The Pressure Equipment Directive 2014/68/EU.

Information for our customers and partners.

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Introduction

One main objective of the European single market is to ensure the free movement of goods. Under the European approach to harmonisation, uniform requirements for products have been established that are mandatory for all Member States. These requirements are specified in the EU Directives and take into account essential safety requirements. Examples include 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.

WHAT DOES THIS ENTAIL?

Since May 2002 all pressure equipment and assemblies (simply referred to in the following as pressure equipment) that are placed on the market throughout the entire European Union must 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). Annex I to the Directive specifies essential safety requirements for pressure equipment and describes the procedure for assessing compliance with the requirements of the PED, the so-called conformity assessment procedure. Further pertinent testing specifications are the harmonised European product standards or other suitable technical regulations such as e.g. "the AD 2000 Merkblätter" which provide detailed specifications relating to the practical implementation of the requirements of the Directives.

Finally, the PED also contains regulations regarding the use of conformity marking – CE-marking. This marking demonstrates 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

CONFORMITY ASSESSMENT

Irrespective of the design parameters and the associated potential hazard of the pressure equipment, the PED sets out different procedures for conformity assessment. These procedures may only be performed by Notified Bodies (with the exception of Modulee A). TÜV Rheinland Industrie Service GmbH has been notified by the EU under the notification number 0035 for all activities in connection with the PED. In the following, you will find further information about the conformity assessment procedure comprising product testing or system audits, as specified in Annex III of the PED.

WHO DO THESE REGULATIONS APPLY TO?

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

CLASSIFICATION

In accordance with Annex II of the PED, pressure equipment shall be classified by the categories I to IV according to an ascending level of hazard, dependent on pressure, volume or nominal size, the fluid group and state of aggregation. Pressure equipment that is to be classified below category I (Article 4 (3) pressure equipment) is the exception as although included within the scope of the PED, such equipment is not required to comply with the essential safety requirements of the Directive and consequently must not bear any CE-marking. This 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

Your one-stop source for essential PED services

As a Notified Body for Pressure Equipment, we offer a full and comprehensive range of services thus ensuring compliance with the requirements of the Pressure Equipment Directive. Amongst others these include the

- Design examination of each item of pressure equipment
- Design examination of assemblies including examination of safety devices such as e.g. the design and suitability of measurement and control protective equipment, circuit diagrams, suitability of electronic components, PCE-devices, safety valves ...
- Qualification of welding operators and joining processes
- Qualification of NDT personnel
- Particular material appraisals, e.g. when using ASME materials under the provisions of the PED
- Single approval of pressure equipment or assemblies, Modules F and G
- Issue of type approvals, Module B (design and production type)
- Auditing QA-systems, modules D/D1, E/E1 and H/H1
- Auditing QA-systems of material manufacturers in accordance with Section 4.3

Expert partner for industry

Our qualified experts provide support from the technical design stage to the approval of the assembly or of individual items of pressure equipment, including issue of the CE-mark. This CE-mark guarantees both quality and safety for the user once the equipment has been placed on the market.

Today's fast-moving markets call for the cutting-edge expertise provided at TÜV Rheinland. Through our consistent focus on customer and market orientation, we are able to offer global services from one single source, not only in the field 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

Pressure vessels	Steam boiler	Piping	Safety accessories	Pressure accessories
>0.5 bar Diagram 1-4 Category I to IV	**>2 Litre>0.5 bar>110°C Diagram 5 Category I to IV**	**>DN25 >0.5 bar Diagram 6-9 Category I to III**	**> 0.5 bar – Category IV**	**>0.5 bar Diagram 1-9 Category I-IV**
Housing designed and built to contain fluids under pressure	Fired or otherwise heated pressure equipment with the risk of overheating intended for the generation of steam or super-heated water	Pipes, piping systems, tubing, fittings, expansion joints, hoses	Safety valves, bursting discs, pressure limiting devices, safety temperature limiters, thermocouples, filling level limiters...	Devices with an operational function that have a pressure-bearing housing; e.g. pressure gauges, slide valves, closures, ball valves, dirt traps ...

