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The Pressure Equipment Directive 2014/68/EU

Information for our Customers and Partners.

One objective of the EU single market is to ensure the smooth technical transfer of trade. Consequently uniform requirements for products are specified in the EU Directives within the framework of the European approach to harmonisation, that also take essential safety requirements into account. These requirements are mandatory for all Member States. Examples of these are the Machinery Directive, the Directive for Transportable Pressure Equipment and the

Simple Pressure Vessels Directive - 2014/29/EU. This brochure focuses on the application of the Pressure Equipment Directive 2014/68/EU and provides information regarding what needs to be observed and which requirements are mandatory when pressure equipment and assemblies are placed on the market. Our aim is to give you a clearer understanding of the Directive and to facilitate its implementation.

What does this entail?

Since May 2002 only pressure equipment and assemblies (simply referred to in the following as pressure equipment) may be placed on the market throughout the entire European Union that comply with the requirements of the Pressure Equipment Directive (PED). The basis for this is the transposition of the requirements of the PED into the national law of all EU Member States; in Germany in the form of the Ordinance on Pressure Equipment (14 ProdSV). The Directive specifies the essential safety requirements for pressure equipment in Annex I and describes the procedure for assessing compliance with the requirements of the PED, the so-called conformity assessment procedure. Further test specifications could be the harmonised European applica-

tion standards or other suitable technical regulations such as e.g. the AD 2000 regulations in which detailed specifications are given regarding practical implementation of the requirements of the Directive.

Finally, the PED also contains regulations regarding the use of conformity marking – CE-marking. This marking shows that the requirements of all EU-Directives, in particular the PED, have been complied with and, as applicable, also states the ID number of the Notified Body involved:

CE 0035

Why was the PED aligned?

The PED 97/23/EC applied up until 18.07.2016, after which the Directive 2014/68/EU for pressure equipment came into force. This new version became necessary as a result of the implementation of the CLP-regulation¹⁾ and alignment to the new European legislative framework - NLF²⁾. The obligations of the so-called economic operators – in addition to the manufacturer these also include the authorised representative, the importers and the distributors – are now clearly described in the PED. If importers or distributors

wish to place pressure equipment on the market under their own name or trademark they must comply with the same requirements as a manufacturer. Finally it is worth noting that all certificates issued by Notified Bodies in accordance with the Directive 97/23/EC before 19.07.2016 will continue to remain valid.

1) Regulation (EC) No. 1272/2008 on the Classification, Labelling and Packaging (CLP) of Substances and Mixtures

2) New Legislative Framework (NLF), Regulation (EC) No. 764/2008 and 765/2008, Decision No. 768/2008/EC

Who is this aimed at?

The scope of the Pressure Equipment Directive applies to all economic operators, in particular all manufacturers who wish to manufacture, import or distribute pressure equipment within the European Union.

Conformity Assessment

Irrespective of the design parameters and the associated potential hazard of the pressure equipment, the PED provides for different procedures for conformity assessment. These procedures may only be performed by Notified Bodies (with the exception of Module A). TÜV Rheinland Industrial Services GmbH is notified in Brussels under the ID number 0035, for all activities within the framework of the PED. In the following we will give you further information about the conformity assessment procedure. It consists of product testing or system audits as specified in Annex III of the PED.

Scope

The Directive applies to the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure greater than 0.5 bar.

Pressure equipment means

- Pressure vessels
- Steam boilers
- Piping
- Safety accessories
- Pressure accessories
- Assemblies

Assemblies

The term assemblies in the sense of the Pressure Equipment Directive refers to several pieces of pressure equipment as-

sembled to an integrated and functional unit that is placed on the market in an assembled state by a manufacturer. Assemblies are to be subjected to an overall assessment of conformity, taking the safety devices into consideration.

For example, process control safety devices must also be included in the assessment as applicable. Assemblies may be intended for direct use by an end user or for installation as a sub-assembly in a larger assembly.

Assemblies may range from simple assemblies (e.g. fire extinguishers) to complex assemblies in the chemical and energy industry (e.g. water tube boilers, refrigeration plants).

Technical Requirements

The essential safety requirements include specifications relating to the design and production of pressure equipment, e.g.

