Assemblies according to the Pressure Equipment Directive

- a consideration provided by the PED-AdCo Group[1] -

1 Preliminary remark

The consideration of assemblies pursuant to the Pressure Equipment Directive (PED[2]) repeatedly raises questions in practice. Particularly due to the sometimes abstract legal requirements and the resulting need for interpretation, uncertainty prevails with regard to specific situations when dealing with the issue of their implementation in compliance with the law.

The following overview is intended to assist relevant players (manufacturers, conformity assessment bodies, operators, authorities) by clarifying

1. when an assembly exists

   and

2. what requirements or measures are derived from the same.

Reference is essentially made to the requirements set out in the PED in this regard. Where these are not exhaustive, the guidelines concerning the PED adopted by the EU Commission Working Group Pressure (WGP) are used as an explanation.

Note:	*The present document does not relate to assemblies intended for generating steam or superheated water at a temperature higher than 110 °C comprising at least one item of fired or otherwise heated pressure equipment presenting a risk of overheating pursuant to Art. 4, Par. 2 a) of the PED.*

[1] For comments and suggestions please email to michael.borzel@tlv.thueringen.de.

[2] Pressure Equipment Directive 20014/68/EU

2 Fundamentals

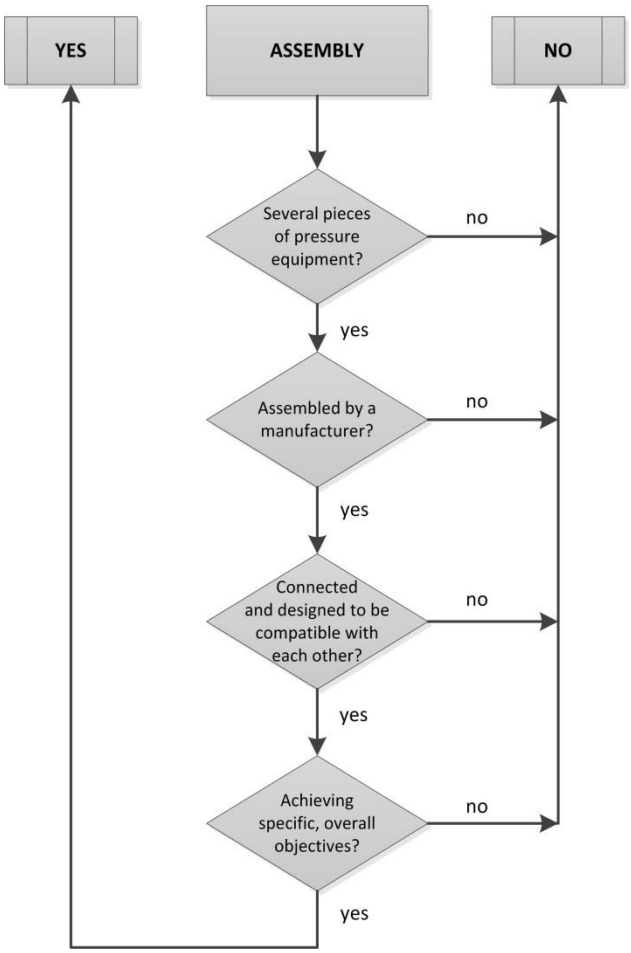
2.1 Terms / criteria

The PED fundamentally defines the term "**assembly**" in Art. 2 (6).

Accordingly, an assembly is concerned if:

- several items of pressure equipment[3]
- from a manufacturer[4]
- are assembled to form an integrated[5] and functional[6] whole.

The following illustration is designed to help in deciding whether an assembly exists with the meaning set out above. Special note should be taken in this regard of the explanations concerning the steps listed in the illustration.



Answer to the question whether an assembly pursuant to Art. 2(6) of the PED is concerned.
There are at least two items of pressure equipment present within the meaning of Art. 2 (1) of the PED.
The items of pressure equipment are, for example, screwed or welded together.
The items of pressure equipment are, for example, compatible with each other regarding pressure stage and/or material selection.
The items of pressure equipment function as a unit and serve the same purpose.

