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INFORMATION LEAFLET ON COMING UP CHANGES IN THE EUROPEAN PRESSURE EQUIPMENT DIRECTIVE (PED)

Pressure equipment for the European market

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 19th July 2016.

Briefly

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 Legislative Framework:" This is a larger initiative by the European Union to bring nine EC "New Approach" directives into alignment with the "New Legislative 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."

EU directives subject to changes due to NLF

Pressure equipment (PED): new 2014/68/EC on 19th July 2016
Lifts (LD): new 2014/33/EU on 20th April 2016

TRANSFER PROCESS TO NEW PED

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.

Radio Equipment (R&TTE): new 2014/53/EC on 13th June 2016
Electromagnetic Compatibility (EMC): new 2014/30/EU on 20th April 2016

Low Voltage (LVD): new 2014/35/EU on 20th April 2016
Devices in explosive atmosphere (ATEX): new 2014/34/EU on 20th April 2016

Recreational crafts (RCD): new 2013/53/EU on 18th January 2016

Measurement Instruments (MID): new 2014/32/EU on 30th October 2016.

Brief overview of changes

Economic Operators

The new PED uses 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 own name and address. He must ensure that, while a product is under his own responsibility, storage or transport conditions do not jeopardise product's 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 manufacturers 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.

Conformity assessment modules

The designation of some conformity assessment modules have changed as below:

- A1 will become A2
- B1 will become B (design type)
- B will become B (production type)
- C1 will become C2

This is how the modules will 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 on 1st of June 2015: Chapter 3, Article 13, “Classification of pressure equipment.” An impact assessment by the European Commission shows 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	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.					

Transition from the DSD to CLP

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 solution to meet the ESR. Manufacturers will have to state if non-harmonized standards are used. This is expressed in the risk analysis requirements, which can now be found in Annex III for each module.

The required content of the Declaration of Conformity is also expressed more in detail, in Annex IV of the new Directive.

Impact on Notified Bodies

Horizontal requirements on Notified Bodies will be implemented in the new PED. This includes stricter requirements on accreditation and on personnel competence at the Notified Bodies.

Changes in detail and consequences on running / new projects

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.

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

Fluid groups 1 and 2 of PED 97/23/EC will remain unchanged. 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 21-23 deg.C. Working Group Pressure Guideline WPG B-01 is providing guidance as well.

Changes to Conformity Assessment Modules (CAMs)

- CAM A2 and C2: Monitoring of final assessment is to be performed at random intervals.
- CAM B (production type): Same approach as under the old PED. Requirements to NoBo have some modifications.
- CAM B (design type): Most remarkable is that CAM B1 is integrated in CAM B and the new CAMB 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.
- Other CAMs: The content of the product modules F and G and the quality modules D,D1, E, E1, H and H1 does not have remarkable changes.

Change 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 of the new Directive. Manufacturers are expected to review and update the standard content of their DoC-template, including the new directive number.

Consequences of the new PED on new and running projects

What the impact on running and new project will be, is determined by the time when conformity assessment activities will be carried out.

Keeping in mind the two key implementation dates of 2014/68/EU, three time intervals shall be considered:

- Time before 1st June 2015: conformity assessment activities are carried out uniquely according to 97/23/EC
- Time between 1st June 2015 included and 18th July 2016 included: fluid classification will be performed according to 2014/68/EU but further assessment activities will be carried out according to 97/23/EC
- Time from 19th July included: conformity assessment activities are carried out uniquely according to 2014/68/EU.

This will imply that projects running over more than one of these time intervals will be assessed according to the articles applicable at the time of assessment. The figure on next page

shows this principle visually.

