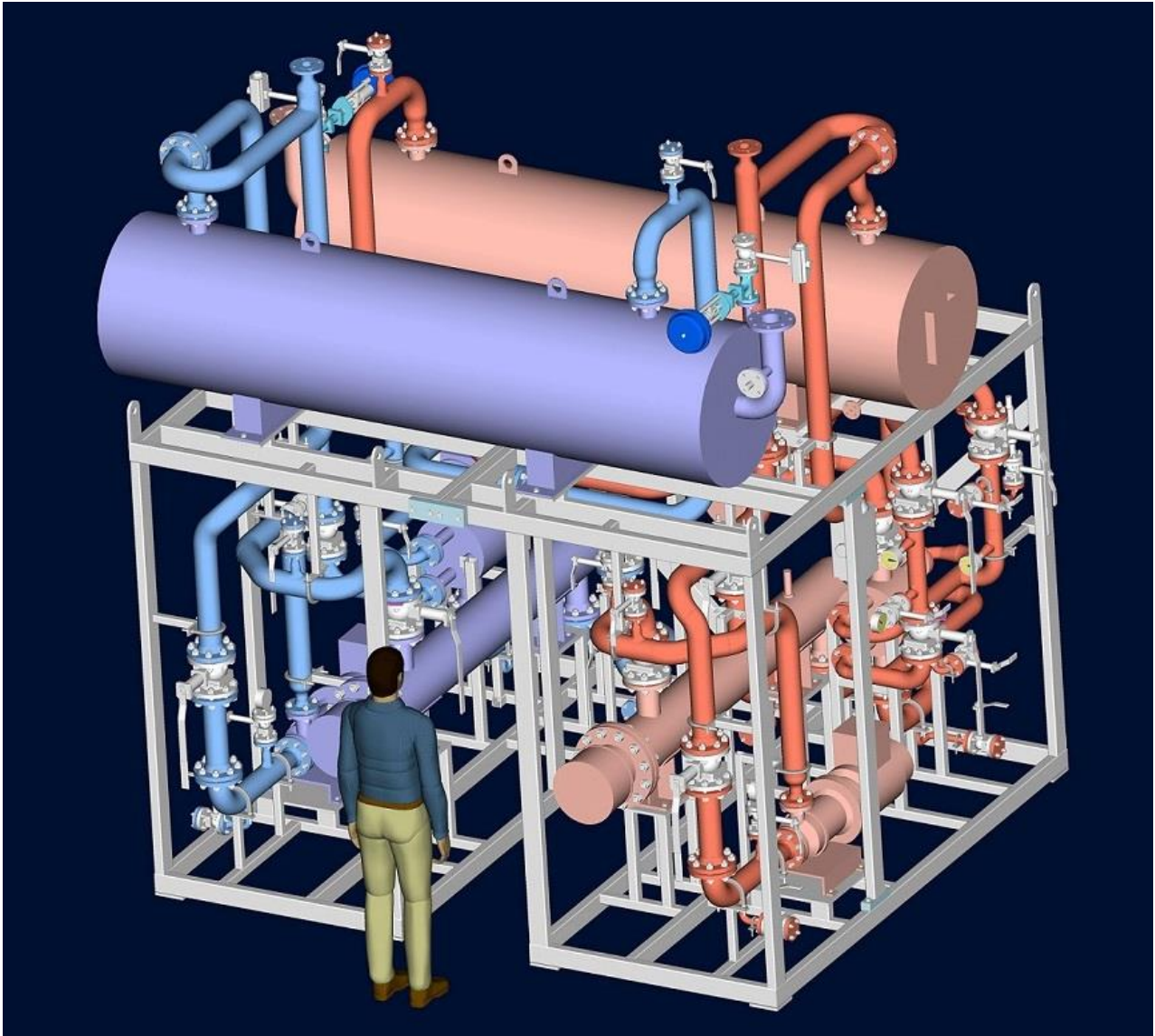


Pressure Equipment Directive – Global Conformity Assessment

A Guide to Site Installed Assemblies

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Forward

This document, A Guide to Site Installed Assemblies (PEDG 1), has been developed and written by the Pressure Equipment Consultation Forum (PECF), Safety Assessment Federation (SAFed) and Engineering Equipment and Materials Users Association (EEMUA) in consultation with other stakeholders within the pressure equipment industry to help installation contractors, purchasers, designers and other parties involved in the creation of pressure equipment assemblies to ensure that global conformity assessment can be successfully applied.

The Health and Safety Executive (HSE) was involved with PECF, SAFed and EEMUA in producing this guidance. HSE endorses the guidance, as it follows a sensible and proportionate approach to managing health and safety.