Fig. 1 Assembly decision flow chart

2.2 Scope / limitations

Apart from the condition that an assembly must contain at least two pressure equipment items within the meaning of Art. 2 (1) of the PED, no other limitation arises from the PED concerning the extent of an assembly.

This could therefore range from a simple combination of, for example, a cylinder for a breathing apparatus + valve or a vessel + safety valve etc. to smaller units such as pressure cookers or fire extinguishers and even complex industrial plants[7].

[3] 'pressure equipment' means, pursuant to Art. 2 (1) of the PED, vessels, piping, safety accessories and pressure accessories, including, where applicable, elements attached to pressurised parts, such as flanges, nozzles, couplings, supports, lifting lugs

[4] 'manufacturer' means, pursuant to Art. 2 (18) of the PED, 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

[5] "integrated" means that the pressure equipment items are connected together and designed in such a way that they are compatible with each other

[6] "functional" means that the pressure equipment items together fulfil certain overall objectives

It is ultimately the task of the manufacturer to specify the limits of "its" assembly and, associated with this, the area of responsibility relevant to it.

Note:	*The client (later user/operator) should also make sure that the assembly issue is given adequate consideration and the respective area of responsibility is clearly defined.*

2.3 Requirements on assemblies

2.3.1 Assemblies intended to be made available on the market

Apart from the criteria listed under point 2.1., no special requirements arise with regard to assemblies.

However, if an assembly is intended by the manufacturer to be made available on the market, the individual pressure equipment items must comply with the requirements currently in force (see Art. 3, Par. 1 of the PED).

Note:	*Making available on the market pursuant to Art. 2 (15) of the PED means any supply of pressure equipment or assemblies for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;*

2.3.2 Assemblies intended to be made available on the market and put into service

As soon as a manufacturer of an assembly stipulates that this is to be made available on the market **and** (may be) put into service [see Art. 4, Par. 2b) of the PED], this has to be subjected to a **global conformity assessment** pursuant to Art. 14, Par. 6 of the PED (see also point 3.2).

Note:	*Putting into service means, pursuant to Art. 2 (17) of the PED, the first use of pressure equipment or an assembly by its user.* *The Blue Guide supplements this under Section 2.5 to the effect that it concerns the first use of a product for the intended purpose by the end user on the territory of the Union.*

3 Measures / duties

The measures / duties described in the following relate exclusively to assemblies intended to be made available on the market.

3.1 Assemblies without a global conformity assessment pursuant to Art. 14, Par. 6 of the PED

In principle, a distinction has to be made between assemblies with a lower and those with a higher risk potential.

3.1.1 Assemblies with pressure equipment < Category I

Assemblies with a lower risk potential are to be assumed when these are composed **exclusively** of pressure equipment items that do **not** reach the limit values stipulated in Art. 4, Par. 1 of the PED (i.e. < Category I).

Both these pressure equipment items and the assemblies resulting from them being put together must, pursuant to Art. 4, Par. 3 of the PED, be designed and produced in accordance with the **Sound Engineering Practice**[8] applying in a Member State.

Adequate operating instructions must then also be provided with the assemblies to guarantee that these can be used safely (see Art. 4, Par. 3, Clause 3 of the PED).

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[7] see PED-GL 3/9 (soon to be C-09)

[8] see PED-GL 9/1 and 9/17

Note: 	***No** conformity assessment procedure under Annex III to the PED has to be carried out for pressure equipment or assemblies coming under the Sound Engineering Practice. **Nor** is **any** EU declaration of conformity issued* or ***any** CE mark affixed (see Art. 4, Par. 3 of the PED).*

3.1.2 Assemblies with pressure equipment ≥ Category I

For assemblies containing at least one item of pressure equipment pursuant to Art. 4, Par. 1 of the PED (i.e. ≥ Category I) (and are "merely" to be made available on the market), the pressure equipment item(s) must meet the relevant essential safety requirements as listed in Annex I[9].

In this respect, the pressure equipment item(s) is/are to be subjected to a conformity assessment procedure pursuant to Art. 14 and have the CE mark affixed to it/them; a declaration of conformity is to be issued (see Art. 6, Par. 2 of the PED).

