Pressure Equipment Directive (PED) – New Directive 2016/68/EU

Introduction

In order to improve the Internal Market for goods a New Legislative Framework (NFL) was adopted in 2008 by the European Commission. It's based on:

- Regulation (EC) 765/2008 setting out the requirements for accreditation and the market surveillance relating to the marketing of products.
- Decision No 768/2008/EC on a common framework for the marketing of products.
- Regulation (EC) No 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State.

The NFL have the aim of:

- improving the market surveillance rules.
- boosting the quality of conformity assessments.
- clarifying the use of CE marking.
- establishing a legal framework for industrial products.

The old PED 97/23/EC in force since 13th May 2002, has been replaced by PED 2016/68/EU, which has been aligned with the new approach of the European Commission.

The updated **PED 2016/68/EU** of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment **is fully in force since 19th July 2016.**

PED 2016/68/EU Changes

The essence of the PED has not changed mostly. The scope, the essential safety requirements and the conformity assessment tables, remain almost unchanged. In fact, all the certificates and decisions issued by conformity assessment bodies under PED 97/23/EC shall be valid under the new PED 2016/68/EU.

Most significant changes:

Fluid classification.

Directive 67/548/ECC related to the classification, packaging and labelling of dangerous substances has been repealed and replaced by the Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labelling and Packaging of substances and mixtures (CLP), fully in force since 15th June 2015.

For the purposes of such classification, PED 2016/68/EU divides fluids into two big groups:

Group 1 consisting of substances and mixtures, as defined in points (7) and (8) of Article 2 of Regulation (EC) No 1272/2008, that are classified as hazardous in accordance with the following physical or health hazard classes laid down in Parts 2 and 3 of Annex I to that Regulation:

- Unstable explosives or explosives of Divisions 1.1, 1.2, 1.3, 1.4 and 1.5;
- Flammable gases, category 1 and 2;
- Oxidising gases, category 1;
- Flammable liquids, category 1 and 2;
- Flammable liquids, category 3 where the maximum allowable temperature is above the flashpoint;
- Flammable solids, category 1 and 2;
- Self-reactive substances and mixtures, type A to F;
- Pyrophoric liquids, category 1;
- Pyrophoric solids, category 1;
- Substances and mixtures which in contact with water emit flammable gases, category 1, 2 and 3;
- Oxidising liquids, category 1, 2 and 3;
- Oxidising solids, category 1, 2 and 3;
- Organic peroxides types A to F;
- Acute oral toxicity, category 1 and 2;
- Acute dermal toxicity, category 1 and 2;
- Acute inhalation toxicity, category 1, 2 and 3;
- Specific target organ toxicity – single exposure, category 1.

(Group 1 comprises also substances and mixtures contained in pressure equipment with a maximum allowable temperature TS which exceeds the flashpoint of the fluid)

Group 2 comprises all other substances and mixtures not referred to in Group 1.

An Impact Assessment Study on the Alignment of the Pressure Equipment Directive to the CLP Regulation was conducted in 2013. It was prepared for DG Enterprise & Industry by Risk & Policy Analysts Limited. The final report is avaiable by clicking on the link.

Brieffly, according to the study, a significantly smaller number of 35 substances may change of fluid group following PED alignment with CLP.

Conformity assessment procedures.

The designation of some conformity modules have been renamed in order to align it to the reference provisions in the NFL as bellow.

DIR 97/23/EC Modules (Art 10)	DIR 2014/68/EU Modules (Art 14)
A1	A2
B1	B (design type)
B	B (production type)
C1	C2

The conformity assessment procedures to be applied for the various categories are the following.

Category	Module	
	DIR 97/23/EC (Article 10)	DIR 2014/68/EU (Article 14)
I	A	A
II	A1	A2
	D1	D1
	E1	E1
III	B1 + D	B(dt) + D
	B1 + F	B(dt) + F
	B + E	B(pt) + D
	B + C1	B(pt) + C2
	H	H
IV	B + D	B(pt) + D
	B + F	B(pt) + F
	G	G
	H1	H1

Category I

Category II

Category III

Category IV

The manufacturer may also choose to apply one of the procedures which apply to a higher category, if available.

Economic Operators

The new PED incorporates the term "economic operators" and lays down legal obligations for each one. Now importers and distributors have role and responsabilities in the supply chain too.

An economic operators is:

- A manufacturer: Any natural or legal person who manufactures pressure equipment or an assembly or has such equipment or assembly designed or manufactured, and markets that pressure equipment or assembly under his name or trademark or uses it for his own purposes.
- An authorized representative: Any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks.
- An importer: Any natural or legal person established within the Union who places pressure equipment or assemblies from a third country on the Union market.
- A distributor: Any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes pressure equipment or assemblies available on the market.

Declaration of Conformity

The “CE Declaration of Conformity” is renamed to “EU declaration of conformity” in PED 2016/68/EU .The model structure is set out in Annex IV.

PED Guidelines

PED 2016/68/EU Guidelines are available as a reference for ensuring consistent application of the Directive.

DISCLAIMER

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Sources

- http://ec.europa.eu/
- PED 97/23/EC
- PED 2016/68/EU