

ANNEX II

CONFORMITY ASSESSMENT PROCEDURES

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

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.