Regulations of 30 August 2016 No. 1042 on marine equipment

Legal basis: Laid down by the Norwegian Maritime Authority on 30 August 2016 under the Act of 16 February 2007 No. 9 relating to ship safety and security (Ship Safety and Security Act) sections 9, 32 and 45, cf. Formal Delegation of 16 February 2007 No. 171, Formal Delegation of 31 May 2007 No. 590 and Formal Delegation of 29 June 2007 No. 849, Act of 16 June 1994 No. 20 relating to Notified Bodies responsible for carrying out conformity assessments section 7, cf. Formal Delegation of 10 December 1998 No. 1568 and Act of 12 April 2013 No. 13 on the free movement of goods in the EEA (EEA Trade Act) section 2.
EEA references: EEA Agreement Annex II chapter XXXII point 2 (Directive 2014/90/EU).
Amendments: Amended by Regulations of 10 March 2017 No. 385, 8 September 2017 No. 1442, 13 June 2018 No. 859, 14 December 2018 No. 1980, 27 September 2019 No. 1276 (in force on 3 October 2019).

Section 1. *Scope of application*

These Regulations apply to marine equipment placed or to be placed on board Norwegian ships and mobile offshore units on or after the dates set out in Appendix IV, and to marine equipment being made available on the market for placement on board EEA ships.

Marine equipment means equipment regulated by Directive 2014/90/EU of the European Parliament and of the Council on marine equipment.

EEA ships means ships flying the flag of an EEA member state, which are subject to the scope of application of relevant Conventions from the International Maritime Organization (IMO).

Amended by Regulations of 10 March 2017 No. 385 (in force on 16 March 2017), 8 September 2017 No. 1442, 13 June 2018 No. 859 (in force on 19 June 2018).

Section 2. *Requirements for marine equipment*

Annex II Chapter XXXII point 3 of the EEA Agreement (Commission Implementing Regulation (EU) 2019/1397) applies as regulation with the adaptations that follow from Annex XIII, Protocol 1 to the Agreement and the Agreement in general.

Marine equipment shall satisfy the design, construction, performance and testing requirements set out in the first paragraph.

Relevant conformity assessments procedures referred to in Appendix II shall be used to demonstrate that the marine equipment satisfies the requirements pursuant to the first paragraph.

Marine equipment satisfying the requirements of this provision shall be wheel-marked.

Amended by Regulations of 10 March 2017 No. 385 (in force on 16 March 2017), 8 September 2017 No. 1442, 13 June 2018 No. 859 (in force on 19 June 2018), 27 September 2019 No. 1276 (in force on 3 October 2019).

Section 3. *Wheel-marking of marine equipment*

The form of the wheel mark shall be in accordance with Appendix I.

The wheel mark shall be affixed visibly, legibly and indelibly to the product or to its data plate. Where relevant, the wheel mark shall be shown in the product's software.

Where affixing pursuant to the second paragraph is not possible on account of the nature of the product, the wheel mark shall be affixed to the packaging and to the accompanying documentation.

The wheel mark shall be affixed at the end of the production phase, along with the year in which the mark is affixed and the identification number of the notified body that has been involved in the quality assurance of the production process.

Section 3a. *Electronic tagging of marine equipment*

The EEA Agreement Annex II Chapter XXXII point 4 (Regulation (EU) 2018/414) on technical criteria for electronic tags for marine equipment and the EEA Agreement Annex II Chapter XXXII point 5 (Regulation (EU) 2018/608) on supplementary provisions to the Ship Equipment Directive regarding the identification of certain ship equipment that may be fitted with electronic tags, shall apply as regulation with the adaptations that follow from Annex XIII Protocol 1 and the Agreement in general.

Added by Regulation of 14 December 2018 No. 1980.

Section 4. ***The manufacturer's responsibilities***

In addition to ensuring that the relevant requirements of Appendix II are satisfied, the manufacturer is responsible for guaranteeing that products to which the wheel mark is affixed are in compliance with section 2, and that the relevant conformity assessment procedure has been carried out. Manufacturer means any person who manufactures marine equipment or has marine equipment designed or manufactured, and markets that equipment under its name or trademark.

