

3. Assemblies

Guideline 3/1
<p>[Original version as adopted on: <i>08 Nov 2000</i>]</p> <p>Pressure equipment directive 97/23/EC Commission's Working Group "Pressure"</p> <p>Guideline related to: Article 3 Paragraph 2.1 , Article 10 Paragraph 2</p> <p>Question: Must the global conformity assessment procedure be applied to assemblies covered by article 3.2.1, e.g. to boilers, even if the assembling is done under the responsibility of the user?</p> <p>Answer: NO.</p> <p>Reasons: PED Article 1.2.1.5 states that "assembly" in the sense of the directive must be assembled by a manufacturer, otherwise it is not in the scope of the directive. This is further supported by recital 5 last sentence. An installation performed by or under the responsibility of the user would normally not be under the scope of the Directive. It would be under the applicable national legislation. See guideline 3/2.</p>
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Remarks:

Guideline 3/2
<p>[Original version as adopted on: <i>08 Nov 2000</i>]</p> <p>Pressure equipment directive 97/23/EC Commission's Working Group "Pressure"</p> <p>Guideline related to: Article 1 Paragraph 2 , Article 3 Paragraph 2</p> <p>Question: Are joining operations on site covered by the PED ?</p> <p>Answer: For the joining on site of components or equipment, two cases have to be considered :</p> <p>1) Joining of component parts : joining of component parts to comprise an item of pressure equipment is subject to the requirements of the Directive. The manufacturer -even if he is the user- has the responsibility that the resulting item of pressure equipment is in compliance with the Directive.</p>

2) Joining of items of pressure equipment.

The joining is not covered by the PED if it is carried out to constitute an installation (1) under the responsibility of the user but remains covered by national rules.

If the joining is carried out under the responsibility of a manufacturer to constitute an assembly covered by the definition given in Article 1.2.1.5, this assembly must fulfil the requirements of the Directive.

Reason : The fifth recital of the Directive says : " This Directive does not cover the assembly of pressure equipment on the site and under the responsibility of the user, as in the case of industrial installations ".

NOTE 1: The definition of assembly in Article 1.2.1.5 is limited to those assemblies assembled by a manufacturer. When items of pressure equipment or assemblies are being put together by a user, to avoid confusion, the term "installation" is used

NOTE 2: See also guideline [3/8](#)

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Guideline 3/3

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**Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"**

Guideline related to: [Article 3 Paragraph 2.3](#)

Question: The effect of the derogation in Article 3.2.3 from the introductory paragraph in Article 3.2 is not clear. In the circumstances, how should Article 3.2.3 be applied ?

Answer: The assemblies set out in Article 3.2.3 must comply with the essential requirements referred to in 2.10, 2.11, 3.4, 5(a) and 5(d) of Annex I of the Directive, even if all the items of pressure equipment comprising the assembly fall under Article 3.3.

Reason: This was the intention of the Member States which proposed the text and the intention of the Council when approving the text.

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Guideline 3/4

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Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: [Article 3 Paragraph 2.1](#) , [Annex I Section 5](#)

Question: What shall be the minimum extent of the assembly "boiler" which shall be subjected to a global conformity assessment procedure in accordance with article 3 section 2.1 ?

Answer: The assembly shall comprise, as a minimum, the boiler including all the pressure parts from the feedwater inlet (including the inlet valve) up to and including the steam and/or hot water outlet (including the outlet valve or, if there is no valve, the first circumferential weld or flange downstream of the outlet header). This includes all economisers, superheaters and inter-connecting tubing which may be exposed to a risk of overheating and are not capable of isolation from the main system by interposing shut-off-valves. Additionally included are the associated safety accessories and the tubing connected to the boiler involved in services such as draining, venting desuperheating, etc., up to and including the first isolating valve in the tubing line downstream of the boiler.

NOTE 1 : This definition is based on draft standard prEN 12952-1:1997 and is in conformity with annex 1 section 5 of the directive.

NOTE 2 : This is a MINIMUM definition of the assembly.

NOTE 3 : The ISOLATABLE superheaters, reheaters, economisers and related interconnecting tubing are not part of this minimum assembly. They can bear a CE marking separately or be integrated in the assembly if the manufacturer wishes so ;

NOTE 4 : The means of providing the boiler with feedwater and the means of preparing and feeding the fuel to the boiler are not part of this minimum assembly. They can bear a CE marking separately or be integrated in the assembly if the manufacturer wishes so.

