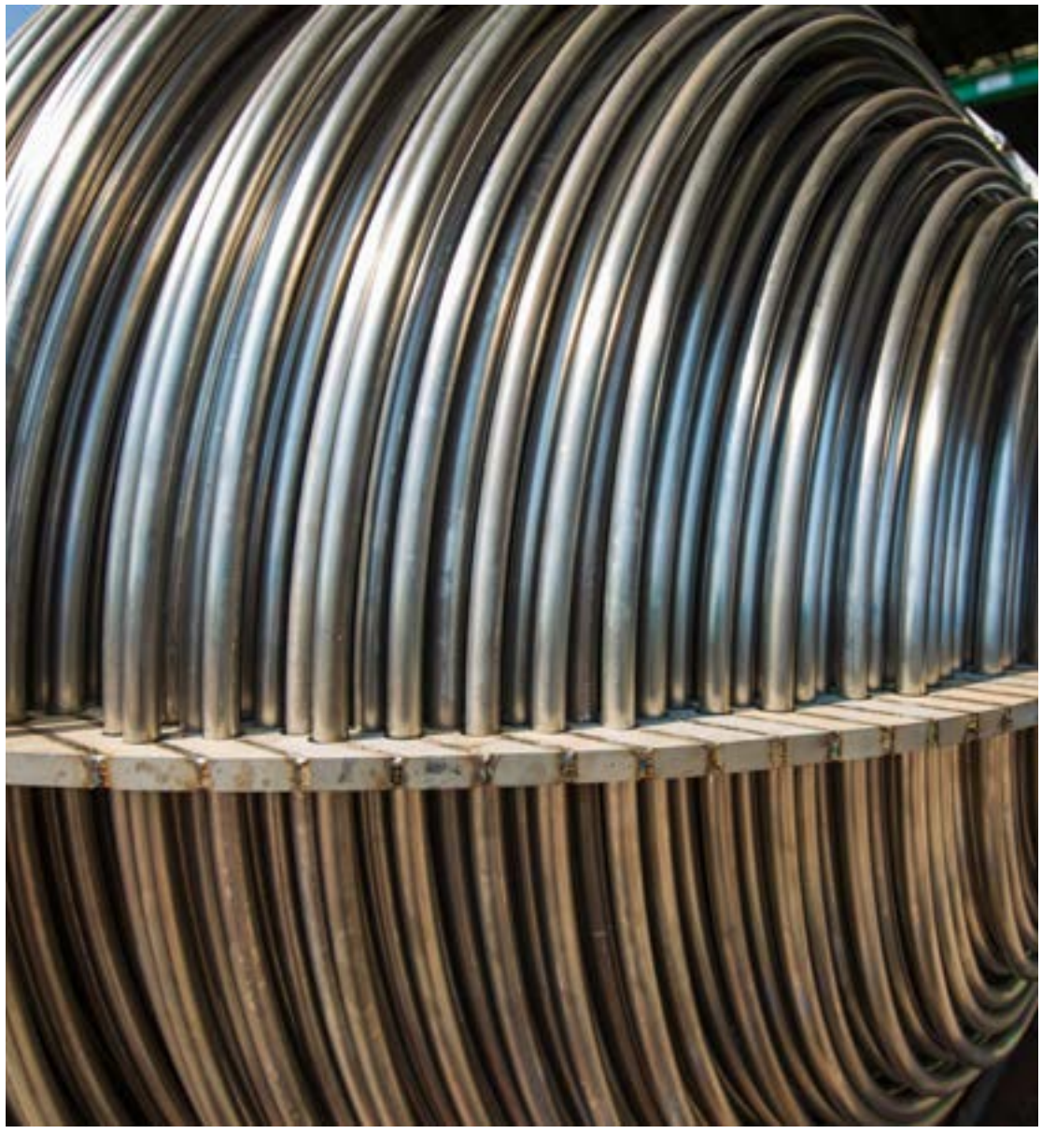
The Pressure Equipment Directive 2014/68/EU has been replaced by the Pressure Equipment (Safety) Regulations 2016 which is still in draft but is expected to mirror the existing PED. The main effect of this is that where self-declaration of conformity for Category 1 pressure equipment is currently allowed, it can continue but under the UKCA mark.