The manufacturer shall mark the product with a serial number or similar element that can identify the product. The product shall furthermore be marked with the manufacturer's name or registered trademark and contact address.

Where marking pursuant to the second paragraph is not possible on account of the nature of the product, the information shall be indicated on the packaging or in the accompanying documentation.

The product shall be accompanied by the necessary information for correct installation, proper use and maintenance of the product.

When the manufacturer has reason to believe that a product which is wheel-marked by that manufacturer, is not in conformity with section 2, corrective measures shall be implemented immediately to bring that product into conformity. If necessary, the manufacturer shall recall products that have been placed on the market or on board. Where the product presents a risk, the manufacturer shall immediately inform the Norwegian Maritime Authority.

Manufacturers who are not established in the EEA shall, by a written mandate, appoint an authorised representative who can fulfil the manufacturer's obligations to provide information and documentation and to cooperate with the market surveillance authorities. The representative shall keep declarations of conformity for at least 10 years after the products were wheel-marked, and in no case for a shorter period than the expected life of the products. The manufacturer's responsibility pursuant to the first paragraph cannot be delegated.

Section 5. ***Importers and distributors***

Persons or companies established in the EEA are considered importers if they place marine equipment from a third country on the market in the EEA.

Persons or companies in the supply chain other than the manufacturer or the importer, are considered distributors.

The importer shall ensure that the product is marked with the importer's name or registered trademark and contact address.

Where marking pursuant to the third paragraph is not possible on account of the nature of the product, the information shall be indicated on the packaging and in the accompanying documentation.

An importer or distributor who makes marine equipment available on the market or places such equipment on board under its name or trademark, has the same responsibilities as the manufacturer. The same applies when an importer or distributor modifies products already made available on the market in such a way that compliance with section 2 may be affected.

Amended by Regulation of 13 June 2018 No. 859 (in force on 19 June 2018).

Section 6. ***Conformity assessment procedures***

The manufacturer or the manufacturer's representative shall choose conformity assessment procedures set out in Appendix II. The conformity assessment procedures allowed for the equipment in questions are laid down in section 2.

If module B is used, module D, E or F shall also be used.

Conformity assessments shall be carried out by companies which are designated pursuant to the Act of 16 June 1994 No. 20 relating to Notified Bodies, or which are designated pursuant to other member states' rules for conformity assessment bodies and are published on the European Commission's list of notified bodies.

Amended by Regulations of 10 March 2017 No. 385 (in force on 16 March 2017), 8 September 2017 No. 1442.

Section 7. ***Declaration of conformity***

The manufacturer or the manufacturer's representative shall issue a declaration of conformity in English in accordance with Appendix III.

The manufacturer shall provide a copy of the declaration of conformity to the company and to the notified body or bodies that carried out the conformity assessments.

The company shall keep the declaration of conformity on board the ship or unit where the equipment is placed.

Section 8. ***Market surveillance***

The Norwegian Maritime Authority supervises the compliance with the provisions of these Regulations.

The Norwegian Maritime Authority shall be given access to the manufacturer's premises, and the Norwegian Maritime Authority may instruct the manufacturer to make product samples available for control. When the Norwegian Maritime Authority so requires, manufacturers or their representatives, importers and distributors (economic operators) shall provide all necessary information and documentation in Norwegian or English to demonstrate that a product is in compliance with section 2.

Economic operators shall keep information about other economic operators to whom they have supplied products or who have supplied them with products. The information shall be kept for at least 10 years after the products were wheel-marked, and in no case for a shorter period than the expected life of the products.

Section 9. ***Marine equipment presenting a risk to life, health, the environment or material values***

If any marine equipment is found to present a risk to life, health, the environment or material values, the economic operators are obliged to cooperate with the Norwegian Maritime Authority and to ensure that necessary corrective measures are implemented for equipment placed on the marked and for equipment placed on board.

If any marine equipment is found not to be in compliance with section 2, or when the Norwegian Maritime Authority has reason to believe that a product that is in compliance with section 2, nevertheless presents a risk to life, health, the environment or material values, the Norwegian Maritime Authority may instruct economic operators to implement appropriate corrective measures. If necessary, such instructions may include that products that have been placed on the market or on board, are recalled.