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Guideline 3/5

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Pressure equipment directive 97/23/EC

Commission's Working Group "Pressure"

Guideline related to: [Article 3 Paragraph 2.3](#) , [Article 15 Paragraph 2](#) , [Annex II Table T4](#)

Question: Shall the assemblies defined in the article 3 paragraph 2.3 carry the CE-marking? **(GL revised 26-Jun-2001)**

Answer: Yes, in accordance with Article 15 paragraph 2, but the identification mark of the notified body is left out if the manufacturer has selected the use of module B1.

Reasons: The applied conformity assessment procedure is defined in table 4 of the Annex II, where the modules B1 and H are given as alternatives. In the case of module B1 there is no notified body involved at the production control phase, and according to article 15 paragraph 1 no identification mark is accompanied.

NOTE: Article 3 paragraph 2.3 assemblies to be CE-marked shall comprise, as a minimum, the boiler with its protection devices.

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Guideline 3/6

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Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: [Annex I Section 3.2.2](#) , [Annex I Section 7.4](#)

Question: Must a hydrostatic pressure test be carried out on an assembly and should the value laid down in section 7.4 then be followed ?

Answer: Using the global conformity assessment of Article 10.2, each item of pressure equipment and the integration of the items of pressure equipment (Annex I, section 2.8) should be assessed.

Annex I, first preliminary observation determines that the requirements of Annex I also apply to assemblies, if corresponding hazard exists.

Each item of pressure equipment making up the assembly and referred to in Article 3.1 shall meet Annex I, section 3.2.2, and the pressure containment aspects for the connects/joinings should be assessed by appropriate methods, for example pressure test, NDT.

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Guideline 3/7

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Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: [Article 10 Paragraph 2](#)

Question: Which conditions shall be used in the assessment of an item of pressure equipment referred to in Article 3.1 without a separate CE-marking in an assembly being subject to the global conformity assessment procedure?

Answer: The conditions to be used to determine the category of this item shall be :

- the volume or nominal size DN, as appropriate, of the item ;
- at least the conditions PS, TS or group of fluid, for which the assembly is designed, which can be lower than the intrinsic conditions of the item.

For safety accessories, article 2 of Annex II applies.

Reasons: According to article 10.2. (a) the global conformity assessment procedure shall comprise assessment of each item of pressure equipment making up the assembly and referred to in Article 3 (1) which has not been previously subjected to a conformity assessment procedure and to a separate CE marking. The assessment procedure shall be determined by the category of the item, which may be based on the conditions of the assembly.

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Guideline 3/8

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Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: [Article 1 Paragraph 2.1.5](#)

Question: Can some guidance be provided on the terms used in the definition of an assembly?

Answer: Items of pressure equipment form an assembly if :

1. they are integrated, i.e. they are connected and designed to be compatible with each other and

2. they are functional, i.e. together, they achieve specific, overall objectives and could be put into operation, and
3. they form a whole, i.e. all the items which are necessary for the assembly to function and be safe are present and
4. they are assembled by one manufacturer who intends the resulting assembly to be placed on the market and who will subject the assembly to a global conformity assessment procedure.

It is irrelevant whether completion of the assembly takes place at the manufacturer workshop or by the manufacturer on site.

Other factors will need to be considered to determine whether the Directive applies to a particular assembly. (See guideline [3/2](#)).

Some possible examples of assemblies are pressure cookers, portable extinguishers, breathing apparatus, skid mounted systems, autoclaves; air conditioner, compressed air supply in a factory, refrigerating system, shell boilers, water tube boilers, distillation, evaporation or filtering units in process plants, oil heating furnaces

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**Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"**

Guideline related to:

Question: Application and limits of the assembly definition

Answer: The PED does not limit the extent of an assembly, which can range from simple standard products up to large complex industrial plants.

An assembly can itself be composed of other assemblies and further items of pressure equipment.