KEY CHANGES TO NOTE IN THE DECLARATION OF CONFORMITY: WHAT'S CHANGED AND WHAT'S STAYING THE SAME

The information required on the Declaration of Conformity is largely the same as what was required on an EU Declaration of Conformity. This can vary depending on the application.

The UK standards are currently the same in substance and with the same reference as the standards used in the EU.

The EU and UKCA Declarations of Conformity are largely the same, but come with some extra rules to satisfy both regions' criteria

Information still required on the Declaration of Conformity, per the guidance on the new UKCA Marking includes:

- Your name and full business address or that of your authorised representative
- The product's serial number, model or type identification
- A statement, stating 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 legislation with which the product complies
- Your name and signature
- The date the declaration was issued
- Supplementary information (if applicable)

You will also need to list:

- Relevant UK legislation (rather than EU legislation)
- UK designated standards rather than standards cited in the Official Journal of the European Union

The UK standards are currently the same in substance and with the same reference as the standards used in the EU.

The following general rules apply:

- UKCA markings must only be placed on a product by you as the manufacturer or your authorised representative (where allowed for in the relevant legislation)
- When attaching the UKCA marking, you take full responsibility for your product's conformity with the requirements of the relevant legislation
- You must only use the UKCA marking to show product conformity with the relevant UK legislation
- You must not place any marking or sign that may misconstrue the meaning or form of the UKCA marking to third parties
- You must not attach other markings on the product which affect the visibility, legibility or meaning of the UKCA marking
- The UKCA marking cannot be placed on products unless there is a specific requirement to do so in the legislation

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 here. The marking is at least 5mm in height for the whole logo, not individual letters (unless a different minimum dimension is specified in the relevant legislation). The UKCA marking is easily visible, legible (from 1 January 2023 it must be permanently attached).

