



PED 97/23/EC update

# Changes to the Pressure Equipment Directive (PED)

The history and future of PED Certification

A whitepaper

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# The **PED** at a glance

The Pressure Equipment Directive (PED) 97/23/EC is a fundamental piece of European legislation relating to the safety of pressure equipment throughout Europe. It covers the design, manufacture and conformity assessment of pressure equipment and assemblies of pressure equipment with a maximum allowable pressure greater than 0.5 bar and it is mandatory if the pressure equipment falls within the scope of the directive. However, there is a full list of exemptions in Article 1.

The PED was implemented into UK law as the Pressure Equipment Regulations 1999 (SI 1999/2001). These Regulations were made on 15th July 1999 and entered fully into force on 29 November

1999. The regulations were subject to minor amendment (SI 2003/1267) made 06 May 2002 and came into force on 30 May 2002.

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## Why is the **PED** changing?

The PED is one of the New Approach Directives and is now over 17 years old. The old directive 97/23/EC will be replaced by the new directive 2014/68/EU.

The change will implement alignment with the NLF (New Legislative Framework 765/2008 and 768/2008) which aims to streamline and simplify the rules for putting pressure equipment on the market in the face of increasing competition from fraudulently certified equipment.

Further information can be found in the Blue Guide 2014 <http://ec.europa.eu/DocsRoom/documents/11502/attachments/1/translations/en/renditions/native>

### Legal Requirements

Important to note is that whilst the old directive will be replaced by the new directive following a transition period, there is already a legal requirement which is now in place and must be met. Article 13 of 2014/68/EU was effective 1st June 2015, and relates to fluid classification, i.e. CLP regulations 1272/2008.

The new directive is required to be enacted into UK Law via a Statutory Instrument (SI) by the UK Government. Until this is completed the directive is not enforceable with the exception of Article 13 as this is already covered by the CLP Regulations 1278/2008, which has been enacted into UK Law via SI 2015 No. 399.

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## What are the **main changes**?

There are a wide variety of changes in 2014/68/EU, the main changes are: -

- **Fluid group classification** will now follow the CLP Regulations 1278/2008 per 2014/68/EU Article 13. This regulation introduced a division and categorisation structure for different fluid types, with the aim of clearly and accurately identifying and marking labelling and packaging for these fluids. The PED has been updated to recognise these new categorisations. The fluid groups cited in 2014/68/EU remain the same, i.e. 1 and 2. Fluid Group 1 still includes flammable, toxic and oxidising fluids, and Fluid Group 2 includes all other fluids not captured in Group 1. However, the seven Fluid Group 1

descriptors cited in PED 97/23/EC Article 9 clause 2.1 have been replaced by seventeen group 1 descriptors in 2014/68/EU Article 13 clause 1a. Fluid group 2 remains the same, i.e. those fluids that aren't in group 1. It is possible that some fluids may have changed groups but most will remain the same.

Further guidance on the impact of the CLP can be found on the HSE website: <http://www.hse.gov.uk/chemical-classification/legal/clp-regulation.htm>

- **Distributors and importers** are now included and have legal obligations placed upon them
- **Some conformity assessment modules** have been renamed and the

requirements for manufacturers and notified bodies restructured:

- **Module A1** is now Module A2 and **Module C1** is now Module C2 – both new Modules A2 and C2 have enhanced explanations relating to technical file requirements and Notified Body involvement.
- **Module B** – EC Type Examination and Module B1 – EC Design Examination in 97/23/EC have been integrated together under new Module B – EU Type Examination in 2014/68/EU. There are two routes to this EU Type Examination – Production Type (similar to Module B in 97/23/EC) and Design Type (similar to Module B1 in 97/23/EC)

# What are the **main changes**?

- **All QA based Conformity Assessment modules D/D1/E/E1/H/H1** require specific documentation to be submitted with the application and impose additional requirements on the Notified Body's auditor competency/experience. For Modules H and H1 the manufacturer shall provide technical documentation for one model of each type to be manufactured
- **Module H1** now appears to be independent of Module H and refers to a Design Examination – this would appear to be a third type of design review independent of the new Module B (Design Type) or (Production Type)
  - There are a few minor changes to the **Essential Safety Requirements (ESR)**:
  - The words "and risks" have been added to Preliminary Observation 3.
- Designers and those compiling technical files will need to consider the impact of these words
  - The word "must" has been changed to "shall" throughout the ESRs.
  - All recitals, articles and annexes have been restructured to align with the 'reference provisions' of the 'NLF';
    - 37 new recitals
    - 31 new articles
    - One fewer annex.