For such a final assembly, two cases are possible :

1. When a manufacturer places on the market a product as a final assembly, consisting of assemblies and items of pressure equipment, intended to be put into service as such, he has to perform the global conformity assessment resulting in the CE-marking of the final assembly. If some of the constituent assemblies are not CE-marked – see guideline [3/10](#) - the individual items of pressure equipment shall be included in the

- global conformity assessment.
2. When a user takes the responsibility for the final assembly, it constitutes an installation as explained in guideline 3/2.

Note : The definition of an assembly is explained in guideline 3/8.

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Guideline 3/10

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Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: [Article 3 Paragraph 2.2](#) , [Article 14 Paragraph 3](#) , [Article 15 Paragraph 2](#)

Question: Is it possible to put assemblies on the market which are not CE-marked?

Answer: Yes, for assemblies referred to in Article 3, paragraph 2.2 :

-If the intention of the manufacturer is to place on the market an assembly not to be put into service as such but to become part of a bigger assembly or installation (see guideline [3/2](#)), the global conformity assessment according to PED does not need to be applied to this assembly, which in this case will not be CE-marked. In this case, conformity assessment according to PED shall have been conducted for each item of pressure equipment.
-However, if the intention of the manufacturer is to place on the market an assembly to be put into service as such, the global conformity assessment procedure described in the directive must be conducted, resulting in the CE-marking of the assembly.
For boilers (Article 3 paragraph 2.1) refer to guidelines [3/1](#), [3/4](#) and [3/5](#).

Note 1: Assemblies the conformity of which has been assessed by a user inspectorate shall not bear the CE-marking.

Note 2: Assemblies in accordance with Article 3 paragraph 3 shall not bear the CE-marking (see guideline [2/18](#)).

Note 3: This does not restrict the integration of CE-marked assemblies into bigger assemblies.

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Pressure equipment directive 97/23/EC

Commission's Working Group "Pressure"

Guideline related to: [Article 3 Paragraph 2](#) , [Article 10 Paragraph 2](#) , [Article 20](#)

Question: If an item of pressure equipment complies with national pre-PED Regulations and is placed on the market on, or before, 29 May 2002, is it possible for it to be subsequently included in an assembly which is placed on the market after 29 May 2002?

Answer: Only if it is shown that such pre-PED item of pressure equipment also complies with the requirements of the directive.

If an assembly, as referred to in Article 3, section 2, is placed on the market after 29 May 2002 then it must comply with the Directive. This requirement can only be met if the individual items of pressure equipment which form the assembly also comply with the Directive. This is achieved by using the global conformity assessment procedure as per Article 10.2a, where required (see also guideline [3/7](#)).

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Guideline 3/12

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Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: [Article 10 Paragraph 2](#) , [Annex I](#)

Question: Do only the essential requirements given in Article 10 paragraph 2 apply to assessment of the integration of assemblies?

Answer: No, according to Annex I, first preliminary observation, the requirements of Annex I also apply to assemblies, where the corresponding hazards exist.

Examples of other ESRs which may be relevant to assemblies: 3.1.2 Permanent joining, 3.2.2 Proof test (see guideline [3/6](#)), 3.4 Operating instructions, 6 (a) and (d) Thermal expansion and vibration of piping,...

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Guideline 3/13

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**Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"**

Guideline related to: [Article 1 Paragraph 2.1.5](#) , [Article 3 Paragraph 2.2](#) , [Article 10 Paragraph 2](#)

Question: When several items of pressure equipment are assembled by a manufacturer to constitute a functional whole, and when one or several of those items are excluded from the PED, is the resulting whole considered as an assembly covered by the PED ? **(GL revised 23-May-2002)**

Answer: The definition 2.1.5 of Article 1 does not prohibit non PED pressure equipment (pressurised equipment excluded by Article 1 paragraph 3) to be included in an assembly covered by the PED.
In the case of a PED assembly, the global conformity assessment required by Article 10 paragraph 2 does not include the assessment of non-PED items of pressure equipment.

The assessment of

- the integration of the assembly
- the protection of the assembly against exceeding the permissible operating limits

shall be conducted in the light by the highest category of PED items of pressure equipment included, but it shall also take account of the characteristics of the non-PED items of the assembly.

See also guideline [3/12](#).

Note 1 : A hydraulic system of an item of machinery can meet the definition of Article 1 paragraph 2.1.5, but as it is not intended to be put into service as such, it is not covered by Article 3 paragraph 2.2 (see guideline [3/10](#)). On the other hand, a refrigeration system is considered to be a PED assembly even if some of the pieces under pressure are excluded from PED.