3.2 Assemblies with a global conformity assessment pursuant to Art. 14, Par. 6 of the PED

3.2.1 Fundamentals

It can be inferred from Art. 4, Par. 2 of the PED that only those assemblies

- containing at least one item of pressure equipment under Category I, II, III or IV and
- intended by the manufacturer
  - to be made available on the market as assemblies
    and
  - be put into service

must also meet the essential safety requirements set out in Annex I to the PED.

Art. 6, Par. 2 of the PED furthermore stipulates that the manufacturer of such an assembly

- must draw up the necessary technical documentation in accordance with Annex III to the PED and
- is responsible for the relevant conformity assessment procedure(s) being carried out pursuant to Art. 14 (see also Fig. 3).

3.2.2 Conformity assessment

Assemblies pursuant to Art. 4, Par. 2 of the PED do require a "superordinate" assessment. They are to be subjected to a **global conformity assessment** pursuant to Art. 14, Par. 6 of the PED. This includes the following:

a) Assessment of each individual pressure equipment item[10] the assembly is composed of and which has not previously been subjected to any separate conformity assessment procedure or CE mark; the assessment procedure depends in this regard on the category of the respective item of pressure equipment;

b) Assessment of the putting together of the different individual parts of the assembly in relation to:
   - the safety precautions during handling and operation (see Annex I no. 2.3 of the PED),
   - the reliability and suitability of the components used and fitted in a due and proper manner (see Annex I no. 2.8 of the PED) and
   - where appropriate, guaranteeing safe filling and emptying (see Annex I no. 2.9 of the PED);

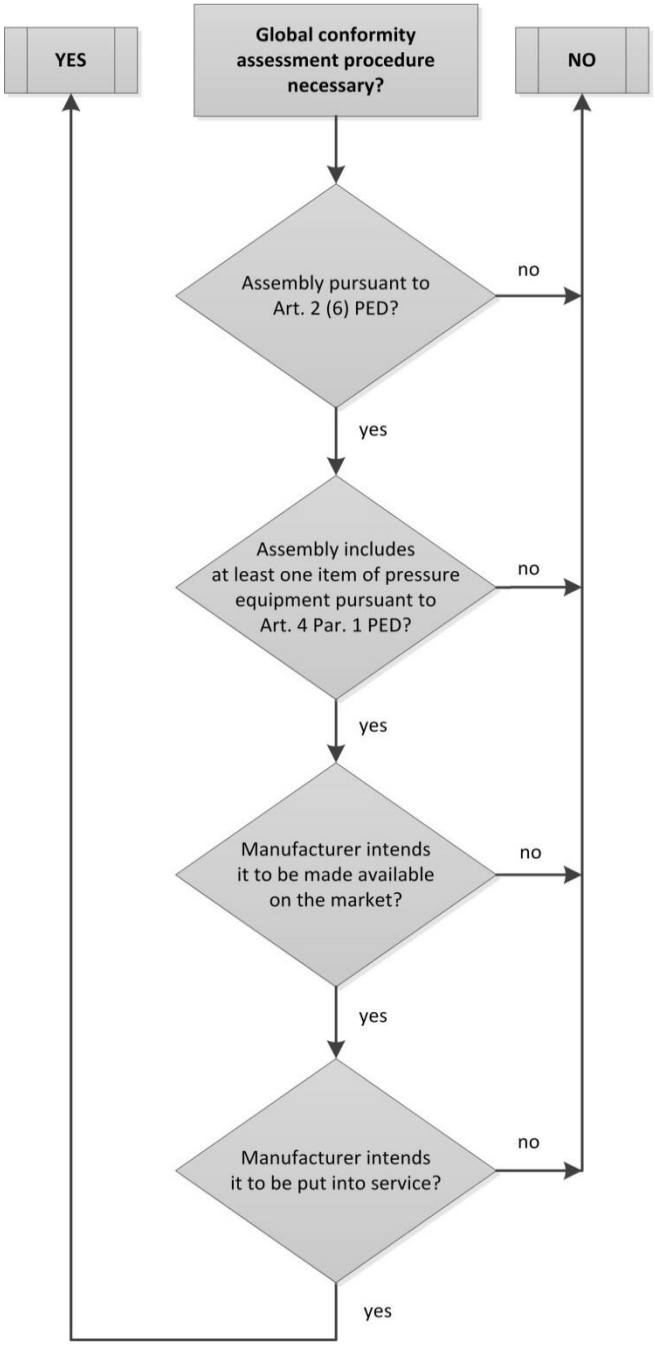
   the assessment is to be carried out according to the highest category of the relevant pressure equipment, whereby safety accessories are not taken into consideration;