## Where to from here?

### What manufacturers of pressure equipment need to do now

All manufacturers of pressure equipment need to be aware of the impending changes and familiarise themselves with the requirements of 2014/68/EU. e.g. making the necessary changes to procedures, processes, forms, etc., identifying which of the changes (if any) will have an impact on their business. Any changes should only implemented when the Statutory Instrument (SI) has been issued.

**Understand that Article 13 of 2014/68/EU was effective 01 June 2015 and is now a legal requirement per SI 2015 No. 399.**

This relates to fluid classification, i.e. CLP regulations 1272/2008. This will require all PED equipment manufacturers who CE mark their products to cite Article 13 of 2014/68/EU on their respective Declarations of Conformity in addition to PED 97/23/EC.

**Manufacturers should be aware that any previously issued certificate under PED 97/23/EC remains valid under 2014/68/EU per Article 48 clause 3.**

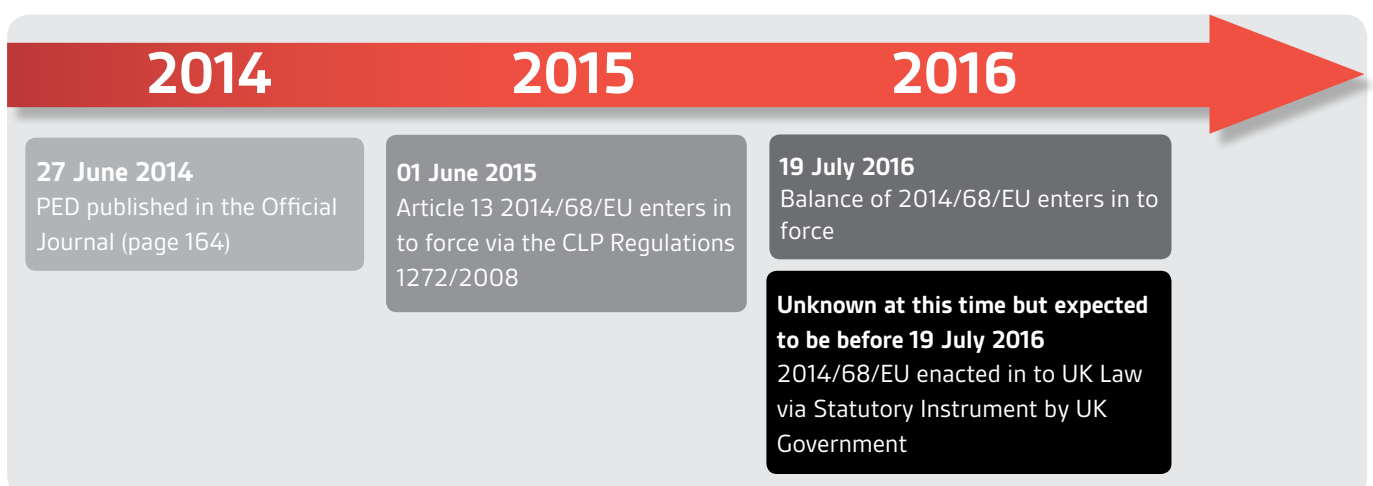
### Legal Obligations

There are legal obligations on all of the "Economic Operators". 2014/68/EU Article 2 item 22 defines these Economic Operators as the Manufacturer, the Authorised Representative, the Importer and the Distributor and Chapter 2 Articles 6, 7, 8 and 9 define the obligations of each of these Economic Operators.

#### Early preparation is key

**By starting to prepare for these changes now, you will be better equipped to handle the impact of the new directive on your company.**

## PED 2014/68/EU timescales



# Support from **BSI**

## How BSI can help you through the changes

We will continue to monitor the progress of these changes and keep all our clients updated when more information is released from the European Commission and UK Government. This information will be available on our website [bsigroup.com/ped](https://bsigroup.com/ped)

We are also offering awareness sessions. Our Certification Managers and other colleagues will be aware of any changes so that we can let you know in advance about the impact that these changes may have.

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## The role of a **Notified Body** (BSI)

BSI is a Notified Body for the PED and numerous other EU Directives. We have a comprehensive scope for PED, being able to carry out Notified Body activities under all applicable Conformity Assessment Modules.

In the UK a Notified Body is a body which has been appointed by the department for Business Innovations and Skills (BIS), to carry out one or more of the conformity assessment procedures cited in a directive.

The details of all Notified Bodies and their scope of approval is listed on the Europa website

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## Why **BSI**?

Our knowledge, expertise and drive can make a difference to your business:

- We are the pioneers of many of the world's first standards.
- We are renowned for our innovative work in many fields.
- We continue to lead the way with ongoing developments in various industries.
- You can enjoy the benefits of working with BSI teams who have decades of experience helping businesses of all sizes.
- We provide end-to-end support, helping you monitor and maintain your excellence throughout.

Please contact us.

**Our team will be happy to help you.**

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