Section 10. ***Formal non-compliance***

If marine equipment does not satisfy the requirements for marking, technical documentation or declaration of conformity pursuant to sections 3, 4 and 7, the Norwegian Maritime Authority may instruct the economic operators to implement corrective measures.

If the economic operators do not implement sufficient corrective measures in accordance with the first paragraph, the Norwegian Maritime Authority may restrict or prohibit the marine equipment being made available on the market, or require the marine equipment to be recalled.

Section 11. ***Exemptions from requirement for wheel-marked equipment for technical innovations***

In the event of technical innovation, the Norwegian Maritime Authority may in exceptional circumstances permit marine equipment which is not wheel-marked, to be placed on board. The company must document, by trial or otherwise, that the safety is properly ensured.

For such equipment, the Norwegian Maritime Authority shall issue a certificate as evidence that the equipment may be placed on board. Restrictions or other conditions relating to the use of the equipment shall be set out in the certificate. The certificate shall be kept on board and shall follow the equipment.

Section 12. ***Exemptions from requirement for wheel-marked equipment for testing and evaluation of equipment***

The Norwegian Maritime Authority may permit marine equipment which is not wheel-marked, and which is not covered by section 11, to be placed on board when the purpose is testing and evaluation of the equipment. Such equipment shall not replace, nor be used in such a way that it may interfere with, equipment required pursuant to section 2.

The Norwegian Maritime Authority shall issue a certificate as evidence that the equipment may be placed on board. Restrictions or other conditions relating to the use of the equipment shall be set out in the certificate. The certificate shall be kept on board, be time-limited and shall follow the equipment.

Section 13. ***Exemptions from requirement for wheel-marked equipment when replacing equipment in a port outside the EEA***

In exceptional circumstances when marine equipment needs to be replaced in a port outside the EEA, and where it would take unreasonably long time or cause unreasonably high costs to obtain wheel-marked equipment, other equipment may be placed on board.

Such equipment shall be accompanied by documentation issued by, or on behalf of, a State which has acceded to the relevant convention or conventions. The documentation shall attest compliance with the requirements of the relevant international conventions.

The company shall inform the Norwegian Maritime Authority at once of the equipment in question and give a description of its characteristics. The company shall furthermore give a detailed description of the circumstances causing such equipment to be placed on board.

The company shall as soon as possible provide the Norwegian Maritime Authority with sufficient documentation, including documentation of testing, to enable the Norwegian Maritime Authority to assess whether the equipment complies with the relevant international conventions.

Section 14. ***Exemptions from requirement for wheel-marked equipment when wheel-marked equipment is not available on the market***

When the company can document that any specific wheel-marked equipment is not available on the market, the Norwegian Maritime Authority may permit other equipment to be placed on board.

The equipment shall comply, as much as possible, with the requirements of section 2, and shall be accompanied by an interim certificate issued by the Norwegian Maritime Authority or by another EEA State. The certificate shall provide information on:

a) the wheel-marked equipment being replaced;

b) the background for and the necessity of the certificate being issued;

c) the design, construction and performance requirements on which the certification is based; and

d) the testing standards applied, if any, for the certification.

Section 15. ***Transfer of a ship to the Norwegian flag***

Ships being transferred to the Norwegian flag from a register outside the EEA shall carry marine equipment required in accordance with the relevant international conventions.

The marine equipment shall be wheel-marked. Compliance with international conventions may alternatively be documented in another equivalent way. For such equipment, the Norwegian Maritime Authority shall issue a certificate. Restrictions or other conditions relating to the use of the equipment shall be set out in the certificate.

Marine equipment not satisfying the requirements of the second paragraph shall be replaced.