UK
CA

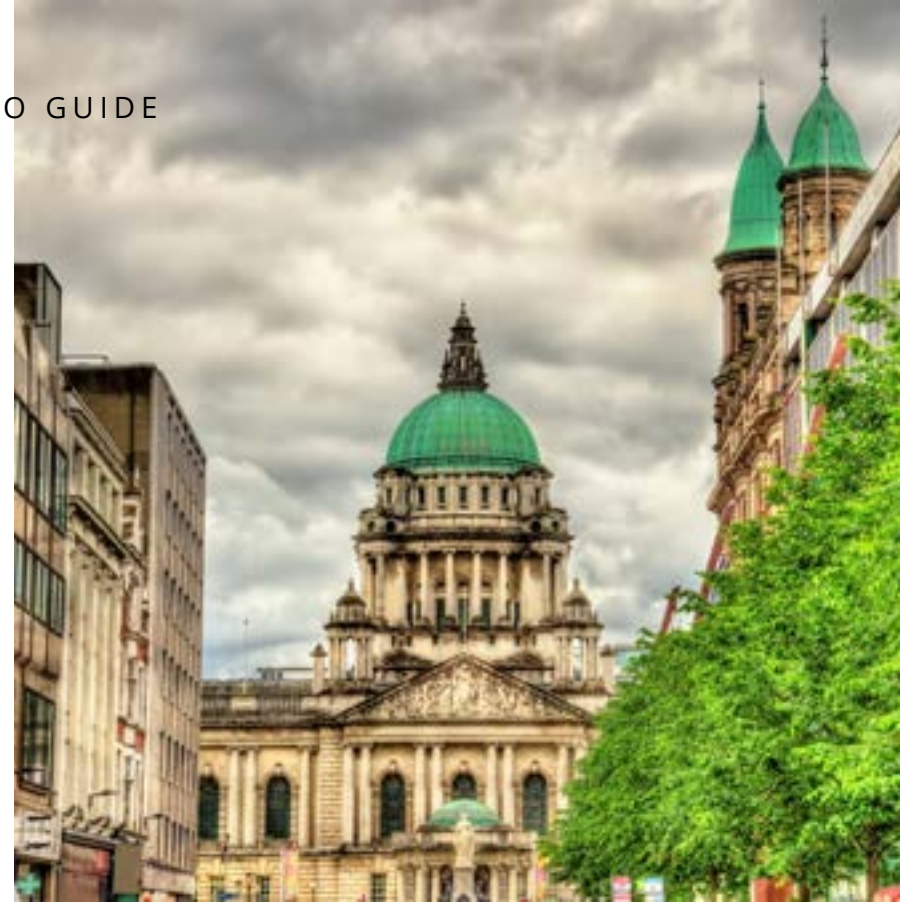
Record Keeping

You, or your authorised representative (where allowed in the relevant legislation), must keep documentation to demonstrate that your product conforms with the regulatory requirements. This must be kept for up to 10 years after the product is placed on the market.

This information can be requested at any time by market surveillance or enforcement authorities to check that your product conforms with the statutory requirements. The information you must keep will vary depending on the specific legislation relevant to your product. You must keep general records of:

- how the product is designed and manufactured
- how the product has been shown to conform to the relevant requirements
- the addresses of the manufacturer and any storage facilities

You should keep the information in the form of a technical file which can be supplied if requested by a market surveillance authority.