[9] reference is made to Art. 1, Par. 2 f) of the PED

[10] pursuant to Art. 4, Par. 1 of the PED

c) Assessment of the protection of the assembly against exceeding of the allowable limits in accordance with Annex I no. 2.10 and 3.2.3 of the PED; this to be carried out according to the highest category of the pressure equipment to be protected.

The following overview is intended to clarify whether and when the aforementioned global conformity assessment is to be carried out for the assembly and Art. 14, Par. 6 of the PED is thus to be applied.



Answer to the question whether a global conformity assessment is necessary.
The criteria pursuant to Art. 2 (6) of the PED (see Fig. 1) are met.
The assembly includes at least one item of pressure equipment (≥ Category I) that meets the requirements of Annex I to the PED and has been/should be assessed for conformity and have the CE mark affixed.
The pressure equipment items forming the assembly represent an integrated and functional whole. This is intended to be made available on the market as such. These are not separate components whose compatibility has not been considered (see Recital 7 on the PED).
The manufacturer has stipulated that the assembly can be used or put into service for the first time by its (end) user [see Recital 7 on the PED / see also definition of putting into service in Art. 2 (17)].

Fig. 2 Decision flow chart for overall assessment of the assembly

3.2.3 Parties involved / responsible

The manufacturer is responsible for the relevant assembly being subjected to a conformity assessment procedure.

Note:	*Deemed to be a manufacturer under Art. 2 (18) of the PED is 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.*

Depending on the category[11] in which the relevant assembly is to be categorised, it can be necessary for the manufacturer to have this assessed by a **conformity assessment body**[12] or to have its quality assurance system certified by such as body. In any case, the manufacturer bears full responsibility for the conformity of the assembly.

Category		Conformity assessment procedure (module)	
I		A	Internal production control
II	Involvement of a conformity assessment body[13] required	A2	Internal production control plus supervised pressure equipment/assembly checks at random intervals
		D1	Quality assurance of the production process
		E1	Quality assurance of final pressure equipment inspection and testing
III		$B_{(E)}$ + D	EU type examination (design type) **+** quality assurance of the production process
		$B_{(E)}$ + F	EU type examination (design type) **+** verification of the pressure equipment
		$B_{(B)}$ + E	EU type examination (production type) **+** quality assurance of the pressure equipment
		$B_{(B)}$ + C2	EU type examination (production type) **+** internal production control plus supervised pressure equipment checks at random intervals
		H	Comprehensive quality assurance
IV		$B_{(B)}$ + D	EU type examination (production type) **+** quality assurance related to the production process
		$B_{(B)}$ + F	EU type examination (production type) **+** verification of the pressure equipment
		G	Unit verification
		H1	Full quality assurance plus design examination

Fig. 3 Overview of assembly conformity assessment

3.2.4 EU declaration of conformity

To demonstrate that the essential safety requirements are met pursuant to Annex I to the PED, the manufacturer must issue an EU declaration of conformity[14]. In doing so, it assumes responsibility for the conformity of the assembly to the requirements of the PED.

It is furthermore under an obligation to keep the EU declaration of conformity available for the competent authorities for a period of 10 years[15].

Formal and content-related requirements arise from Art. 17 of the PED. Accordingly, it must:

- comply with the specimen according to Annex IV to the PED in terms of its structure,
- contain the elements specified in the relevant conformity assessment procedures of Annex III to the PED (e.g. assignment to the specific assembly),
- kept up to date at all times,
- be available in the language(s) stipulated by the Member State in which the assembly is circulated or made available on its market.

Fig. 4 presents an example of a corresponding EU declaration of conformity.