Note 2 : In the sense of PED, an assembly is a pressurised system ; a machine-tool, an earthmoving machinery, an agricultural tractor, a mobile crane is not, as a whole, a PED assembly.

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Guideline 3/14

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**Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"**

Guideline related to: [Article 1 Paragraph 2.1.5](#) , [Article 3 Paragraph 2.3](#) , [Annex II Table T4](#)

Question: Article 3, paragraph 2.3 states that the manually fed assemblies must comply with certain essential requirements. Furthermore article 1, section 2.1.5

states that the assemblies shall be assembled by the manufacturer.

Assuming that the manufacturer wants to use EC design-examination (module B1) in accordance with annex II, table 4, is it then sufficient that the manufacturer of the boiler gets an EC design-examination certificate or shall it be the installer (plumber), who assembles the protective devices to the boiler on site that must obtain the EC design-examination certificate?

Answer: As stated in guideline 3/5, Article 3 paragraph 2.3 assemblies comprise, as a minimum, the boiler with its protective devices.

However, it is sufficient that the manufacturer of the boiler gets an EC design-examination certificate, provided that he clearly specifies in his installation instructions which protective device can be used in the assembly and how it shall be installed.

The installation instructions shall be part of the EC design-examination.

See also guidelines [3/3](#) and [3/5](#).

NOTE : The module B1 assessment shall comprise essential safety requirements from Article 3 paragraph 2.3 as well as the operating instructions.

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Guideline 3/15

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Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: [Article 10 Paragraph 2](#) , [Annex I Section 3.1.2](#)

Question: How are the categories of permanent joints in an assembly determined ?

Answer: The category of permanent joints between the items of pressure equipment of an assembly shall be determined individually, taking into account the effect of the joining on the integrity of each of the items to be joined.

For example, the connection of a pipe to a vessel through a nozzle (already connected to the vessel) will, in general, be made according to the category of the pipe, provided that it does not affect the integrity of the vessel.

Note 1: For assemblies, the directive defines a global conformity assessment procedure and determines the category to be followed for essential safety requirements related to design (as stated in Article 10 paragraph 2b), and for the assessment of the protection (as stated in Article 10 paragraph 2c). For the other essential safety requirements applicable to the assembly (see guideline [3/12](#)), in the absence of specific information in the directive for the category, it should be based on the categories of the items concerned.

Note 2: This is consistent with guideline [2/15](#), which makes a distinction between the category used for the assessment of the design, and the determination of the category regarding essential safety requirements.

See also guideline [3/16](#) for the category of the global conformity assessment procedure.

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Guideline 3/16

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Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: [Article 10 Paragraph 2](#)

Question: In Article 10.2.b what does the "highest category applicable to the equipment concerned" mean?

Answer: The category of each item of equipment making up the assembly is based on the conditions which can occur in the assembly, taking into account:

- the volume or nominal size DN, as appropriate, of the item ;
- at least the conditions PS, TS, type or group of fluid, for which the assembly is designed, which can be lower than the intrinsic conditions of the item.

The highest category determined from these conditions will then determine the assessment of the integration of the items in the assembly.

See also guidelines [3/7](#) and [3/15](#).

Note: When determining the conformity assessment module(s) for an assembly, it is possible to assign to an item of pressure equipment a lower category than that to which it was originally assessed. As a consequence, an assembly which is covered by Article 3 paragraph 3 can include a CE-marked item of pressure equipment.

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Guideline 3/17

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Pressure equipment directive 97/23/EC
Commission's Working Group "Pressure"

Guideline related to: [Article 1 Paragraph 2.1.5](#) , [Article 10 Paragraph 2](#) , [Annex I Section 2.10](#)

Question: Is it permissible to place on the market a CE marked assembly not equipped with protective devices where there is a risk of exceeding the allowable limits?

Answer: No, see guidelines [3/8](#), [3/9](#), [3/10](#) and [5/6](#).

Note 1: As required in Annex I section 3.2.3, the final assessment of the assembly includes checking of the safety devices. In some cases, this can be done only after assembly at the user's premises.

Note 2: The Declaration of Conformity shall not be drawn up for the assembly until the checking of safety devices has been completed.

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