ASSEMBLIES

Within the meaning of the PED, the term assemblies refers to several pieces of pressure equipment assembled to constitute an integrated and functional whole. Items of pressure equipment can be assembled into an assembly with removable or permanent joints. In accordance with Annex I to the PED "Essential safety requirements" assemblies shall be designed in such a manner that

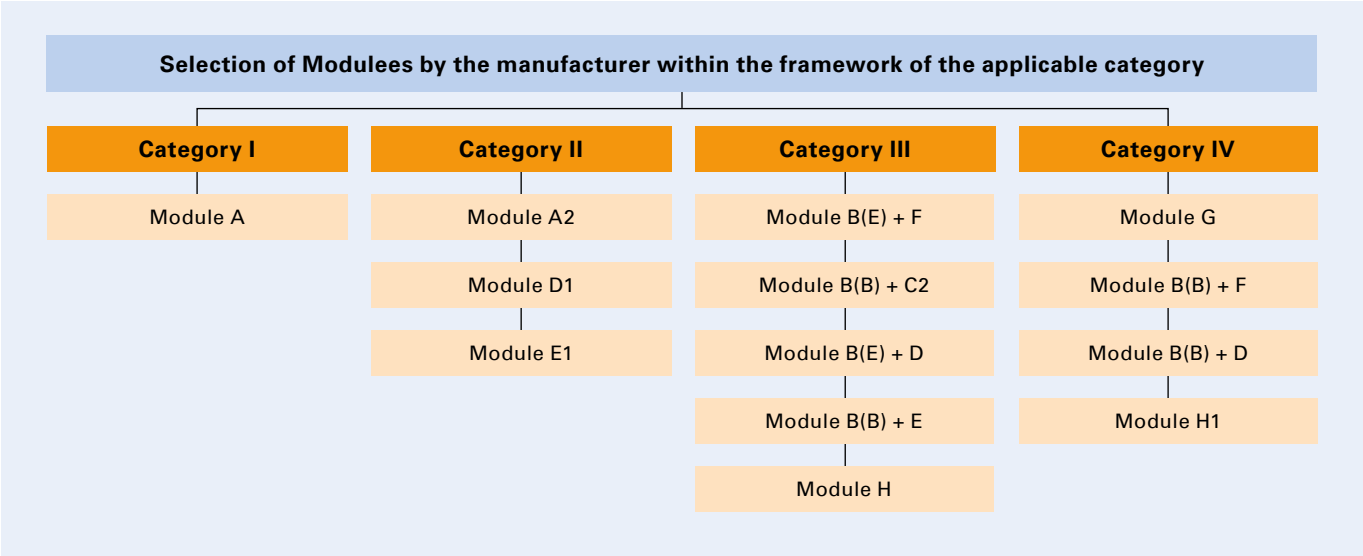
- The components to be assembled together are suitable and reliable for their duty,
- All the components are properly integrated and assembled in an appropriate manner.

The final assessment of assemblies also comprises the testing of safety accessories, in order to examine compliance with the requirements relating to the protection of the pressure equipment against the allowable limits being exceeded. The suitable protective device or combination of such devices shall be determined on the basis of the particular characteristics of the equipment or assembly and the corresponding operating conditions.

Pressure vessels-PV Steam boiler-SB Piping-P	Manufacturer's serial no. / type	PS [bar]	DN [bar]	TS [°C]	V [L]	Fluid	Fluid group	PED category	l/min	Identification (test report no. certificate no. approval)	ID no. of Notified Body
PV 1	4711	10	–	80	500	Luft	2	IV	–	Declaration of conformity of 01.07.2018	0035
PV 1 Safety valve	TÜV-SV-18-4711-10-D/G-0,64	6	–	–	–	Luft	2	IV	10.000	Certificate no.: 01-202 4711 Z 18	0035
PV 1 Pressure gauge	Pressure gauge	0-16	–	150	–	Luft	2	Art. 4.3	–	Manufacturer's declaration of 24.06.2018	–
P 1	Steel piping	PN16	20	–	–	Luft	2	Art. 4.3	–	Material certificate 3.2 of 24.11.2015	–
PV 1 Ball valve	1" - DN25	16	–	–	–	Luft	2	Art. 4.3	–	Manufacturer's declaration of 24.06.2018	–

Assessment Procedure

Manufacturers of pressure equipment must subject each item of pressure equipment to the conformity assessment procedure described in Annex III of the Directive, before such equipment is placed on the market, based on the category in which the equipment has been classified.



