

ANNEX II

CONFORMITY ASSESSMENT PROCEDURES

1. EU-Type examination (Module B)

- 1.1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a vessel and verifies and attests that the technical design of the vessel meets the requirements of this Directive that apply to it.
- 1.2. EU-type examination shall be carried out in either of the following manners in accordance with Article 13:
 - assessment of the adequacy of the technical design of the vessel through examination of the technical documentation and supporting evidence referred to in point 1.3, plus examination of a prototype, representative of the production envisaged, of the complete vessel (production type),
 - assessment of the adequacy of the technical design of the vessel through examination of the technical documentation and supporting evidence referred to in point 1.3, without examination of a prototype vessel (design type).
- 1.3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) the technical documentation. The technical documentation shall make it possible to assess the vessel's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the vessel. The technical documentation shall contain, wherever applicable, at least the following elements:

- (i) a general description of the vessel;
- (ii) conceptual design and manufacturing drawings and schemes of components, etc.;
- (iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the vessel;
- (iv) a list of the harmonised standards applied in full or in part, the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- (v) results of design calculations made, examinations carried out, etc.;

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- (vi) test reports;
- (vii) the instructions and safety information referred to in point 2 of Annex III;
- (viii) a document describing:
 - the materials selected,
 - the welding processes selected,
 - the checks selected,
 - any pertinent details as to the vessel design;
- (d) where applicable, the prototype vessels representative of the production envisaged. The notified body may request further prototype vessels if needed for carrying out the test programme;
- (e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

When a prototype vessel is examined, the technical documentation shall also include:

- the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators,
- the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel,
- a report on the examinations and tests performed or a description of the proposed checks.

1.4. The notified body shall:

For the vessel:

- 1.4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the vessel.

For the prototype vessel(s):

- 1.4.2. verify that the prototype vessel(s) has/have been manufactured in conformity with the technical documentation, that it may safely be used under its intended working conditions and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards, as well as the elements which have been designed in accordance with other relevant technical specifications;
- 1.4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly;
- 1.4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential safety requirements of this Directive;

- 1.4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.
- 1.5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 1.4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.
- 1.6. Where the type meets the requirements of this Directive, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured vessels with the examined type to be evaluated and to allow for in-service control. It shall also indicate any conditions to which its issue may be subject and be accompanied by the descriptions and drawings necessary for identification of the approved type.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

- 1.7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the vessel with the essential safety requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

- 1.8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

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- 1.9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the vessel has been placed on the market.
- 1.10. The manufacturer's authorised representative may lodge the application referred to in point 1.3 and fulfil the obligations set out in points 1.7 and 1.9, provided that they are specified in the mandate.

2. Conformity to type based on internal production control plus supervised vessel testing (Module C1)

- 2.1. Conformity to type based on internal production control plus supervised vessel testing is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2.2, 2.3 and 2.4, and ensures and declares on his sole responsibility that the vessels concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2.2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured vessels with the type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

Before commencing manufacture, the manufacturer shall provide a notified body of his choice with all necessary information, and in particular:

- (a) the technical documentation, which shall also include:
- the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators,
 - the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel,
 - a report on the examinations and tests performed;
- (b) the inspection document, describing the appropriate examinations and tests to be carried out during manufacture, together with the procedures in respect thereof and the frequency with which they are to be performed;
- (c) the EU-type examination certificate.

2.3. Vessel checks

- 2.3.1. For each individual vessel manufactured, the notified body shall carry out the appropriate examinations and tests in order to verify the conformity of the vessel with the type described in the EU-type examination certificate and with the corresponding requirements of this Directive in accordance with the following points:

- (a) The manufacturer shall present his vessels in the form of uniform batches and shall take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced.
- (b) When a batch is examined, the notified body shall ensure that the vessels have been manufactured and checked in accordance with the technical documentation, and shall perform a hydrostatic test or a pneumatic test of equivalent effect on each vessel in the batch at a pressure P_h equal to 1,5 times the vessel's design pressure in order to

check its strength. The pneumatic test shall be subject to acceptance of the test safety procedures by the Member State in which the test is performed.

- (c) Moreover, the notified body shall carry out tests on test-pieces taken from a representative production test-piece or from a vessel, as the manufacturer chooses, in order to examine the weld quality. The tests shall be carried out on longitudinal welds. However, where differing weld techniques are used for longitudinal and circumferential welds, the tests shall be repeated on the circumferential welds.
- (d) For the vessels subject to the experimental method referred to in point 2.1.2 of Annex I, these tests on test-pieces shall be replaced by a hydrostatic test on five vessels taken at random from each batch in order to check that they conform to the essential safety requirements set out in point 2.1.2 of Annex I.
- (e) In the case of accepted batches, the notified body shall affix its identification number, or cause that number to be affixed, to each vessel and shall draw up a written certificate of conformity relating to the tests carried out. All vessels in the batch may be placed on the market except for those which have not successfully undergone a hydrostatic test or a pneumatic test.
- (f) If a batch is rejected, the notified body shall take appropriate measures to prevent the placing on the market of that batch. In the event of frequent rejection of batches, the notified body may suspend the statistical verification.
- (g) The manufacturer shall be able to supply on request by the relevant authorities the notified body's certificates of conformity referred to in point (e).

2.3.2. The notified body shall supply the Member State which notified it and, on request, the other notified bodies, the other Member States and the Commission, with a copy of the inspection report issued by it.