Section 16. ***Exemptions***

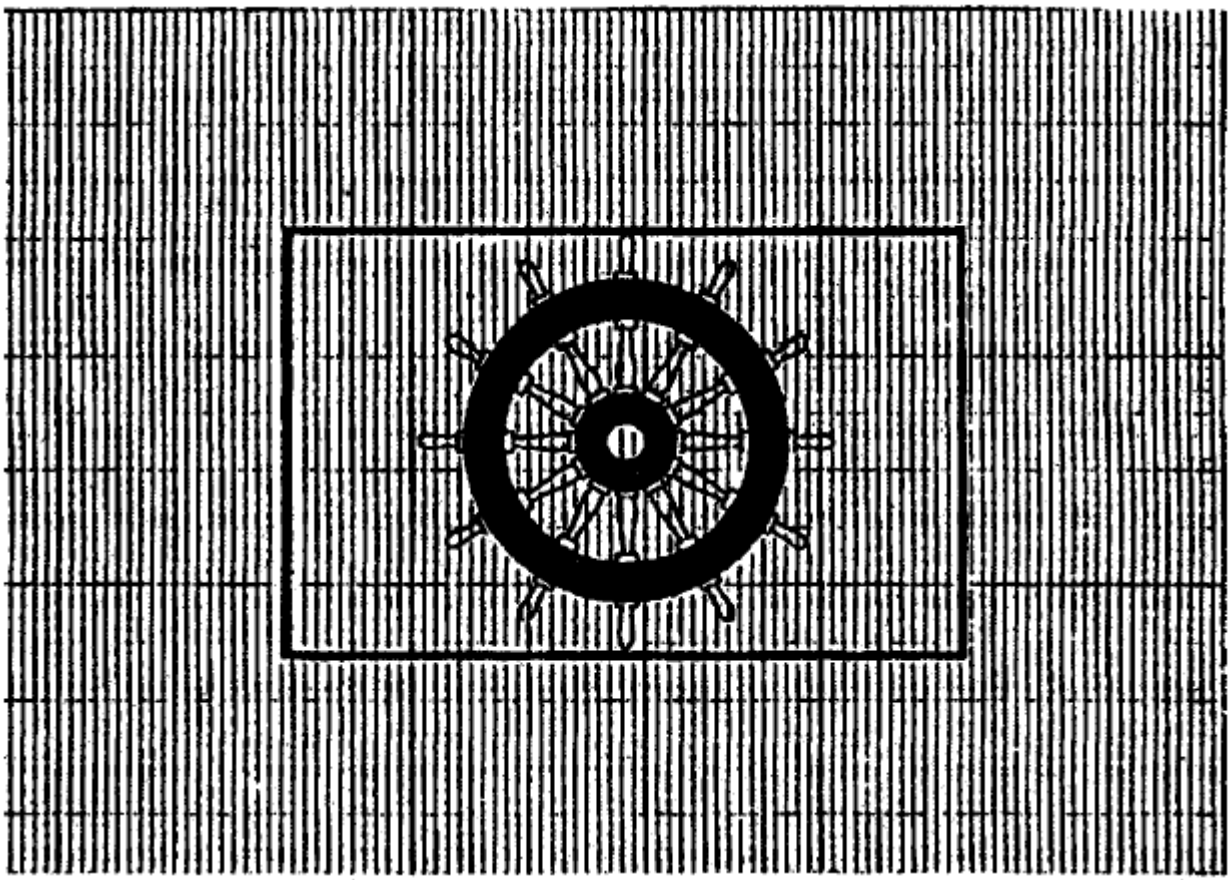
For ships engaged on domestic voyages and mobile offshore units the Norwegian Maritime Authority may, upon written application, grant exemptions from the requirements of these Regulations if it is necessary and justifiable in terms of safety.

Section 17. ***Entry into force***

These Regulations enter into force on 18 September 2016. As from the same date, the Regulations of 29 December 1998 No. 1455 on marine equipment are repealed.

Appendix I
Wheel mark

The mark of conformity must take the following form:



If the wheel mark is reduced or enlarged the proportions given in the graduated drawing must be respected.

The various components of the wheel mark must have substantially the same vertical dimension, which may not be less than 5 mm.

That minimum dimension may be waived for small devices.

Appendix II
Conformity assessment procedures

I. Module B: EC type-examination

1. EC type-examination is the part of a conformity assessment procedure in which a notified body examines the technical design of marine equipment and verifies and attests that the technical design of the marine equipment meets the relevant requirements.

2. EC type-examination may be carried out in either of the following manners:
   - examination of a specimen, representative of the production envisaged, of the complete product (production type);
   - assessment of the adequacy of the technical design of the marine equipment through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the product (combination of production type and design type).

