

## New PED

### Introduction

The Pressure Equipment Directive (PED 97/23/EC) has been in vigor since the 29<sup>th</sup> May 2002. It will now be replaced by PED 2014/68/EU on 19.07.2016

Two main factors have enforced the new PED;

1. 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.
2. 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 essentials of the current PED **will not change**:

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

The introduction of the new PED will not act in retrospective 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."

### Transfer process

Below table shows the two steps of the timeline for the introduction for the new PED.

1 June 2015: Start of application of Art.13 in new PED (i.e.CLP)

19 July 2016: Start of full application of the new PED

### Changes in brief

#### Economic operators:

The new PED defines the term "economic operators" defining roles and responsibilities:

- Manufacturer – no changes
- Authorized representative – also no changes
- Importer – juridical/physical person in the EU placing pressure equipment from Third Country on the European market. Must verify the Manufacturer's technical file, the compliance with the concerned equipment with the PED ESR and that an European authority will have access. The importer must issue a DoC (double marked) and mark the product. Note: this is not double-marking, but adding the importers name on the manufacturer's marking. The importer must be able to provide the technical file to authorities if required.
- 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. The distributor must keep a copy of the DoC and mark the product with its name. He must verify that the product is correctly CE-marked and accompanied with operating instructions.

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

Conformity assessment modules:

The designation of some conformity assessment modules have 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 now 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

Fluid Classification Change

The new fluid classification goes into effect from 1st 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:

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	<b>Flammable Liquids*</b>				
	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.					

### **Impact on Manufacturers**

Beside the changes in CAM 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. These requirements are now found in Annex III for each module.

The content of a DoC in Annex IV is also expressed more detailed.

### **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 competences in the Notified Bodies.

### **What do the changes mean for your specific CE-marking scope?**

For further information please contact the respective DNV GL PED Notified Bodies in UK (Notified Body 0097), Netherlands (Notified Body 0427), Italy (Notified Body 0496), Norway (Notified Body 0575) and Denmark (Notified Body 2099).