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1. Introduction

The Pressure Equipment Directive (PED) requires that individual items of pressure equipment undergo conformity assessment where appropriate. This also applies to assemblies of pressure equipment which need to undergo global conformity assessment (GCA) and CE marking. Experience within the UK indicates that generally this process works well when assemblies are placed on the market as complete, factory supplied products. However when assemblies are created on site at the place of installation the legal process of global conformity assessment is often found to be non-compliant. There are a number of reasons why this can happen:

- Large installations can involve work done by several parties and it becomes unclear who has overall responsibility to ensure global conformity assessment happens
- Sub-contractors appointed by a main contractor may not be aware they have a role to play in the global conformity assessment process
- Industrial Installations under the responsibility of the end user do not have to undergo global conformity assessment but end users are not always clear on what “under the responsibility of” entails.
- New assemblies can be incorporated into existing assemblies or incorporate an existing pressure vessel built before the implementation of the PED which leads to uncertainty on the extent of global conformity assessment required.

Assemblies which do not have a global conformity assessment when they are handed over to the end user, may require additional verification to confirm their suitability for service under national legislation such as Pressure Systems Safety Regulations (PSSR).

Other than certain Working Party Guidelines published by the European Commission there is no comprehensive guidance to PED currently available to assist the various stakeholders involved in the assembly process.

2. Scope

This guidance is aimed at all parties (other than notified bodies or user inspectorates – see note below) who are involved in the design and manufacturer of site installed assemblies [in the UK](#). This includes the following parties:

- End users (including those responsible for procurement of the assembly or appointment of contractors)
- Main contractors
- Site erection contractors
- Design consultants
- Control and instrumentation contractors
- Piping contractors
- Commissioning teams

Note: The Conformity Assessment Body Forum (CABF) has published guidance on assemblies aimed at conformity assessment bodies (see CABF PED/SPVD 2014-06-17 on the CIRCA database).

The document is intended to provide the necessary guidance to all parties with responsibilities for the pressure equipment assembly to ensure global conformity assessment can take place.

It applies to the following directives:

- Pressure Equipment Directive (97/23/EC), as implemented by the Pressure Equipment Regulations (PER) 1999
- Pressure Equipment Directive (2014/68/EU), as implemented by the Pressure Equipment (Safety) Regulations (PESR) 2016

Note: The PED is transposed into UK law through Pressure Equipment (Safety) Regulations (PESR) 2016 but this document makes reference to the PED throughout.

It excludes assemblies which are placed on the market as complete, factory supplied products. An example of this is a small (bench top) autoclave which is delivered ready for use (ie it is a functional whole with no site based operations required to complete the assembly).

The PED states: *“this Directive should not apply to the assembly of pressure equipment on the site and under the responsibility of a user who is not the manufacturer, as in the case of industrial installations.”* Guidance on the application of national legislation to industrial installations is beyond the scope of this document but some guidance is included on when and how this exception should be applied.

3. Key roles and responsibilities

The PED provides definitions of all the key players who may have involvement in the supply chain for pressure equipment or assemblies. Key definitions relating to assemblies are repeated in this section along with further explanation focussing on how they are likely to apply to site installed assemblies. Certain parts of the explanations have been taken from “The Blue Guide” version 26 July 2016 (see references section).

3.1 Economic operator

‘economic operator’ means a manufacturer, an importer, authorised representative or a distributor.

“relevant economic operator” means, in relation to pressure equipment or an assembly, an economic operator who has obligations in respect of that pressure equipment or assembly under these Regulations

3.2 Manufacturer

‘manufacturer’ means 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.

The definition contains two cumulative conditions: the person has to manufacture (or have a product manufactured) and to market the product under their own name or trademark. So, if the product is marketed under another person’s name or trademark, this *named* person will be considered as the manufacturer. In the vast majority of cases there will be a number of parties directly contributing to a site installed assembly (see section 2). However there can only be one party who is the manufacturer for the assembly and that party will be the one who places their name or trademark on the completed assembly. They will also be responsible for the conformity assessment and CE marking. It will need to be agreed at the start of a contract which party is nominated as the manufacturer for the assembly.