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

2.4. *CE marking and EU declaration of conformity*

2.4.1. The manufacturer shall affix the CE marking to each individual vessel that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

2.4.2. The manufacturer shall draw up a written EU declaration of conformity for each vessel model and keep it at the disposal of the national authorities for 10 years after the vessel has been placed on the market. The EU declaration of conformity shall identify the vessel model for which it has been drawn up.

2.4.3. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

2.5. *Authorised representative*

The manufacturer's obligations set out in point 2.4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

3. **Conformity to type based on internal production control plus supervised vessel checks at random intervals (Module C2)**

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3.1. Conformity to type based on internal production control plus supervised vessel checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 3.2, 3.3 and 3.4, and ensures and declares on his sole responsibility that the vessels concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

3.2. *Manufacturing*

3.2.1. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured vessels with the type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3.2.2. Before commencing manufacture, the manufacturer shall provide a notified body of his choice with all necessary information, and in particular:

- (a) the technical documentation, which shall also include:
- the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators,
 - the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel,
 - a report on the examinations and tests performed;
- (b) the EU-type examination certificate;
- (c) a document describing the manufacturing processes and all of the predetermined systematic measures taken to ensure conformity of the vessels with the type described in the EU-type examination certificate.

The notified body shall, before the date on which any manufacture begins, examine those documents in order to certify their conformity with the EU-type examination certificate.

3.2.3. The document referred to in point (c) of point 3.2.2 shall include:

- (a) a description of the means of manufacture and checking appropriate to the construction of the vessels;
- (b) an inspection document describing the appropriate examinations and tests to be carried out during manufacture, together with the procedures in respect thereof and the frequency with which they are to be performed;
- (c) an undertaking to carry out the examinations and tests in accordance with the inspection document and to have a hydrostatic test or, subject to the agreement of the Member State, a pneumatic test carried out on each vessel manufactured at a test pressure equal to 1,5 times the design pressure; those examinations and tests shall be carried out under the responsibility of qualified staff who are independent from production personnel, and shall be the subject of a report;
- (d) the addresses of the places of manufacture and storage and the date on which manufacture is to commence.

3.3. *Vessel checks*

The notified body shall carry out vessel checks or have them carried out on random samples at random intervals determined by the body, in order to verify the quality of the internal checks

on the vessel, taking into account, inter alia, the technological complexity of the vessels and the quantity of production. An adequate sample of the final vessels, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards and/or equivalent tests set out in other relevant technical specifications, shall be carried out to check the conformity of the vessel with the type described in the EU-type examination certificate and with the relevant requirements of this Directive.

The notified body shall also ensure that the manufacturer actually checks series-produced vessels in accordance with point (c) of point 3.2.3.

Where a sample does not conform to the acceptable quality level, the notified body shall take appropriate measures.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the vessel performs within acceptable limits, with a view to ensuring conformity of the vessel.

The notified body shall supply the Member State which notified it and, on request, the other notified bodies, the other Member States and the Commission, with a copy of the inspection report issued by it.

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

3.4. *CE marking and EU declaration of conformity*

3.4.1. The manufacturer shall affix the CE marking to each individual vessel that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

3.4.2. The manufacturer shall draw up a written EU declaration of conformity for each vessel model and keep it at the disposal of the national authorities for 10 years after the vessel has been placed on the market. The EU declaration of conformity shall identify the vessel model for which it has been drawn up.

3.4.3. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

3.5. *Authorised representative*

The manufacturer's obligations set out in point 3.4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

4. **Conformity to type based on internal production control (Module C)**

4.1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 4.2 and 4.3, and ensures and declares that the vessels concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

4.2. *Manufacturing*

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured vessels with the approved type described

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in the EU-type examination certificate and with the requirements of this Directive that apply to them.

Before commencing manufacture, the manufacturer shall provide the notified body which issued the EU-type examination certificate with all necessary information, and in particular:

- (a) the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators;
- (b) the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel;
- (c) a report on the examinations and tests performed;
- (d) a document describing the manufacturing processes and all of the predetermined systematic measures taken to ensure conformity of the vessels with the type described in the EU-type examination certificate.

That document shall include:

- (i) a description of the means of manufacture and checking appropriate to the construction of the vessels;
- (ii) an inspection document describing the appropriate examinations and tests to be carried out during manufacture, together with the procedures in respect thereof and the frequency with which they are to be performed;
- (iii) an undertaking to carry out the examinations and tests in accordance with the inspection document and to have a hydrostatic test or, subject to the agreement of the Member State, a pneumatic test carried out on each vessel manufactured at a test pressure equal to 1,5 times the design pressure; those examinations and tests shall be carried out under the responsibility of qualified staff who are independent from production personnel, and shall be the subject of a report;
- (iv) the addresses of the places of manufacture and storage and the date on which manufacture is to commence.

The notified body shall, before the date on which any manufacture begins, examine those documents in order to certify their conformity with the EU-type examination certificate.

4.3. *CE marking and EU declaration of conformity*

4.3.1. The manufacturer shall affix the CE marking to each individual vessel that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

4.3.2. The manufacturer shall draw up a written EU declaration of conformity for each vessel model and keep it at the disposal of the national authorities for 10 years after the vessel has been placed on the market. The EU declaration of conformity shall identify the vessel model for which it has been drawn up.

4.3.3. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

4.4. *Authorised representative*

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The manufacturer's obligations set out in point 4.3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.