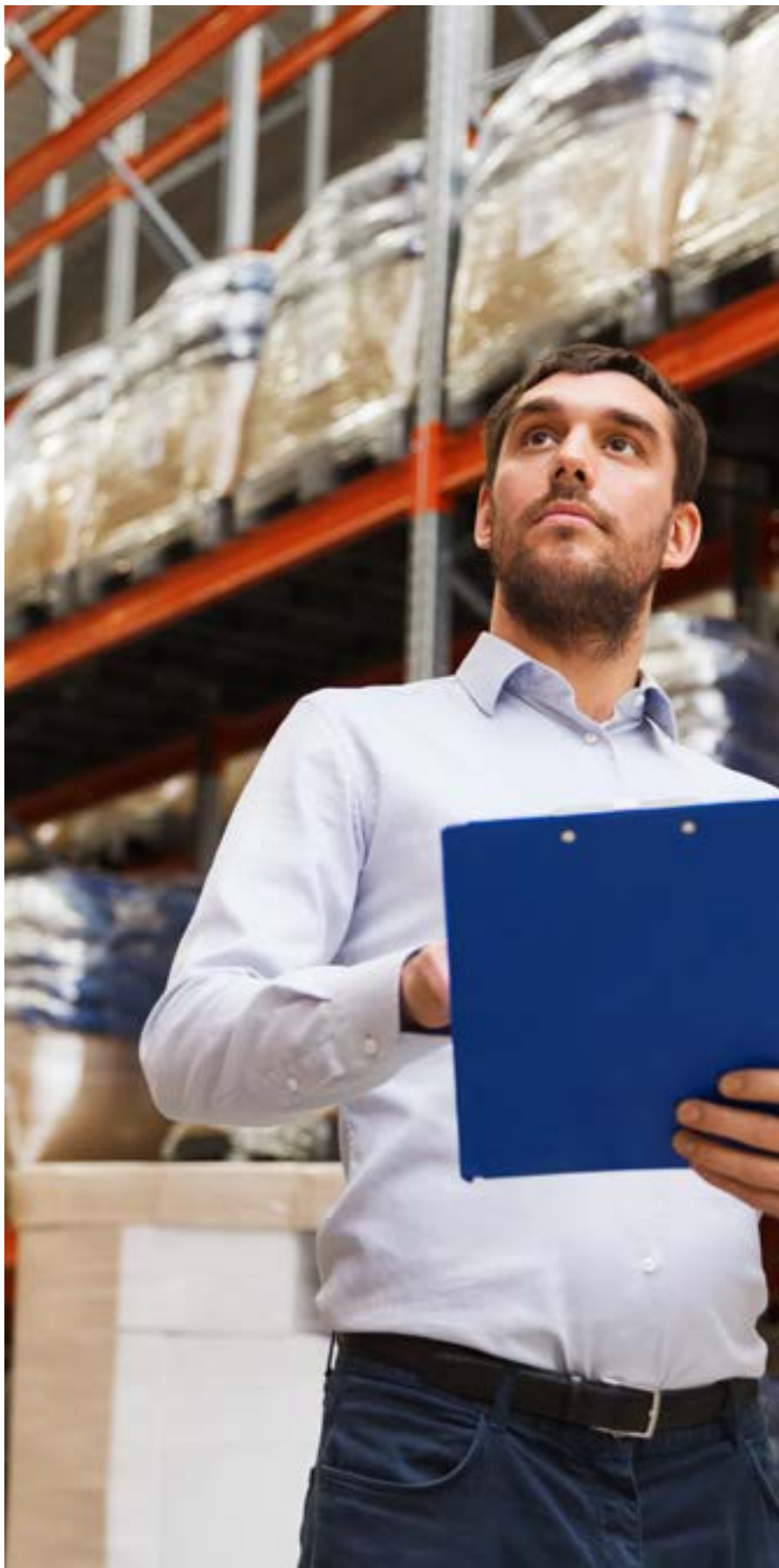


The position of Northern Ireland

Harmonised standards remain the relevant standards for placing goods on the Northern Ireland market, where EU rules continue to apply.

Products for the Northern Ireland market can use either the CE or the CE mark with the newly-introduced UKNI marking. For goods being marketed in Northern Ireland, where a UK Approved Body is used to carry out mandatory third-party conformity assessment, then a UKNI marking must be applied from 1 January 2021.

This mark cannot be used on its own. It can only be used in conjunction with an EU mark, such as the CE mark. However, the combined CE and UKNI marking will not be recognised in the EU – the CE mark must be used on its own.



The position of exports into the EU

The UKCA marking is not recognised on the EU market.

Products need a CE marking for sale in the EU.

A manufacturer or importer established in the United Kingdom can no longer be considered as an economic operator established in the EU.

As a consequence, an economic operator established in the EU who, prior to 1st January 2021, was considered as an EU distributor of products received from the United Kingdom will become an importer for the purposes of the legislation.

This operator will have to comply with the more stringent obligations imposed on importers, including verification of product compliance and, where applicable, including their contact details on the product or product label.

This basically means that a unit designed and manufactured to ASME VIII, PD5500 or other non-EU codes will have to be additionally examined by an EU based Notified Body to ensure it complies.

The Directive 2014/68/EU is not a pressure vessel code as such and only stipulates the level of inspection required, test pressures, etc.

Where EU legislation provides for a "responsible person" *established in the EU* to be appointed by the manufacturer, and to whom specific tasks are designated to ensure continuing regulatory compliance and be the point of contact with regulatory authorities, then UK-based responsible individuals have similarly lost their status, regardless of when products were placed on the market.

Therefore, manufacturers need to ensure that their designated responsible persons are established in the EU.

The position of Codes and Standards

The government will ensure that the standards applicable in the UK best suit the UK's needs, including designated standards businesses can use to provide presumption of conformity with GB law.

It will update the list of designated standards as and when necessary to retain and enhance the high levels of consumer safety. It may decide not to designate or to designate with restriction. Any such restrictions will be published on GOV.UK, and businesses should check frequently.

IS IT POSSIBLE TO USE A DOCUMENT OTHER THAN A HARMONISED STANDARD FOR DESIGN AND MANUFACTURE OF PRESSURE EQUIPMENT FOR THE APPLICATION OF PED?

The use of the harmonised standard is not mandatory. However, the directive did not include provisions to give presumption of conformity to documents other than harmonised standards. A manufacturer using another document shall describe in their technical documentation the solutions adopted to meet the essential requirements of the directive. The notified body (or the user inspectorate) shall validate, if required by the module chosen, these solutions.

The technical requirements of the Directive are given in Annex I. When using a national standard, a professional code or a private technical document for fulfilling Annex I, only the technical content of that document is relevant. Further provisions of the document (e.g. about bodies or certification procedures) are not relevant for the application of PED.

References of Designated Standards

Designated standards are prefixed “BS”, “EN”, “EN ISO” or “EN IEC”. The “EN” prefix indicates that the standard has been adopted by a European standardising body. Where the designated standard specified in the notice of publication is prefixed “EN” it is acceptable to reference this version in technical documentation, or a version of the same standard with a national prefix. This is because European standards are adopted identically by the 34 national members of CEN and CENELEC.