The manufacturer may design and manufacture the assembly themselves. As an alternative, they may have it designed, manufactured, assembled, packed, processed or labelled with a view to placing it on the market under their own name or trademark, and thus presenting themselves as a manufacturer. Where subcontracting takes place, the manufacturer must retain the overall control for the product and ensure that they receive all the information that is necessary to fulfil their responsibilities in the conformity assessment. At the start of a contract it should be made clear to other parties/subcontractors of their obligation to provide information to the assembly manufacturer. The manufacturer who subcontracts some or all of their activities may in no

circumstances discharge themselves from their responsibilities, for example to an authorised representative, a distributor, a retailer, a wholesaler, an end user or a subcontractor.

Any organisation who manufactures items of pressure equipment for its own use must assume all of the responsibilities of a manufacturer. However this does not preclude an end user from putting together items of equipment under national legislation to form an industrial installation.

The manufacturer has sole and ultimate responsibility for the conformity of the product to the applicable Union harmonisation legislation, whether they designed and manufactured the product themselves or is considered as a manufacturer because the product is placed on the market under their name or trademark.

3.3 Authorised representative

‘authorised representative’ means 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.

Whether the manufacturer is established in the EU or not, they may appoint an authorised representative in the Union to act on their behalf in carrying out certain tasks required in the applicable Union harmonisation legislation. A manufacturer established outside the European Union is not obliged to have an authorised representative.

For the purposes of Union harmonisation legislation, to be able to act on behalf of the manufacturer, the authorised representative must be established inside the Union. Commercial representatives of the manufacturer (such as authorised distributors or agents), are not to be confused with the authorised representative in the meaning of Union harmonisation legislation.

This role is not often used in the UK. It may arise where a main contractor appoints a consultancy to assist them with their duties for global conformity assessment of an assembly. However the role must be made clear in the contract for the consultancy to be regarded as the authorised representative.

3.4 Place on the market

- *A product is placed on the market when it is made available for the first time on the Union market.*
- *Products made available on the market must comply with the applicable Union harmonisation legislation at the moment of placing on the market (reference ‘Blue Guide’)*

In the context of a site installed assembly it is considered to be placed on the market when a manufacturer, erection contractor, design consultant etc. has completed all manufacturing, testing and commissioning operations, such that it is capable of being put into use.

Note: Placing on the market does not apply to industrial installations.

3.5 Importer

‘importer’ means any natural or legal person established within the Union who places pressure equipment or assemblies from a third country on the Union market.

The importer is the economic operator established in the Union who places a product from outside the EU on the Union market. They have important and clearly defined responsibilities under

Union harmonisation legislation. To a large extent, they build on the type of responsibilities to which a manufacturer based in the EU is subjected.

The importer must ensure that the manufacturer has correctly fulfilled their 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.

If an end user or an assembly manufacturer purchases pressure equipment or an assembly directly from outside of the EU then they would become the importer, taking on the associated responsibilities.

3.6 Distributor

‘distributor’ means 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.

Along with manufacturers and importers, distributors are the third category of economic operators who are subject to specific obligations. The distributor is a natural or a legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market.

A distributor acquires products for further distribution either from a manufacturer, from an importer, or from another distributor.

Distributors must act with due care in relation to the applicable requirements. They have to know for instance, which products must bear the CE marking, what information is to accompany the product (for example the instructions for use), what are the language requirements for labelling, user instructions or other accompanying documents, and what is a clear indication of the product being non-compliant.

Note: the distributor may also need to consider other applicable product directives in addition to the PED.

3.7 Notified Body

A body that performs conformity assessment activities on pressure equipment and assemblies, including testing, certification and inspection. In the UK notified bodies are accredited by United Kingdom Accreditation Service (UKAS) and appointed by the relevant government department.

3.8 User Inspectorate

A body that performs conformity assessment activities on pressure equipment and assemblies under conformity modules A2, C2, F and G within their own organisation, including testing, certification and inspection. In the UK User Inspectorates are accredited by United Kingdom Accreditation Service (UKAS) and appointed by the relevant government department. Equipment and assemblies assessed by a User Inspectorate shall not be CE marked.

3.9 End User

End-users are not defined in Union harmonisation legislation. However many products covered by Union product harmonisation legislation are used at work and thus also subject to Union safety at work legislation.

Union harmonisation legislation does not create obligations for the end-users of the products in their scope. Consequently, the term is not defined in that legislation. It is certain however that the term covers both professional users and consumers. The use of a product as a component to be

built into a new product that again is placed on the market is not considered end-use. The concept of “end use” by a professional or a consumer is intrinsically related to the concept of “intended use”.

However if an end-user is the purchaser and is involved in the conceptual design and or specification of the assembly then it will need to provide all necessary information relating to the design/specification to the manufacturer for the purpose of conformity assessment.