- Relating to the procedures used for permanent joints (as a rule welding procedure); here approval is granted by the Notified Body,
- Relating to the qualifications of welding operators and NDT personnel; here approval is granted by the Notified Body,
- Relating to the materials used; here the Notified Body – as applicable – assesses the particular material appraisals,
- Relating to specific assessment of the quality management system of materials manufacturers by the Notified Body,
- Relating to the final assessment of pressure equipment by the Notified Body; this also includes examination of the design, final assessment and pressure test

Classification

The pressure equipment shall be classified in accordance with Annex II of the PED in the categories I to IV according to an ascending level of hazard, depending on pressure, volume or nominal size, the fluid group and state of aggregation. This does not apply to pressure equipment that is to be classified below category I (Article 4 (3) pressure equipment). This pressure equipment is included within the scope of the PED, however, it does not need to comply with the essential safety requirements of the Directive

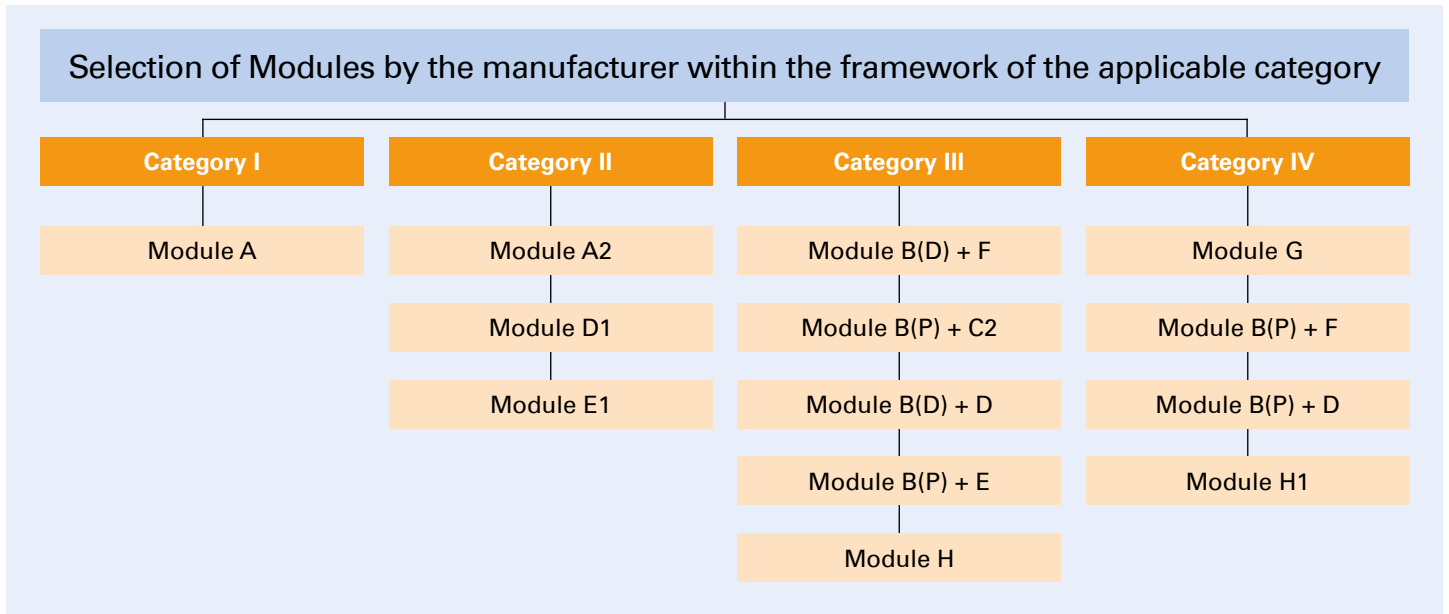
and consequently shall not bear any CE-marking. Such equipment is to be designed and manufactured in accordance with sound engineering practice.

For the purpose of classification, the fluids (media in the pressure equipment) are divided into two groups:

- Group 1 > hazardous fluids
- Group 2 > all other fluids that are not included in Group 1

Assessment Procedure

The manufacturer of pressure equipment must subject each item of pressure equipment to the conformity assessment procedure described in Annex III of the Directive, before it is placed on the market. This procedure is determined by the category in which the equipment is classified.



1. Modules A und A2

Internal production control

With Module A the manufacturer himself is responsible for continuous internal production control. In the case of Module A2 random pressure equipment checks are to be performed in addition to the internal production control.

2. Module B(P)

EU-type examination (production type)

The objective of this type examination is that the Notified Body determines whether the requirements of the PED are complied with on the basis of an inspection of the technical documentation and a production type.

3. Module B(D)

EU-type examination (design type)

In contrast to the EU-type examination (P) the design type examination is only performed on the basis of the technical documentation, without any production type or product test being performed.

4. Module C2

Conformity to type

Whereby the manufacturer declares that the pressure equipment conforms to the type described in the EU-type examination certificate (production type). The Notified Body

monitors the production and testing on a random basis at the manufacturer's site.

5. Modules F and G

Unit verification

Beside type examinations and QA modules, the PED also specifies unit verification to assess that the pressure equipment conforms to the directive. Unit verification ensures the highest possible degree of product safety, as each product is inspected by an independent body, and the highest possible flexibility. This is the procedure with which the Notified Body inspects the technical documentation and carries out the final assessment of the pressure equipment. Once the inspection has been completed successfully the Notified Body issues the certificate of conformity. This is the basis for issue of the declaration of conformity and for CE-marking by the manufacturer.

