

Information leaflet on coming up changes in the European Pressure Equipment Directive (PED)

1 Introduction to new PED 2014/68/EU

The Pressure Equipment Directive (PED 97/23/EC) has been in place since the 29th May 2002. It will be replaced by [PED 2014/68/EU](#) as per **19 July 2016**.

Two main factors have enforced the new PED

- The current basis for the determination of fluid group (1 or 2) in PED Article 9 (i.e. Directive 67/548/EEC) is being replaced by a new Classification, Labelling and Packaging Regulation from **1st June 2015**.
- The "New Legal Framework:" This is a larger initiative by the European Union to bring nine EC "New Approach" directives into alignment with the "New Legal Framework," (NLF) which was adopted in 2008.

The following aspects of the current PED will remain unchanged

- The scope of the PED
- The essential safety requirements (annex I)
- The categorisation tables (annex II)

The introduction of the new PED will not act in retrospect on certificates issued under the existing PED. Article 48 states, "Certificates and decisions issued by conformity assessment bodies under Directive 97/23/EC shall be valid under this Directive."

Not only the PED changes, but also a number of other EU directives will change, due to the new NLF, like:

Directive	Products	Revision
PED 97/23/EC	Pressure Equipment	New PED (2014/68/EU) in force 19 July 2016
LD 95/16/EC	Lifts	New LD (2014/33/EU) in force 20 April 2016
R&TTE 99/5/EC	Radio Equipment	Replaced by new Radio Equipment Directive 2014/53/EC on 13 June 2016
EMC 2004/108/EC	Electromagnetic Compability	New EMC (2014/30/EU) in force 20 April 2016
LVD 2006/95/EC	Low Voltage	New LVD (2014/35/EU) in force 20 April 2016
ATEX 94/9/EC	Devices in Explosive Atmosphere	New ATEX (2014/34/EU) in force 20 April 2016
RCD 94/25/EC	Recreational Crafts	New RCD (2013/53/EU) in force 18 January 2016
MID 96/98/EU	Measurements Instruments	New MID (2014/32/EU) in force 30 October 2016

2 New PED Transfer process

The dates below show the two timeline steps for the introduction of the new PED.

1st June 2015 Art.13 of the new PED applies (i.e.CLP)

19th July 2016 Full application of the new PED

All EU member states are required to transpose the new PED 2014/68/EU in their national legislation before these dates.

3 Brief overview of changes

3.1 Economic operators

The new PED defines the term “economic operators” defining roles and responsibilities as below

- Manufacturer – unchanged
- Authorized representative – unchanged
- Importer - The importer is the economic operator established in the Union who places a product from a third country on the Union market. The importer must ensure that the manufacturer has correctly fulfilled his obligations. The importer is not a simple re-seller of products, but has a key role to play in guaranteeing the compliance of imported products. He is obliged to contact the manufacturer if the compliance with the PED requirements is doubted. He must mark the product with his name and address. He must ensure that, while a product is under his responsibility, storage or transport conditions do not jeopardise its compliance. He must keep a copy of the EU Declaration of Conformity for 10 years after the product has been placed on the market and ensure that the technical documentation can be made available to the competent national authority upon request.
- Distributor- juridical/physical person in the EU in the supply chain between any of the above defined (both Third Country and inside the EU) and the User. Retailers, wholesalers and other distributors in the supply chain are not required to have a direct agreement with the manufacturer like the authorised representative. A distributor acquires products for further distribution either from a manufacturer, from an importer, or from another distributor. However they have an obligation to be aware of the PED requirements and their responsibility. They must keep a copy of the manufacturer’s operation manual and the DoC.

The revision of the PED also makes clear that if an importer or distributor places pressure equipment or assemblies on the market under their own name or trademark, or modifies the equipment in a certain way, they will be considered manufacturer and will therefore have to take legal responsibility for the product's compliance including conformity assessment.

3.2 Conformity assessment modules

The designation of some conformity assessment modules has changed as below.

97/23/EC	2014/68/EU
A1	A2
B1	B (design type)
B	B (production type)
C1	C2

This is how the modules fall under each category:

- Category I = Module A
- Category II = Modules A2, D1, E1
- Category III = Modules B (design type) + D, B (design type) + F, B (production type) + E, B (production type) + C2, H
- Category IV = Modules B (production type) + D, B (production type) + F, G, H1

3.3 Fluid Classification Change

The new fluid classification goes into effect on 1st of June 2015: Chapter 3, Article 13, "Classification of pressure equipment." An impact assessment by the European Commission showed that very few substances would actually change groups in the PED because of this change. The only significant change concerns the definition of flammable fluids, where the CLP has considered the PED definition. The below figure from the EC study illustrates the new classification.

