INDUSTRIEARMATUREN

Conformity assessment procedures

for categorie III Module H

acc. to PED 2014/68/EU

FAQ
Cat. III
Module H

MANUFACTURING:

The manufacturer shall operate an approved quality system for design, manufacture, final product inspection and testing of the pressure equipment and shall be subject to surveillance by a notified body.

QUALITY SYSTEM:

The manufacturer must apply to a notified body of his choice for the assessment of his quality system for the pressure equipment concerned. The application should include the following:

- *Name and address of the manufacturer (and of the authorized representative, if necessary)*
- *the technical documentation for a model of each type of pressure equipment to be manufactured:*
  - *ageneral description of the pressure equipment,*
  - *conceptualdesign and manufacturing drawings and diagrams of components, sub-assemblies,circuits, etc.,*
  - *descriptionsand explanations necessary for the understanding of those drawings anddiagrams and the operation of the pressure equipment,*
  - *alist of the harmonised standards the references of which have been publishedin the Official Journal of the European Union, applied in full or in part,and descriptions of the solutions adopted to meet the essential safe-tyrequirements of this Directive where those harmonised standards have notbeen applied. In the event of partly applied harmonised standards, thetechnical documentation shall specify the parts which have been applied,*
  - *resultsof design calculations made, examinations carried out, etc.,*
- *testreports,*
- *the documentationconcerning the quality system, and*
- *a written declarationthat the same application has not been lodged with any other notifiedbody.*

The quality system shall ensure compliance of the pressure equipment with the requirements of the relevant directive that apply to it. The manufacturer shall ensure that the elements, requirements and provisions adopted are systematic and orderly. This shall ensure a consistent interpretation of the quality programs, plans, manuals and records.

In particular, they must contain an adequate description of:

- *Quality objectives and organizational structure, responsibilities and authority of management with respect to design and product quality;*
- *technical design specifications, including the applied standards;*
- *Techniques for controlling the development and testing the development result, procedures and systematic measures used in the development of the pressure equipment belonging to the product category in question;*
- *the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, in particular the approved working procedures that will be used to produce the permanent joints*
- *examinations and tests carried out before, during and after manufacture, specifying their frequency;*
- *the quality-related records, e.g. test reports, qualification or approval of involved employees, etc.*
- *Means of monitoring the achievement of the required development and pressure equipment quality and the effective operation of the quality system.*

The notified body shall assess the quality system to determine whether the above requirements have been met.

ACI Industriearmaturen GmbH · Königskamp 19 · 52428 Jülich
info@aci24.com
+49 (0) 2461 91634 00
+49 (0) 2461 91634 44
www.aci24.com

20210823

In addition to experience with quality management systems, at least one member of the audit team shall have experience as an assessor in the relevant pressure equipment field and pressure equipment technology concerned, as well as knowledge of the applicable requirements of the directive concerned. The audit shall also include an inspection visit to the manufacturer's premises. The auditing team shall review the technical documentation to verify the manufacturer's ability to identify the applicable requirements of the directive concerned and to carry out the necessary examinations with a view to ensuring compliance of the pressure equipment with those requirements.

The manufacturer shall undertake to fulfil the obligations arising out of the approved quality system and to uphold it so that it remains adequate and efficient.
The manufacturer shall keep the notified body informed of any intended change of the quality system. The notified body shall evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements referred to above or whether a reassessment is required.

SURVEILLANCE UNDER THE RESPONSIBILITY OF THE NOTIFIED BODY

The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
The manufacturer shall, for assessment purposes, allow the notified body access to the locations of design, manufacture, inspection, testing and storage, and shall provide it with all necessary information, in particular

- *the documentation on the quality assurance system;*
- *quality-related records intended for the development area, such as results of analyses, calculations or tests;*
- *quality-related records intended for the manufacturing area, for example, inspection reports, test data, or reports on the qualifications of the employees working in this area.*

The notified body shall periodically carry out audits to ensure that the manufacturer maintains and applies the quality system.

In addition, the notified body may pay unannounced visits to the manufacturer, taking into account in particular the following factors:

- *Category of the pressure equipment;*
- *Results of previous monitoring visits;*
- *required tracking of corrective actions;*
- *any special conditions attached to the approval of the system;*
- *significant changes in manufacturing organization, manufacturing concepts, or manufacturing techniques.*

During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, to verify that the quality system is functioning correctly.

ACI Industriearmaturen GmbH · Königskamp 19 · 52428 Jülich
info@aci24.com
+49 (0) 2461 91634 00
+49 (0) 2461 91634 44
www.aci24.com

INDUSTRIEARMATUREN

Conformity assessment procedures

for categorie III Module H

acc. to PED 2014/68/EU

FAQ
Cat. III
Module H

CE MARKING AND EU DECLARATION OF CONFORMITY:

The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to above, the latter's identification number to each item of pressure equipment where required by the Directive.
In addition, a written EU declaration of conformity shall be issued for one model of the pressure equipment and kept at the disposal of the national authorities for ten years after the pressure equipment has been placed on the market, together with the technical documentation. The EU declaration of conformity must clearly identify the pressure equipment for which it was issued.
A copy of the EU declaration of conformity shall be made available to the competent authorities upon request.

The documents to be kept available by the manufacturer are in particular:

- *technical documentation*
- *quality assurance system documentation*
- *approved modifications*
- *decisions and reports of the notified body*

The EU declaration of conformity must contain the following information:

1. Pressure equipment or assembly (product, type, batch or serial number).
2. Name and address of the manufacturer and, if applicable, of his authorized representative.
3. The manufacturer has the sole responsibility for issuing this declaration of conformity.
4. Subject of the declaration (designation of the pressure equipment or assembly for traceability purposes; it may include a picture if necessary to identify the pressure equipment or assembly):
   I. Description of the pressure equipment or assembly;
   II. conformity assessment procedures applied;
   III. in the case of assemblies, description of the pressure equipment making up the assembly and the conformity assessment procedures applied.
5. The subject of the declaration described above complies with the relevant harmonization legislation of the European Union:
6. Indication of the relevant harmonized standards applied or indication of the other technical specifications in relation to which conformity is declared:
7. Where applicable, name, address and number of the notified body that carried out the conformity assessment, number of the certificate issued and reference to the EU type-examination certificate (design type), EU design examination certificate (design type), EU design examination certificate or certificate of conformity.
8. Additional information:

   . Signed for and on behalf of:
   . (place and date of issue)
   . (Name, function) (Signature)
   . (If applicable: details of the signatory authorized to sign the declaration with legally binding effect for the manufacturer or his authorized representative)

ACI Industriearmaturen GmbH · Königskamp 19 · 52428 Jülich
info@aci24.com
+49 (0) 2461 91634 00
+49 (0) 2461 91634 44
www.aci24.com