INDUSTRIEARMATUREN

Conformity assessment procedures

for categorie II Module A2

acc. to PED 2014/68/EU

FAQ
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TECHNICAL DOCUMENTATION:

The documentation prepared by the manufacturer shall enable the conformity of the pressure equipment with the applicable requirements to be assessed and shall include an appropriate risk analysis and assessment. The technical documentation shall specify the applicable requirements and, as far as necessary for the assessment, cover the design, manufacture and operation of the pressure equipment. The technical documentation shall include at least the following elements, as appropriate:

- a general descriptionof the pressure equipment,
- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits,etc.,
- descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment,
- a list of which harmonized standards have been applied in full or in part and a description of the solutions adopted to meet the essential safety requirements of this Directive where those harmonized standards have not been applied; in the case of partially applied harmonized standards, those parts shall be indicated in the technical file,
- results of design calculations made, examinations carried out, etc.,
- test reports.

MANUFACTURING:

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured pressure equipment with the technical documentation and with the requirements of this Directive.

FINALASSESSMENT AND PRESSURE EQUIPMENT CHECKS:

The manufacturer shall perform a final assessment of the pressure equipment, which is monitored in the form of unannounced visits by the manufacturer‘s selected notified body.
The notified body carries out product tests or has them carried out at irregular intervals determined by it in order to check the quality of the internal pressure equipment tests. In doing so, it takes into account, among other things, the technical complexity of the pressure equipment and the production volume.

During these visits, the notified body shall:

- *make sure that the manufacturer actually carries out the final assessment according to Annex I point 3.2 of the PED;*
- *take samples of pressure equipment in the manufacturing or storage facilities for inspection purposes. The notified body shall decide on the number and, if necessary, whether to carry out or have carried out all or part of the final assessment test.*

The purpose of this sampling procedure is to determine if the manufacturing process of the pressure equipment is within acceptable limits to ensure the conformity of the pressure equipment.

In case of non-conformity of one or more pressure equipment, the notified body shall take appropriate measures.

The manufacturer shall, under the responsibility of the notified body, affix its identification number during the manufacturing process.

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CE MARKING AND EU DECLARATION OF CONFORMITY:

- The manufacturer shall affix the CE marking to each item of pressure equipment that satisfies the applicable requirements of this Directive.
- The manufacturer shall draw up a written EU declaration of conformity for one model of the pressure equipment and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment has been placed on the market. 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 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, where applicable, his authorisedrepresentative:
3. This declaration of conformity is issued under the sole responsibility of themanufacturer.
4. Object of the declaration (identification of pressure equipment or assembly allowingtraceability; it may, where necessary for the identification of the pressureequipment or assembly, include an image):
   I. description of the pressure equipment or assembly,
   II. conformity assessment procedure followed,
   III. in the case of assemblies, description of the pressure equipment constituting the assembly,and the conformity assessment procedures followed,
5. The object of the declaration described above is in conformity with the relevantUnion harmonisation legislation:
6. References to the relevant harmonised standards used or references to the other technicalspecifications in relation to which conformity is declared:
7. Where appropriate, the name, address and number of the notified body which carriedout the conformity assessment and the number of the certificate issued ,and a reference to the EU-type examination certificate – production type, EU- type examination certificate – design type, EU design examinationcertificate or certificate of conformity.
8. Additionalinformation:

   . Signed for and on behalf of:
   . (place and date of issue):
   . (name, function) (signature):
   . (where appropriate, particulars of the signatory authorised to sign thelegally binding declaration for the manufacturer or his authorised representative)

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