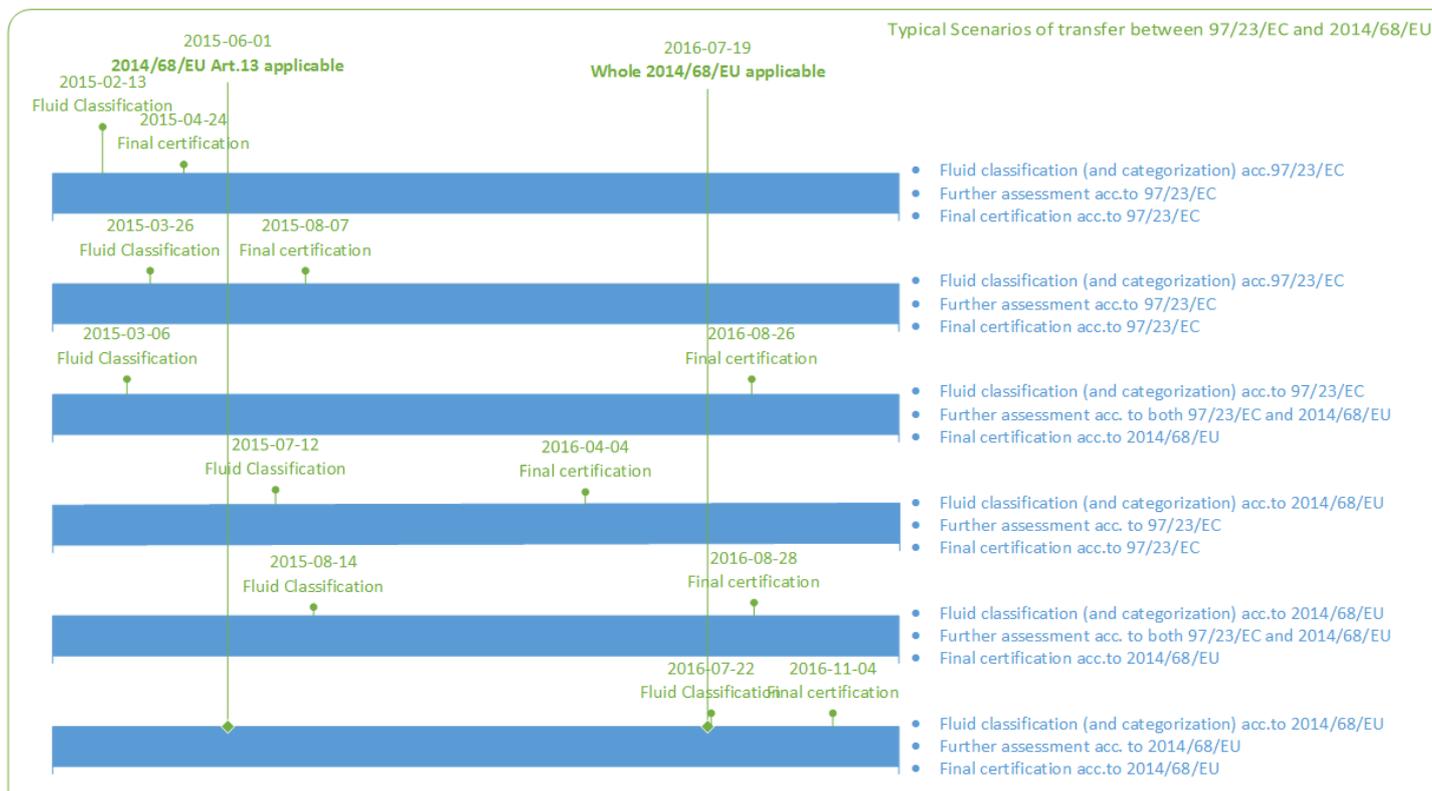
General principles:

- Manufacturers are advised to classify fluids according to both 97/23/EC and 2014/68/EU from now on
- Decisions taken/reporting and assessments carried out/certificates issued under 97/23/EC within 18th July 2016 included, will still be valid under 2014/68/EU. Also applicable for Particular Material Appraisals, approval of WPS/WPQR
- Issue of Declaration of Conformity (by Manufacturer) and applicable Certificates (by Conformity Assessment Body) according 2104/68/EU before 19th July 2016, is prohibited
- Certificates issued under 97/23/EC within 18th July 2016



included, can be combined with conformity assessment modules of 2014/68/EU, eg. CAM B1 (97/23/EC) + CAM F (2014/68/EU)

- Manufacturers issuing Declarations of Conformity after 18th July 2016, based on certificates issued within this date, should make reference to Article 48 of 2014/68/EU.



PED Notified Bodies in DNV GL

This information leaflet is a common publication of the DNV GL Notified Bodies* for PED:

- Notified Body no. 0097 UK
- Notified Body no. 0427 The Netherlands
- Notified Body no. 0496 Italy
- Notified Body no. 0575 Norway

* Other Notified Body is DNV GL Denmark, no. 2099

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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