Table 3.4: Translation from the DSD to CLP (Flammable (Liquids))					
DSD	F +; Extremely Flammable R12	F; Highly Flammable R11	F; Flammable R10*		
* Substances classified as F; Flammable (R10) will be Group 1 if the intended maximum allowable temperature is above its flashpoint.					
PED	Classified as 'Group 1' fluid under PED				
FP °C	≤ 0	0 - 21	21 - 23	23 - 55	55 - 60
CLP	Flammable Liquids*				
	Category 1	Category 2	Category 3**		
* As discussed further in Annex 1, the demarcation between Category 1 and 2 flammable liquids also takes account of the boiling point. Nevertheless, extremely flammable liquids (R12) under DSD will generally become Category 1 flammable liquids under CLP					
** Substances classified as a Flammable Liquid, Category 3 will be a Group 1 fluid if the intended maximum allowable temperature is above its flashpoint.					

3.4 Impact on Manufacturers

Beside the changes in the Conformity Assessment Modules and fluid classification as described above, the harmonized standards will increase in importance as solutions to meet the ESR must be stated by the manufacturer if non-harmonized standards are used. This is expressed in the risk analysis requirements, which can be found in Annex III for each module.

The content of a Declaration of Conformity in Annex IV is also expressed more in detail.

3.5 Impact on Notified Bodies

The horizontal requirements on Notified Bodies will be implemented in the new PED. This includes stricter connection to accreditation and more focus on personnel competences at the Notified Bodies.

4 Changes in detail

Changes of the new PED affecting the daily work of relevant stakeholders are addressed in this chapter. A transfer list in the new PED provides guidance on how the PED 97/23/EC is transferred into the new one in higher degree of detail.

4.1 Changes in fluid categorisation (art 13) as per 1st June 2015

Fluid groups 1 and 2 of PED 97/23/EC will remain. However the base for Group classification will be changed as the old Dangerous Substances directive – 67/548/EEC - is being replaced by the new CLP legislation. In practice these changes only concern some toxic fluids and flammable liquids with a flash point between 21 and 23 centigrade.

Working Group Pressure Guideline WPG B-01 is providing guidance as well.

4.2 Module A1 into new PED Module A2

Monitoring of final assessment is to be performed at random intervals.

4.3 Module C1 into new PED Module C2

Same change as for Module A1 into A2.

4.4 Module B into new Module B (production type)

Same approach as under the old PED. Requirements to NoBo have some modifications.

4.5 Module B1 into new Module B (design type)

Most remarkable is that B1 is integrated under module B and the new module B is split up in B (production type) and B (design type). For the B (design type) certificate, no prototype testing is required, the validity is ten years and the technical file is to be stored 10 years from expiry.

4.6 Other Product modules and Quality System Modules

The content of the product modules F and G and the quality modules D,D1, E, E1, H and H1 do not have remarkable changes.

4.7 Changes to Declaration of Conformity

The minimum required content of the Declaration of Conformity (DoC) to be issued by the manufacturer is described in more detail in Annex IV. Manufacturers are expected to review and update the standard content of their DoC, including the new directive number.

5 Consequences of the new PED on new and running projects

5.1 New projects

As general aspect the implementation of the new PED art 13 will start per 1st of June 2015. DNV GL advises applicants to classify according to both old and new PED from now on.

5.1.1 Quality System Modules

Applications will be assessed according PED 97/23/EC until 18 July 2016 and, when not finished on 19 July 2016, will be continued and certified according PED 2014/68/EU. All reporting and assessments performed under PED 97/23/EC remain valid under PED 2014/68/EU. Issuing Declaration of Conformity (manufacturer) and Certificate of Conformity (NoBo) according 2014/68/EU before 19 July 2016 is not allowed.

Issued Certificates according PED 97/23/EC before 19 July 2016 remain valid after this date for PED 2014/68/EU.

5.1.2 Product Modules

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Issued Certificates according PED 97/23/EC before 19 July 2016 remain valid after this date. Old PED and New PED modules can be combined after 19 July 2016, i.e. Module B (97/23/EC) with module D (2014/68/EU).

5.1.3 Particular Material Appraisals

PMA's issued before 19 July 2016, based on PED 97/23/EC remain valid under the new PED.

5.1.4 Welding approvals

An approval on WPQR's and WPQ's issued before 19 July 2016, based on PED 97/23/EC remain valid under the new PED.

5.2 Running projects on 1 June 2015 and on 19 July 2016

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Issued Certificates according PED 97/23/EC before 19 July 2016 remain valid after this date.

A Manufacturer issuing a Declaration of Conformity after the transfer should make a reference to Art.48 resp. Art.41 if the DoC is based on Certificates issued before the transfer

6 Disclaimer

This leaflet is assembled by DNV GL to provide guidance to clients on the introduction of the new PED 2014/68/EU. Interpretation of the Directive itself is not the responsibility of DNV GL.

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