3. The manufacturer shall lodge an application for EC type-examination with a single notified body of its choice.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, its name and address as well;
- a written declaration that the same application has not been lodged with any other notified body;
- the technical documentation. The technical documentation shall make it possible to assess the conformity of the marine equipment with the applicable requirements of the international instruments as referred to in Article 4, 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 marine equipment. The technical documentation shall contain, wherever applicable, at least the following elements:
  a) a general description of the marine equipment;
  b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
  c) descriptions and explanations necessary for the understanding of those drawings and schemes and of the operation of the marine equipment;
  d) 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;
  e) results of design calculations made, examinations carried out,
  f) test reports;
- the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;
- the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on the manufacturer's behalf and under its responsibility.

4. The notified body shall:

For the marine equipment:

4.1 examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the marine equipment;

For the specimen(s):

4.2 verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant requirements and testing standards, as well as the elements which have been designed without applying the relevant provisions of those standards;

4.3 carry out appropriate examinations and tests, or have them carried out, in accordance with this Directive;

4.4 agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 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.

6. Where the type meets the requirements of the specific international instruments that apply to the marine equipment concerned, the notified body shall issue an EC type-examination certificate to the manufacturer. The 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 certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.

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

7. If the approved type no longer complies with the applicable requirements, the notified body shall determine whether further testing or a new conformity assessment procedure is necessary.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EC type-examination certificate of all modifications to the approved type that may affect the conformity of the marine equipment with the requirements of the relevant international instruments or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EC type-examination certificate.

8. Each notified body shall inform its notifying authorities concerning the EC 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 authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

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

9. The manufacturer shall keep a copy of the EC type-examination certificate, its annexes and additions together with the technical documentation 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.

10. The manufacturer’s authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

II. Module D: Conformity to type based on quality assurance of the production process

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on its sole responsibility that the marine equipment concerned is in conformity with the type described in the EC type-examination certificate and that it satisfies the requirements of the international instruments that apply to it.

2. *Manufacturing*

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the products concerned as specified in point 3, and shall be subject to surveillance as specified in point 4.

3. *Quality system*

3.1 The manufacturer shall lodge an application for assessment of its quality system with the notified body of its choice, for the marine equipment concerned.

The application shall include:
- the name and address of the manufacturer and, if the application is lodged by the authorised representative, its name and address as well;
- a written declaration that the same application has not been lodged with any other notified body;
- all relevant information for the marine equipment category envisaged;
- the documentation concerning the quality system;
- the technical documentation of the approved type and a copy of the EC type-examination certificate.

3.2 The quality system shall ensure that the products are in conformity with the type described in the EC type-examination certificate and that they comply with the requirements of the international instruments that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:
- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.; and
- the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.3 The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant marine equipment field and marine equipment technology concerned, and knowledge of the applicable requirements of the international instruments. The audit shall include an assessment visit to the manufacturer’s premises. The auditing team shall review the technical documentation referred to in the fifth indent of point 3.1 in order to verify the manufacturer’s ability to identify the relevant requirements of the international instruments and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

Produsenten skal underrettes om beslutningen. Underretningen skal inneholde konklusjonene av revisjonen og en begrunnelse for beslutningen.

3.4 The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5 The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. *Surveillance under the responsibility of the notified body*

4.1 The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2 The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

- the quality system documentation;
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3 The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system, and shall provide the manufacturer with an audit report.

4.4 In addition, the notified body may pay unexpected visits to the manufacturer, except where, under national law, and for defence or security reasons, certain restrictions apply to such visits. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

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 3.1, the latter’s identification number to each individual product that is in conformity with the type described in the EC type-examination certificate and that satisfies the applicable requirements of the international instruments.

5.2 The manufacturer shall draw up a written declaration of conformity for each product model 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 marine equipment model 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. The manufacturer shall keep at the disposal of the competent 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 documentation referred to in point 3.1;
- the change referred to in point 3.2, as approved;
- the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

8. *Authorised representative*

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by its authorised representative, on its behalf and under its responsibility, provided that they are specified in the mandate.

III. Module E: Conformity to type based on product quality assurance

1. Conformity to type based on product quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on its sole responsibility that the marine equipment concerned is in conformity with the type described in the EC type-examination certificate and that it satisfies the requirements of the international instruments that apply to it.