1. Modules A und A2

INTERNAL PRODUCTION CONTROL

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

2. Module B(B)

EU-TYPE EXAMINATION (PRODUCTION TYPE)

The objective of this type examination is for the Notified Body to verify whether the product complies with the requirements of the PED, on the basis of an examination of the technical documentation plus a production type.

3. Module B(E)

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 conducting any production type or product test.

4. Module C2

CONFORMITY TO TYPE

The manufacturer must declare that their pressure equipment conforms to the type described in the EU-type examination certificate (production type). The Notified Body monitors the production and testing, also by performing unexpected visits to the manufacturer's site.

5. Modules F and G

UNIT VERIFICATION

Beside type examinations and QA modules, the PED also specifies unit verification to verify that the pressure equipment conforms to the directive. Unit verification ensures the highest possible degree of product safety and flexibility, as each product is inspected by TÜV Rheinland as the Notified Body. During the conformity assessment the Notified Body examines the technical documentation and carries out the final assessment of the pressure equipment. Once the examination has been completed successfully, the Notified Body draws up the certificate of conformity which forms the basis for issuance 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 resulting from the provisions in Annex I and III of the PED.

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

WHAT DOES A QA-SYSTEM IN ACCORDANCE WITH THE PRESSURE EQUIPMENT DIRECTIVE ACTUALLY MEAN?

The PED stipulates a QA-system, which specifies the effective responsibilities and procedures thus ensuring, for example, that

- Quality objectives are set, and compliance therewith is monitored,
- Information and data are controlled,
- Construction specifications are defined, construction results 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 monitored; 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

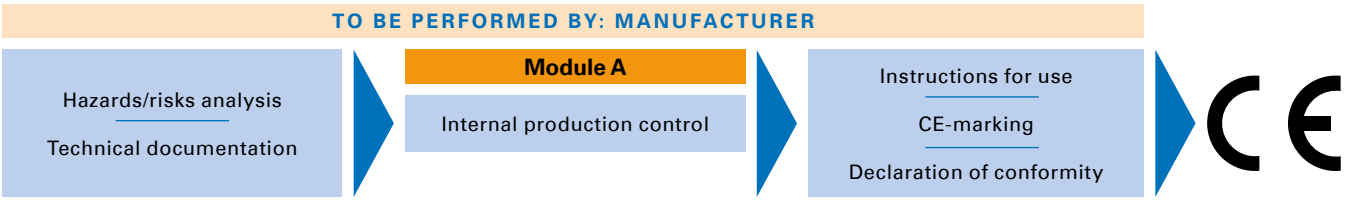
7. Material Manufacturers

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

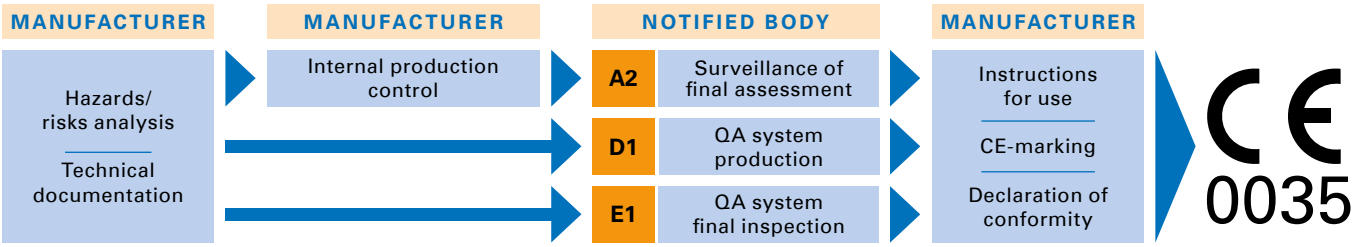
How to obtain CE-marking

The manufacturer provides the Notified Body with the corresponding technical documentation in accordance with the applicable module.