6. Modules D, D1, E, E1, H, H1

QA-systems

In addition to conventional product testing the PED also stipulates the introduction of a QA-system and assessment thereof by a Notified Body. The QA-system requirements of the PED are based, as regards content, on the applicable requirements of certification in accordance with DIN EN ISO 9001, supplemented by product-specific requirements that result from the provisions in Annex I and III of the PED.



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- Module D/D1** Quality assurance production process
- Module E/E1** Quality assurance product
- Module H** Full quality assurance
- Module H1** Full quality assurance with design examination and surveillance under the responsibility of the Notified Body

But what does a QA-system in accordance with the Pressure Equipment Directive actually mean?

The PED stipulates a QA-system in which the responsibilities and procedures are specified and effective ensuring, for example, that

- quality objectives are set and compliance therewith is monitored,
- information and data are controlled,
- construction specifications are defined, construction results are verified and validated,
- the highest possible process safety is guaranteed,
- objective and reliable procedures for inspecting incoming goods are performed during and after production,
- clear product quality records are compiled and the effectiveness of the implemented QA-system is monitored and, as applicable, corrective and preventive action is taken.

The procedure for assessing the QA-system in accordance with the PED is divided into four phases. The first phase is optional.

- Phase 1** Pre-audit as preparation for the certification audit
- Phase 2** Inspection of QA-documentation with regard to conformity with the PED
- Phase 3** Certification audit and issue of certificate
- Phase 4** Monitoring the effectiveness of the QA-system through surveillance audits and repeat audits

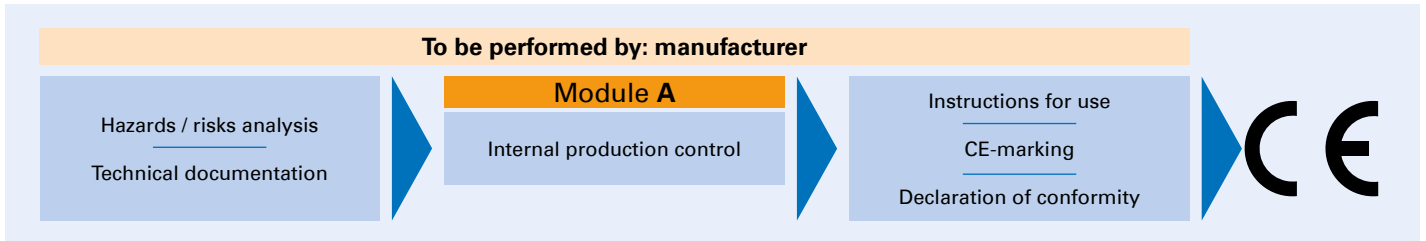
7. Material Manufacturer

The requirements for material manufacturer are not described in one module, but in Annex I Section 4.3. The Notified Body accordingly audits the QA-system of the material manufacturer with a specific assessment of the materials.

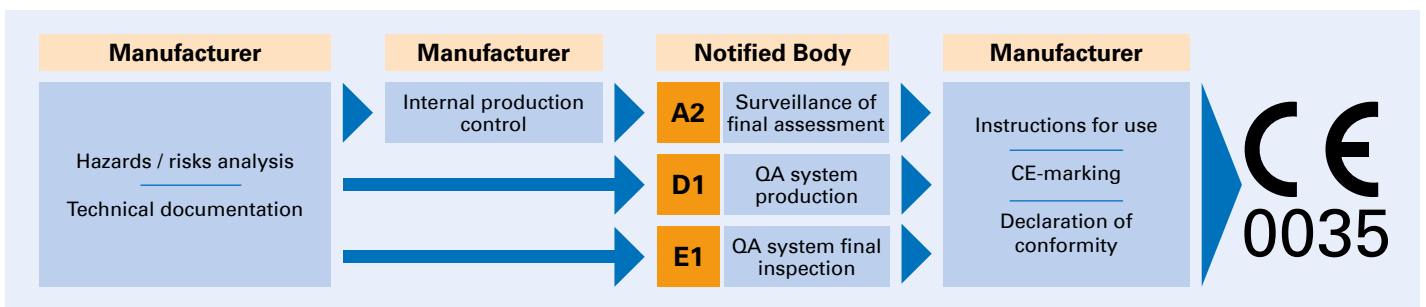
How to get CE-marking

The manufacturer provides the Notified Body with the corresponding technical documentation depending on the module.