2. *Manufacturing*

The manufacturer shall operate an approved quality system for final product inspection and testing of the products concerned as specified in point 3, and shall be subject to surveillance as specified in point 4.

3. *Quality system*

3.1 The manufacturer shall lodge an application for assessment of its quality system with the notified body of its choice, for the marine equipment concerned.

The application shall include:
- the name and address of the manufacturer and, if the application is lodged by the authorised representative, its name and address as well;
- a written declaration that the same application has not been lodged with any other notified body;
- all relevant information for the marine equipment category envisaged;
- the documentation concerning the quality system; and
- the technical documentation of the approved type and a copy of the EC type-examination certificate.

3.2 The quality system shall ensure compliance of the products with the type described in the EC type-examination certificate and with the applicable requirements of the international instruments.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:
- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- the examinations and tests that will be carried out after manufacture;
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;
- the means of monitoring the effective operation of the quality system.

3.3 The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant marine equipment field and marine equipment technology concerned, and knowledge of the applicable requirements of the international instruments. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in the fifth indent of point 3.1, in order to verify the manufacturer's ability to identify the relevant requirements of the international instruments and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4 The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5 The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. *Surveillance under the responsibility of the notified body*

4.1 The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2 The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

- the quality system documentation;
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3 The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system, and shall provide the manufacturer with an audit report.

4.4 In addition, the notified body may pay unexpected visits to the manufacturer, except where, under national law, and for defence or security reasons, certain restrictions apply to such visits. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

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 3.1, the latter's identification number to each individual product that is in conformity with the type described in the EC type-examination certificate and that satisfies the applicable requirements of the international instruments.

5.2 The manufacturer shall draw up a written declaration of conformity for each product model 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 marine equipment model 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. The manufacturer shall keep at the disposal of the competent 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 documentation referred to in point 3.1;
- the change referred to in point 3.5, as approved;
- the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

8. *Authorised representative*

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by its authorised representative, on its behalf and under its responsibility, provided that they are specified in the mandate.

IV. Module F: Conformity to type based on product verification

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5.1 and 6, and ensures and declares on its sole responsibility that the products concerned, which have been subject to the provisions of point 3, are in conformity with the type described in the EC type-examination certificate and that they satisfy the requirements of the international instruments that apply to them.

2. *Manufacturing*

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the EC type-examination certificate and with the requirements of the international instruments that apply to them.

3. *Verification*

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests in order to check the conformity of the products with the approved type described in the EC type-examination certificate and with the appropriate requirements of the international instruments.

The examinations and tests to check the conformity of the products with the appropriate requirements shall be carried out, at the choice of the manufacturer, either by examination and testing of every product as specified in point 4 or by examination and testing of the products on a statistical basis as specified in point 5.

4. *Verification of conformity by examination and testing of every product*

4.1 All products shall be individually examined and tested in accordance with this Directive, in order to verify conformity with the approved type described in the EC type-examination certificate and with the appropriate requirements of the international instruments.

4.2 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 each approved product or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by 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.

5. *Statistical verification of conformity*

5.1 The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and shall present its products for verification in the form of homogeneous lots.

5.2 A random sample shall be taken from each lot. All products in a sample shall be individually examined and tested in accordance with this Directive, in order to ensure their conformity with the applicable requirements of the international instruments and to determine whether the lot is accepted or rejected.

5.3 If a lot is accepted, all products of the lot shall be considered approved, except for those products from the sample that have been found not to satisfy the tests.

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

5.4 If a lot is rejected, the notified body or the competent authority shall take appropriate measures to prevent that lot being placed on the market. In the event of the frequent rejection of lots, the notified body may suspend the statistical verification and take appropriate measures.

6. *Conformity marking and declaration of conformity*

6.1 The manufacturer shall affix the wheel mark referred to in Article 9, and, under the responsibility of the notified body referred to in point 3, the latter’s identification number to each individual product that is in conformity with the approved type described in the EC type-examination certificate and that satisfies the applicable requirements of the international instruments.

6.2 The manufacturer shall draw up a written declaration of conformity for each product model 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 marine equipment model for which it has been drawn up.

