PED 2014/68/EU update

Pressure Equipment Directive (PED)

A whitepaper

bsi.

...making excellence a habit.™

The **PED history** at a glance

The Pressure Equipment Directive (PED) 97/23/EC was a fundamental piece of European legislation relating to the safety of pressure equipment throughout Europe. The PED is one of the New Approach Directives and is now 20 years old. The old directive 97/23/EC has been replaced by the new directive 2014/68/EU.

The change implements 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.

PED 2014/68/EU 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 is mandatory if the pressure equipment falls within the scope of the directive. However, there is a full list of exemptions in Article 1.

Legal requirements

The PED was implemented into UK law as the Pressure Equipment Regulations 1999 (SI 1999/2001). These Regulations were made on 15 July 1999 and entered fully into force on 29 November 1999. The regulations were subject to minor amendment (SI 2003/1267) made 6 May 2002 and came into force on 30 May 2002. PED 2014/68/EU was enacted into UK Law via a Statutory Instrument (SI) 2016 No. 1105 and came into force on 8 December 2016.

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.
  The fluid groups cited in 2014/68/EU remain the same, i.e. 1 and 2. However, the seven group 1 descriptors cited in PED 97/23/EC Article 9 clause 2.1 have been replaced by seventeen group 1 descriptors in 2014/68/EU Article 13 clause 1a.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.

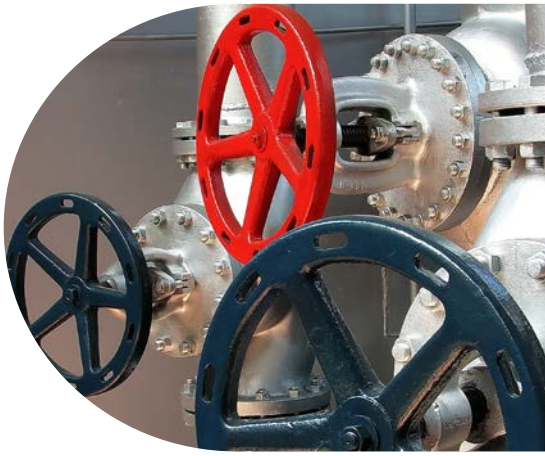
  Further guidance on the impact of the CLP can be found on the HSE website: http://www.hse.gov.uk/chemical-classification/legal/clp-regulation.htm
- **Distributors and importers** are now included and have legal obligations placed upon them
- **Some conformity assessment modules** have been renamed and 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)
  - **All quality assurance 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** is now independent of Module H and refers to an EU Design Examination – a third type of design review independent of the new Module B (Design Type) or (Production Type) and only applicable where Module H1 certification is in force

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



What **manufacturers of pressure equipment** should now have completed

All manufacturers of pressure equipment should be aware of the changes and have familiarized themselves with the requirements of 2014/68/EU.

They should now have conducted an impact assessment of the changes imposed by the new directive and made the necessary changes to technical files, procedures, processes, forms, etc.

And they should have updated their Declaration of Conformity so that it now complies with PED 2014/68/EU Annex IV noting that the required wording has changed, e.g. it now states "Notified Body conducting the Conformity Assessment" not carrying out the inspection or monitoring the quality system.

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 Authorized Representative, the Importer and the Distributor and Chapter 2 Articles 6, 7, 8 and 9 define the obligations of each of these Economic Operators.

Support from **BSI**

Where to find further information

BSI can offer technical advice to help you understand the regulations, testing and CE marking for the PED. Visit our website for more information: **bsigroup.com/ped**

For further information, visit the following resources:

PED 2014/68/EU – http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014L0068

Pressure Equipment Safety Regulations 2016 – SI 2016 No. 1105 – https://www.legislation.gov.uk/uksi/2016/1105/contents/made

Blue Guide 2016 – http://ec.europa.eu/DocsRoom/documents/18027/

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 Energy and Industrial Strategy (BEIS), 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 New Approach Notified and Designated Organisations (NANDO) Information System via this link http://ec.europa.eu/enterprise/newapproach/nando/

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 on-going 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
Call: **+34 91 400 86 20**
Email: **info.esp@bsigroup.com** or visit:
bsigroup.com/ped

BSI Group
Kitemark Court
Davy Avenue, Knowlhill
Milton Keynes MK5 8PP

T: 0345 0765 606
F: 01908 814920
bsigroup.com

BSI/UK/1182/PC/1217/EN/BLD