[11] Category I – IV, see Art. 13 and 14 of the PED

[12] see Art. 24 and Art. 16 of the PED

[13] For user inspectorates only module A2, C2, F and G are applicable (see Art. 16 Par.5 of the PED)

[14] see Art. 6, Par. 2 of the PED

[15] see Art. 6, Par. 3 of the PED

EU DECLARATION OF CONFORMITY

(*No. 12345*)

Any Company

Any Street, 12345 Any City, Any Country

We, the *Any Company*, hereby declare, that the assembly described below:

- *Sample assembly*
- *Type Sample XYZ*
- *Serial number 1234567*

is in conformity with the Pressure Equipment Directive 2014/68/EU.

The following table provides information regarding the pressure equipment constituting the assembly concerned, the conformity assessment procedures applied and the notified bodies involved:

Pressure Equipment	Cat.	Module	Notified Body	ID-No.	Certificate-No.
Vessel	*IV*	*B_B + F*	*Any NoBo, Any Street, Any City*	*0001*	*NB.-1234-ABC*
Piping	*II*	*A2*	*Any NoBo, Any Street, Any City*	*0002*	*NB.-5678-DEF*
Safety valve	*IV*	*H1*	*Any NoBo, Any Street, Any City*	*0003*	*NB.-9012-GHI*
*Regulator**	-	-	-	-	-

*) Art. 4 Par. 3

The global assessment of the assembly (cat. IV) pursuant to Art. 14 Par. 6 of Directive 2014/68/EU has been performed

- under: *Module G*
- by: *Any NoBo, Any Street, Any City*
  ID-No.: *0004*
  Certificate-No.: *NB.-3456-KLM.*

The following harmonised standards or specifications have been applied:

Standard	Title	Date of issue
EN 13445-3	*Unfired vessels* *Part 3: Design*	*2013-12*
EN 13480-3	*Metallic industrial piping* *Part 3: Design and calculation*	*2014-12*
EN 4126-1	*Safety devices for protection against excessive pressure* *Part 1: Safety valves*	*2013-12*

Name and title of the signatory

_____

Any City, JJJJ-MM-DD

Fig. 4 Example of an EU declaration of conformity

If the assembly is subject to more than one EU harmonisation legislation (see also point 4) in which an EU declaration of conformity is required, only one EU declaration of conformity is issued for all EU regulations[16]. The legal regulations concerned are then to be specified in this declaration together with their reference in the Official Journal. The provisions of Art. 17 of the PED and Annex IV must nevertheless be taken into consideration.

3.2.5 CE mark

It follows from Art. 19, Par. 1 b) in conjunction with Art. 4 Par. 2 of the PED that only assemblies for which the manufacturer has stipulated that these are to be made available on the market **and** put into service as such have the CE mark affixed to them.

The CE mark is to be affixed before the assembly is placed on the market.

To this end, the mark is to be affixed to the assembly or its type plate in an easily visible, legible and durable manner. For this, the assembly must have been completed or it must be in a condition that makes the final inspection pursuant to Annex I, 3.2 of the PED (final testing, pressure testing, safety equipment testing) possible.

The CE mark does not have to be affixed to each individual item of pressure equipment making up an assembly. Pressure equipment items already bearing the CE mark when being incorporated into the assembly retain their mark.

3.2.6 Examples of assemblies with a global conformity assessment pursuant to Art. 14, Par. 6 of the PED

Assemblies subjected to global conformity assessment pursuant to Art. 14, Par. 6 of the PED can be used or deployed by the end user.

Examples of this include:

- pressure cookers
- breathing apparatus
- air conditioning units
- ….
- portable fire extinguishers
- pressure sterilizers
- refrigeration plant

4 Relationship with other EU harmonisations regulations

Due to their equipment and their intended use, assemblies pursuant to the PED can also be covered by other EU harmonisation legislation (e.g. ATEX and/or Machinery Directive).
These assemblies may only be placed on the market and put into service once they comply with the provisions applying to them, the conformity assessment has been conducted and the EU declaration of conformity drawn up.

[16] see Recital 35 on the PED and Section 4.4 of the Blue Guide