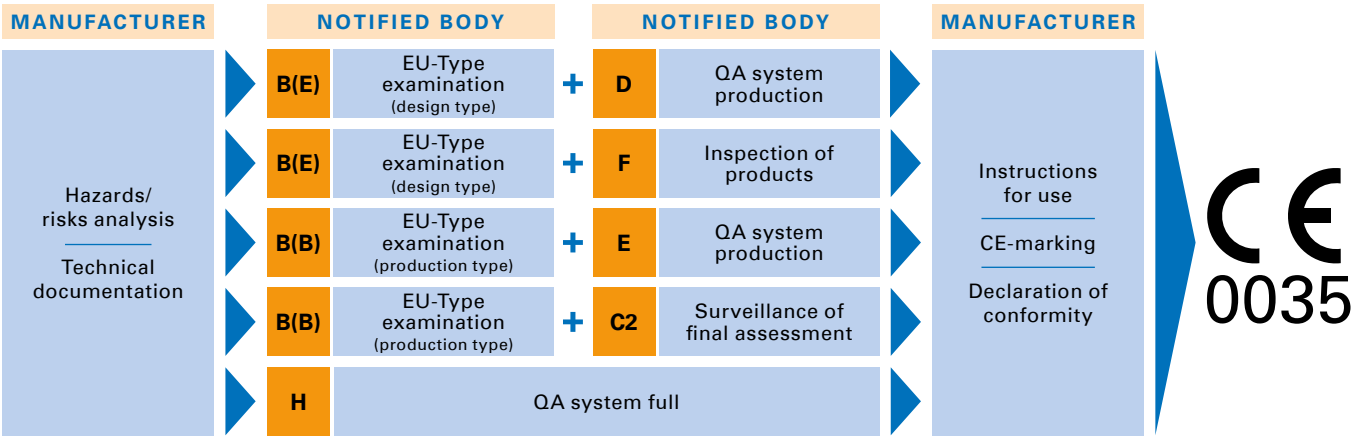
Modules for Category I



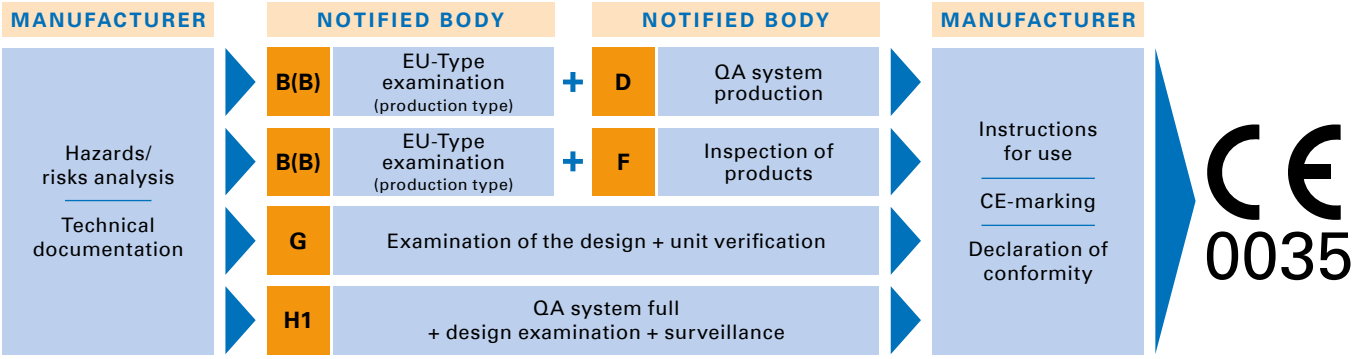
Modules for Category II



Modules for Category III



Modules für Category IV



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