

Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (Text with EEA relevance)

CHAPTER 1

GENERAL PROVISIONS

Article 1	Objective
Article 2	Definitions
Article 3	Scope
Article 4	Requirements for marine equipment
Article 5	Application
Article 6	Functioning of the internal market
Article 7	Transfer of a ship to the flag of a Member State
Article 8	Standards for marine equipment

CHAPTER 2

THE WHEEL MARK

Article 9	The wheel mark
Article 10	Rules and conditions for affixing the wheel mark
Article 11	Electronic tag

CHAPTER 3

OBLIGATIONS OF ECONOMIC OPERATORS

Article 12	Obligations of manufacturers
Article 13	Authorised representatives
Article 14	Other economic operators

CHAPTER 4

CONFORMITY ASSESSMENT AND NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 15	Conformity assessment procedures
Article 16	EU declaration of conformity
Article 17	Notification of conformity assessment bodies
Article 18	Notifying authorities
Article 19	Information obligation on notifying authorities
Article 20	Subsidiaries of, and subcontracting by, notified bodies
Article 21	Changes to notifications
Article 22	Challenges to the competence of notified bodies
Article 23	Operational obligations of notified bodies
Article 24	Obligation of notified bodies to provide information

## CHAPTER 5

### UNION MARKET SURVEILLANCE, CONTROL OF PRODUCTS, SAFEGUARD PROVISIONS

Article 25	EU market surveillance framework
Article 26	Procedure for dealing with marine equipment presenting a risk at national level
Article 27	EU safeguard procedure
Article 28	Compliant products which present a risk to maritime safety, to health or to the environment
Article 29	Formal non-compliance
Article 30	Exemptions based on technical innovation
Article 31	Exemptions for testing or evaluation
Article 32	Exemptions in exceptional circumstances

## CHAPTER 6

### FINAL PROVISIONS

Article 33	Exchange of experience
Article 34	Coordination of notified bodies
Article 35	Implementing measures
Article 36	Amendments
Article 37	Exercise of the delegation
Article 38	Committee
Article 39	Transposition
Article 40	Repeal
Article 41	Entry into force
Article 42	Addressees

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## ANNEX I

### WHEEL MARK

The mark of conformity must take the following form:  
If the wheel mark is reduced or enlarged the proportions...  
The various components of the wheel mark must have substantially...  
That minimum dimension may be waived for small devices.

## ANNEX II

### CONFORMITY ASSESSMENT PROCEDURES

- I. MODULE B: EC TYPE-EXAMINATION
1. EC type-examination is the part of a conformity assessment procedure...
  2. EC type-examination may be carried out in either of the...
  3. The manufacturer shall lodge an application for EC type-examination with...
  4. The notified body shall:

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5. The notified body shall draw up an evaluation report that...
6. Where the type meets the requirements of the specific international...
7. If the approved type no longer complies with the applicable...
8. Each notified body shall inform its notifying authorities concerning the...
9. The manufacturer shall keep a copy of the EC type-examination...
10. The manufacturer's authorised representative may lodge the application referred to...

## II. MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF...

1. Conformity to type based on quality assurance of the production...
2. Manufacturing
3. Quality system
  - 3.1. The manufacturer shall lodge an application for assessment of its...
  - 3.2. The quality system shall ensure that the products are in...
  - 3.3. The notified body shall assess the quality system to determine...
  - 3.4. The manufacturer shall undertake to fulfil the obligations arising out...
  - 3.5. The manufacturer shall keep the notified body that has approved...
4. Surveillance under the responsibility of the notified body
  - 4.1. The purpose of surveillance is to make sure that the...
  - 4.2. The manufacturer shall, for assessment purposes, allow the notified body...
  - 4.3. The notified body shall carry out periodic audits to make...
  - 4.4. In addition, the notified body may pay unexpected visits to...
5. Conformity marking and declaration of conformity
  - 5.1. The manufacturer shall affix the wheel mark referred to in...
  - 5.2. The manufacturer shall draw up a written declaration of conformity...
6. The manufacturer shall keep at the disposal of the competent...
7. Each notified body shall inform its notifying authorities of quality...
8. Authorised representative

## III. MODULE E: CONFORMITY TO TYPE BASED ON PRODUCT QUALITY ASSURANCE...

1. Conformity to type based on product quality assurance is that...
2. Manufacturing
3. Quality system
  - 3.1. The manufacturer shall lodge an application for assessment of its...
  - 3.2. The quality system shall ensure compliance of the products with...
  - 3.3. The notified body shall assess the quality system to determine...
  - 3.4. The manufacturer shall undertake to fulfil the obligations arising out...
  - 3.5. The manufacturer shall keep the notified body that has approved...
4. Surveillance under the responsibility of the notified body
  - 4.1. The purpose of surveillance is to make sure that the...
  - 4.2. The manufacturer shall, for assessment purposes, allow the notified body...
  - 4.3. The notified body shall carry out periodic audits to make...
  - 4.4. In addition, the notified body may pay unexpected visits to...
5. Conformity marking and declaration of conformity
  - 5.1. The manufacturer shall affix the wheel mark referred to in...
  - 5.2. The manufacturer shall draw up a written declaration of conformity...
6. The manufacturer shall keep at the disposal of the competent...
7. Each notified body shall inform its notifying authorities of quality...
8. Authorised representative

