

ANNEX II

CONFORMITY ASSESSMENT PROCEDURES

V. MODULE G: CONFORMITY BASED ON UNIT VERIFICATION

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5 and ensures and declares on its sole responsibility that the product concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of the international instruments that apply to it.

2. Technical documentation

The manufacturer shall draw up the technical documentation and make it available to the notified body referred to in point 4. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and shall cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain at least the following elements:

- a general description of the product;
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product;
- a list of the requirements and testing standards which are applicable to the marine equipment concerned in accordance with this Directive, together with a description of the solutions adopted to meet those requirements;
- results of design calculations made, examinations carried out; and
- test reports.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for at least 10 years after the wheel mark has been affixed on the last product manufactured and in no case for a period shorter than the expected life of the marine equipment concerned.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with the applicable requirements of the international instruments.

4. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests in accordance with this Directive, in order to check the conformity of the product with the applicable requirements of the international instruments.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved product, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for at least 10 years after the wheel mark has been affixed on the last product

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

manufactured and in no case for a period shorter than the expected life of the marine equipment concerned.

5. Conformity marking and declaration of conformity

5.1. The manufacturer shall affix the wheel mark referred to in Article 9 and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each product that satisfies the applicable requirements of the international instruments.

5.2. The manufacturer shall draw up a written declaration of conformity and keep it at the disposal of the national authorities for at least 10 years after the wheel mark has been affixed on the last product manufactured and in no case for a period shorter than the expected life of the marine equipment concerned. The declaration of conformity shall identify the product for which it has been drawn up.

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

6. Authorised representative

The manufacturer's obligations set out in points 2 and 5 may be fulfilled by its authorised representative, on its behalf and under its responsibility, provided that they are specified in the mandate.