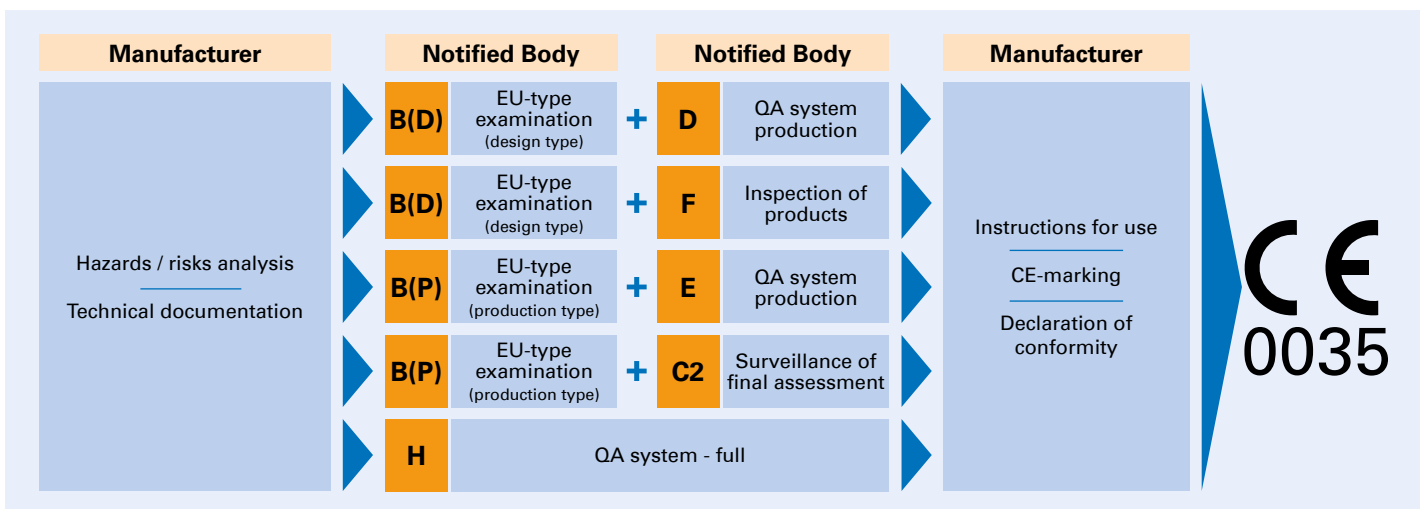
Modules for Category I



Modules for Category II



Modules for Category III



Modules for Category IV

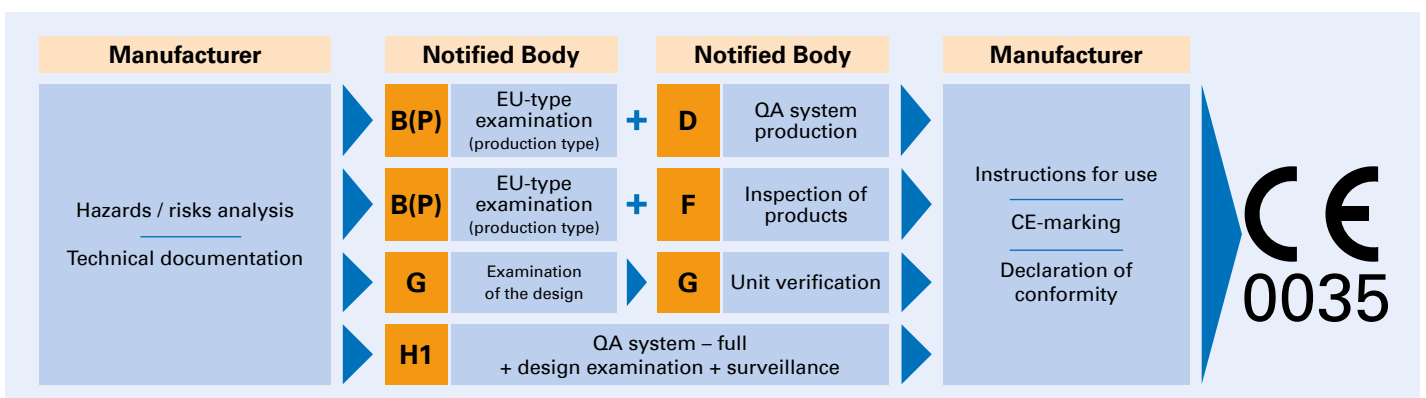




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Expert Partner of Industry

Today's markets move quickly and call for up-to-date know-how. At TÜV Rheinland we have the expertise to meet this challenge. With the consistent customer and market oriented focus of our company, we at TÜV Rheinland Industrial Services GmbH offer all services in this segment from one single source, not only in the context of the Pressure Equipment Directive, all over the world.

Need to Take Action?

Contact us today for more information and to find out where the nearest TÜV Rheinland branch is for your region.

A mark of excellence. The TÜV Rheinland Test Mark.



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