For example: BS EN 71-1:2014+A1:2018, DIN EN 71-1:2014+A1:2018, or simply EN 71-1:2014+A1:2018 are all equally acceptable.

While the essential legal requirements in GB remain the same as the equivalent EU law, the informative Annex ZA/ZZ and any references to EU law in designated standards should be read as applying to the legislation for GB in the same way, subject to any restrictions or points made in the relevant notice of publication. This will change if and when the essential legal requirements in GB change.

Many businesses currently use European harmonised standards to provide presumption of conformity with relevant EU law. As of 1st January 2021 the essential legal requirements that businesses must meet did not change. All harmonised standards that give presumption of conformity with EU law became designated standards, which businesses can use to provide presumption of conformity with GB law.

There are a total of 247 Guidelines where questions to the Committee have been answered. The key ones of interest follow, otherwise they are all available on-line.

Sound Engineering Practice

The Guideline issued for the Pressure Equipment Directive PED 2014/68/EU is as follows, and will be mirrored in the UK legislation.

"Sound engineering practice" means, without prejudice to Article 5, paragraph 1, that such pressure equipment is designed taking into account all relevant factors influencing its safety. Furthermore, such equipment is manufactured, verified and delivered with instructions for use in order to ensure its safety during its intended life, when used in foreseeable or reasonably foreseeable conditions. The manufacturer is responsible for the application of sound engineering practice.

UK Notified Bodies

As of 1st January 2021 the UK's notified bodies lost their status in the EU and are no longer authorised to assess whether products conform to EU standards or determine that a product may be CE marked.

An EU based NoBo will have to be used and Lloyds Register and Zurich Assurance are qualified. A register of UK Approved Bodies can be found on the UKMCAB system: https://www.gov.uk/uk-market-conformity-assessment-bodies

The register also contains details of bodies in other countries such as Australia, New Zealand, Canada, Japan, and the United States of America, which the UK is designating as Approved Bodies through Mutual Recognition Agreements.

Repairs and Modifications

The key phrase is “putting into service” means the first use of the equipment, therefore repairs are outside the scope unless major material changes are made, as the physical size of the unit will remain unchanged.

The level of inspection required such as X-Ray examination of the repair is a matter between the manufacturer / repairer and the customer. Any equipment put into service before the initial introduction of the original Directive 97/23/EC on 29th May 2002 is excluded from the scope.

The Guideline issued for the Pressure Equipment Directive PED 2014/68/EU is as follows, and will be mirrored in the UK legislation : Article 1; Annex I Section 3.4

Are replacements, repairs or modifications of pressure equipment in use covered by the Pressure Equipment Directive (PED) ?

- Entire change: the complete replacement of an item of pressure equipment by a new one is covered by the PED.
- Repairs are not covered by the PED but are covered by national regulations (if any).
- Pressure equipment which has been subject to important modifications that change its original characteristics, purpose and/or type after it has been put into service has to be considered as a new product covered by the directive. This has to be assessed on a case by case basis.

Operating instructions in the sense of the PED (see PED Guideline H-03) cover documentation concerning safe operation including maintenance, but not necessarily detailed information concerning repair or modification of the equipment (e.g. material certificates or qualification of welding procedures). Such information may be provided by a specific contractual agreement between manufacturer and user.

The directive applies only to the first making available on the market and putting into service. See “Blue Guide” chapter 2.

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End Notes & Sources

We hope this has been a useful overview of what is sure to be an evolving situation as the trade agreements between the UK and the EU trading block mature in the years to come.

Information was compiled from the UK and EU Governmental Brexit trade bulletins, as well as existing directives and codes of practice, including Pressure Systems Safety Regulations 2000 and Pressure Equipment (Safety) Regulations 2016.

If you have a specific manufacturing or repair need for heat exchangers of all sizes, in the UK, EU, or around the world, Serck would be happy to consult on your next project, including a no-obligation site visit.

For more information, visit our website: www.serckglobal.com