- IV. MODULE F: CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION
1. Conformity to type based on product verification is the part...
  2. Manufacturing
  3. Verification
  4. Verification of conformity by examination and testing of every product...
    - 4.1. All products shall be individually examined and tested in accordance...
    - 4.2. The notified body shall issue a certificate of conformity in...
  5. Statistical verification of conformity
    - 5.1. The manufacturer shall take all measures necessary so that the...
    - 5.2. A random sample shall be taken from each lot. All...
    - 5.3. If a lot is accepted, all products of the lot...
    - 5.4. If a lot is rejected, the notified body or the...
  6. Conformity marking and declaration of conformity
    - 6.1. The manufacturer shall affix the wheel mark referred to in...
    - 6.2. The manufacturer shall draw up a written declaration of conformity...
  7. If the notified body agrees and under its responsibility, the...
  8. Authorised representative
- V. MODULE G: CONFORMITY BASED ON UNIT VERIFICATION
1. Conformity based on unit verification is the conformity assessment procedure...
  2. Technical documentation
  3. Manufacturing
  4. Verification
  5. Conformity marking and declaration of conformity
    - 5.1. The manufacturer shall affix the wheel mark referred to in...
    - 5.2. The manufacturer shall draw up a written declaration of conformity...
  6. Authorised representative

### ANNEX III

#### REQUIREMENTS TO BE MET BY CONFORMITY ASSESSMENT BODIES IN ORDER TO BECOME NOTIFIED BODIES

1. For the purposes of notification, a conformity assessment body shall...
2. A conformity assessment body shall be established under national law...
3. A conformity assessment body shall be a third-party body independent...
4. A body belonging to a business association or professional federation...
5. A conformity assessment body, its top-level management and the personnel...
6. A conformity assessment body, its top-level management and the personnel...
7. Conformity assessment bodies shall ensure that the activities of their...
8. Conformity assessment bodies and their personnel shall carry out the...
9. A conformity assessment body shall be capable of carrying out...
10. At all times and for each conformity assessment procedure and...

11. A conformity assessment body shall have the means necessary to...
12. The personnel responsible for carrying out conformity assessment activities shall...
13. The impartiality of the conformity assessment bodies, of their top-level...
14. The remuneration of the top-level management and of the assessment...
15. Conformity assessment bodies shall take out liability insurance unless liability...
16. The personnel of a conformity assessment body shall observe professional...
17. Conformity assessment bodies shall participate in, or ensure that their...
18. Conformity assessment bodies shall meet the requirements of standard EN...
19. Conformity assessment bodies shall ensure that testing laboratories used for...

#### ANNEX IV NOTIFICATION PROCEDURE

1. Application for notification
  - 1.1. A conformity assessment body shall submit an application for notification...
  - 1.2. That application shall be accompanied by a description of the...
  - 1.3. Where the conformity assessment body concerned cannot provide an accreditation...
2. Notification procedure
  - 2.1. Notifying authorities may notify only conformity assessment bodies which have...
  - 2.2. They shall notify the Commission and the other Member States...
  - 2.3. The notification shall include full details of the conformity assessment...
  - 2.4. Where a notification is not based on an accreditation certificate...
  - 2.5. The body concerned may perform the activities of a notified...
  - 2.6. Only a body referred to in point 2.5 shall be...
  - 2.7. The Commission and the other Member States shall be notified...
3. Identification numbers and lists of notified bodies
  - 3.1. The Commission shall assign an identification number to a notified...
  - 3.2. It shall assign a single such number even where the...
  - 3.3. The Commission shall make publicly available the list of the...
  - 3.4. The Commission shall ensure that that list is kept up...

#### ANNEX V REQUIREMENTS TO BE MET BY NOTIFYING AUTHORITIES

1. A notifying authority shall be established in such a way...
2. A notifying authority shall be organised and operated in such...

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3. A notifying authority shall be organised in such a way...
4. A notifying authority shall not offer or provide, on a...
5. A notifying authority shall safeguard the confidentiality of the information...
6. A notifying authority shall have a sufficient number of competent...

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- (1) [OJ C 161, 6.6.2013, p. 93](#).
- (2) Position of the European Parliament of 15 April 2014 (not yet published in the Official Journal) and decision of the Council of 23 July 2014.
- (3) Council Directive 96/98/EC of 20 December 1996 on marine equipment ([OJ L 46, 17.2.1997, p. 25](#)).
- (4) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC ([OJ L 218, 13.8.2008, p. 82](#)).
- (5) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products ([OJ L 218, 13.8.2008, p. 30](#)).
- (6) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers ([OJ L 55, 28.2.2011, p. 13](#)).
- (7) Regulation (EC) No 1406/2002 of the European Parliament and of the Council of 27 June 2002 establishing a European Maritime Safety Agency ([OJ L 208, 5.8.2002, p. 1](#)).