The end user is able to assemble appropriated certificated items of pressure equipment without these joining operations complying with PED conformity assessment procedures. Where the end user is taking control of installation and joining operations (as in an “industrial installation”), it will need to understand and manage the integration and joining risks and all relevant legislative requirements and be competent to do so. Further information on end user responsibilities in this context is covered in Section 7.

3.10 Common designations for parties involved

In addition to the parties formally defined in the PED there will inevitably be other parties involved in the creation of the assembly who may not fit the definitions covered above but will nevertheless have responsibilities even if they are not a manufacturer.

3.10.1 The purchaser

The purchaser in the context of this guidance is the organisation who obtains/procures equipment incorporating a pressure equipment assembly for the end user. The purchaser could be part of the end user organisation or a separate organisation appointed to operate on their behalf. The references in this document to purchaser means the “technical purchaser” who draws up the technical specifications and or conceptual design used for procurement of the equipment.

3.10.2 Main contractor

The main contractor may not be directly responsible for the design or manufacture of any of the component parts making up the assembly but ultimately they have overall responsibility for the assembly.

3.10.3 Piping contractor

The piping contractor may be appointed to build and install the piping connecting items of pressure equipment in accordance with a design layout and specification provided by others. If the piping is of a size and pressure that requires conformity assessment then the contractor is required to provide all technical documentation relating to the fabrication to whichever party is deemed to be the manufacturer. This technical documentation will include such things as welding qualifications, weld maps, NDT reports, pressure test certificate etc. and it will need to demonstrate that the piping contractor has complied with all of the applicable Essential Safety Requirements of the PED.

3.10.4 Design consultant

A design consultant may have been appointed by the main contractor or the end user to design part or the whole of the assembly. In most cases a design consultant would not normally act as the manufacturer of the assembly, unless they are specifically contracted to adopt this role. The design consultant will need to support the manufacturer to ensure all aspects of the design comply with the relevant Essential Safety Requirements of the PED and any other directives that might apply. Technical documentation that demonstrates this will need to be provided to whichever party is deemed to be the manufacturer. The technical documentation will include such things as design drawings, descriptions, results of calculations etc.

3.10.5 Erection contractor

An erection contractor (or installer) may be appointed for the purpose of installing items of pressure equipment in accordance with the design drawings/specification or putting together larger items of pressure equipment that have been delivered to site as modules. The erection contractor will have similar duties and responsibilities as the piping contractor with respect to the supply of technical documentation.

3.10.6 Competent person (PSSR)

The end user of the pressure equipment assembly will have appointed a competent person for the purpose of drawing up written schemes of examination and performing examinations on the assembly once it is in service. The competent person has no duties or responsibilities under the PED.

It is a legal requirement of PSSR that the user “*shall not operate the system or allow it to be operated unless he has a written scheme for the periodic examination, by a competent person*”. Furthermore where PSSR applies and if prescribed in a written scheme it will be necessary for the competent person to conduct an examination of the assembly before it is used for the first time. It is therefore important that the end user’s competent person becomes involved at an early stage of the project.

4. Categorisation of assemblies

4.1 An assembly

The directive describes an assembly as being:

composed of several pieces of pressure equipment assembled to constitute an integrated and functional whole. Those assemblies may range from simple assemblies such as pressure cookers to complex assemblies such as water tube boilers. If the manufacturer of an assembly intends to place it on the market and put it into service as an assembly — and not in the form of its constituent non-assembled elements — that assembly should comply with this Directive. However this Directive should not apply to the assembly of pressure equipment on the site and under the responsibility of a user who is not the manufacturer, as in the case of industrial installations.

4.2 Classification of an assembly

Each item making up an assembly must be assessed in order to determine its hazard category for conformity assessment.

The integration of the component parts of the assembly must be assessed according to the highest category applicable to the equipment concerned, disregarding the category of any safety accessories.

The protection of the assembly against exceeding the permissible operating limits must be assessed according to the highest category applicable to the equipment to be protected.

The flow chart in figure 1 provides guidance for this process.

Note 1 Excluded pressure equipment is covered in Article 1.2 of the PED

Note 2 The notified body or user inspectorate (when required) should be appointed after the categorisation of the assembly has been ascertained and the conformity assessment module determined.

Note 3 Further information on classification of an assembly can be found in the Conformity Assessment Body Forum (CABF) guidance document CABF PED/SPVD 2014-06-17.

Note 4 At the end user's preference it can have the conformity assessment steps carried out by another party or parties (eg main contractor, erection contractor, piping contractor etc.). However if the overall assembly does not follow the global conformity assessment route then responsibilities for an 'industrial installation' will apply to the end user.