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

7. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body’s identification number to the products during the manufacturing process.

8. *Authorised representative*

The manufacturer's obligations may be fulfilled by its authorised representative, on its behalf and under its responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 2 and 5.1.

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 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.

Appendix III
EC DECLARATION OF CONFORMITY

1. No . . . (unique identification of the product):
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):
4. Object of the declaration (identification of product allowing traceability. It may include a photograph, where appropriate):
5. The object of the declaration described above is in conformity with the relevant Community harmonisation legislation: . . . . . .
6. References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared:
7. Where applicable, the notified body . . . (name, number) . . . performed . . . (description of intervention) ... and issued the certificate: . . .
8. Additional information:

Signed for and on behalf of: . . . . . .
(place and date of issue):
(name, function) (signature):

Appendix IV

Amended by Regulation of 13 June 2018 No. 859 (in force on 19 June 2018).

Where indicated in the table, equipment within the applicable equipment group shall be wheel-marked, when such equipment is placed on board vessels as referred to in the left column								
X = Equipment within the relevant category shall be wheel-marked	*Date of placement on board*	**I. Life-saving appliances**	**II. Marine pollution prevention** (see separate table below)	**III. Fire protection equipment**	**IV. Navigation equipment**	**V. Radio-communication equipment**	**VI. Navigation light equipment**	**VII. Water level detecting equipment**
Ships with international safety certificate	On or after 1 January 1999	X		X	X	X	X	**Equipment in group VII shall be wheel-marked when placed on board:** * bulk carriers of ≥500 gross tonnage engaged on foreign voyages * single hold cargo ships of ≥500 gross tonnage engaged on foreign voyages * cargo ships engaged on foreign voyages, of ≥500 gross tonnage and of ≥80 metres in length (L) or of ≥100 metres in length (L) if constructed before 1 July 1998, having one single hold below the freeboard deck or cargo holds below the freeboard deck which do not have at least one watertight bulkhead up to the freeboard deck. * passenger ships certified for >36 pax, engaged on foreign voyages

Where indicated in the table, equipment within the applicable equipment group shall be wheel-marked, when such equipment is placed on board vessels as referred to in the left column								
X = Equipment within the relevant category shall be wheel-marked	*Date of placement on board*	**I. Life-saving appliances**	**II. Marine pollution prevention** (see separate table below)	**III. Fire protection equipment**	**IV. Navigation equipment**	**V. Radio-communication equipment**	**VI. Navigation light equipment**	**VII. Water level detecting equipment**
Cargo ships without international safety certificate	On or after 1 January 2005	X		X	X * Does not apply to equipment voluntarily placed on board	X * Equipment voluntarily placed on board may as an alternative be CE-marked	X	
Passenger ships with passenger certificate	On or after 1 January 2005	X		X	X	X	X	
Passenger ships with Passenger Ship Safety Certificate (EU)	On or after 1 January 2004	X		X	X	X	X	
All high-speed craft	On or after 1 January 1999			X	X	X		
Addition for high-speed craft engaged on domestic voyages	On or after 3 July 2009	X						
All mobile offshore units	On or after 1 January 1999					X	X	
Addition for mobile offshore units	On or after 1 July 2003				X			
Fishing vessels of 15 metres in overall length and upwards	On or after 1 April 2001				X * Does not apply to equipment voluntarily placed on board	X * Equipment voluntarily placed on board may as an alternative be CE-marked	X	

Fishing vessels of 15 metres in overall length and upwards	On or after 1 January 2003	X						
Fishing vessels of less than 15 metres in overall length	On or after 1 January 2014	X * Vessels with a crew of ≤3 may have a liferaft in acc. with ISO-9650-1 (group A)		X * Applies only to portable fire extinguishers (transitional arrangement for vessels of OAL < 10,67)				

Ships and mobile offshore units shall have wheel-marked marine equipment for marine pollution prevention as indicated in the table

	II. Marine pollution prevention		
	Equipment A/2.1-2.5	**Equipment A/2.6**	**Equipment A/2.7-2.10**
All ships			X
Ships, GT≥400	X	X	
Oil tankers, GT≥150	X		
Ships cert. for > 15 persons		X	
Mobile offshore units	X	X	X