VERŻJONI ELETTRONIKA

L.N. 428 of 2018

PRODUCT SAFETY ACT
(CAP. 427)

Conformity Assessment of Marine Equipment Regulations (Amendment), 2018

IN EXERCISE of the powers conferred by articles 38 to 40 of the Product Safety Act, the Ministry for Justice, Culture and Local Government, on the advice of the Director General (Technical Regulations), has made the following regulations:-

Citation.

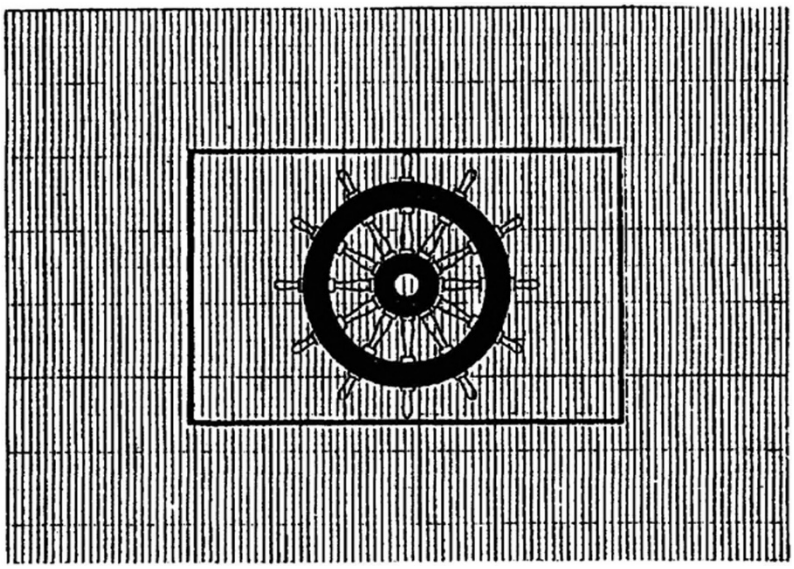
1. The title of these regulations is the Conformity Assessment of Marine Equipment Regulations (Amendment), 2018 and these regulations shall be read and construed as one with the Conformity Assessment of Marine Equipment Regulations hereinafter referred to as "the principal regulations".

S.L. 427.60

Substitutes Schedule I to the principal regulations.

2. Schedule I to the principal regulations shall be substituted by the following:-

"Schedule I
WHEEL MARK



The mark of conformity must take the following form:

VERŻJONI ELETTRONIKA

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.".

Substitutes Schedule II to the principal regulations.

3. Schedule II to the principal regulations shall be substituted by the following:-

"Schedule 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

VERŻJONI ELETTRONIKA

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 regulation 5, 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 these regulations, together with a description of the solutions adopted to meet those requirements;

(e) results of design calculations made, examinations carried out, etc.; and

(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

VERŻJONI ELETTRONIKA

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 these regulations;

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.

VERŻJONI ELETTRONIKA

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.

VERŻJONI ELETTRONIKA

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;

VERŻJONI ELETTRONIKA

— 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.

VERŻJONI ELETTRONIKA

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;

VERŻJONI ELETTRONIKA

—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 regulation 7, 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:

VERŻJONI ELETTRONIKA

—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, 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

The manufacturer shall lodge an application for assessment of its quality system with the notified body of its choice, for

VERŻJONI ELETTRONIKA

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

VERŻJONI ELETTRONIKA

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

VERŻJONI ELETTRONIKA

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 regulation 7, 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

VERŻJONI ELETTRONIKA

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

VERŻJONI ELETTRONIKA

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 these regulations, 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

VERŻJONI ELETTRONIKA

in a sample shall be individually examined and tested in accordance with these regulations, 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 regulation 7, 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

VERŻJONI ELETTRONIKA

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

VERŻJONI ELETTRONIKA

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 these regulations, 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 these regulations, 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

VERŻJONI ELETTRONIKA

5.1 The manufacturer shall affix the wheel mark referred to in regulation 7 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.;".

4. Schedule III to the principal regulations shall be substituted by the following:- Substitutes Schedule III to the principal regulations.

"Schedule 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 meet the requirements laid down in points 2 to 11.

2. A conformity assessment body shall be established under national law and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the marine equipment which it assesses.

4. A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of marine equipment which it assesses, may, on condition that its independence and the absence of any

VERŻJONI ELETTRONIKA

conflict of interest are demonstrated, be considered a conformity assessment body.

5. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the marine equipment which is assessed, nor the authorised representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes

6. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of that marine equipment, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall apply, in particular, to consultancy services.

7. Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

8. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly of a financial nature, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

9. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it under these regulations and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

VERŻJONI ELETTRONIKA

10. At all times and for each conformity assessment procedure and each kind, category or sub-category of marine equipment in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency of those procedures and the possibility of reproducing them. It shall have in place appropriate policies and procedures that distinguish between tasks that it carries out as a notified body and other activities;

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the marine equipment technology in question and the mass or serial nature of the production process.

11. A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner, and shall have access to all necessary equipment and facilities.

12. The personnel responsible for carrying out conformity assessment activities shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the applicable requirements and testing standards and of the relevant provisions of Union legislation on

VERŻJONI ELETTRONIKA

harmonisation and of the regulations implementing that legislation;

(d)the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

13. The impartiality of the conformity assessment bodies, of their top-level management and of the assessment personnel shall be guaranteed.

14. The remuneration of the top-level management and of the assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

15. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

16. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under these regulations or pursuant to any provision of national law giving effect to it, except in relation to the competent authorities of the Member States in which its activities are carried out. Proprietary rights shall be protected.

17. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established these regulations, and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

18. Conformity assessment bodies shall meet the requirements of standard EN ISO/IEC 17065:2012.

19. Conformity assessment bodies shall ensure that testing laboratories used for conformity assessment purposes meet the requirements of standard EN ISO/IEC 17025:2005.".

Substitutes Schedule IV to the principal regulations.

5. Schedule IV to the principal regulations shall be substituted by the following:-

"Schedule IV

VERŻJONI ELETTRONIKA

NOTIFICATION PROCEDURE

1. Application for notification

1.1 A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

1.2 That application shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the marine equipment for which that body claims to be competent, as well as by an accreditation certificate, issued by the National Accreditation Board (Malta) attesting that the conformity assessment body fulfils the requirements laid down in Schedule III

1.3 Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Schedule III.

2. Notification procedure

2.1 Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Schedule III.

2.2 They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

2.3 The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and marine equipment concerned and the relevant attestation of competence.

2.4 Where a notification is not based on an accreditation certificate as referred to in section 1, the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body’s competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in

VERŻJONI ELETTRONIKA

Schedule III.

2.5 The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

2.6 Only a body referred to in point 2.5 shall be considered a notified body for the purposes of these regulations.

2.7 The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

3. Identification numbers and lists of notified bodies

3.1 The Commission shall assign an identification number to a notified body.

3.2 It shall assign a single such number even where the notified body is recognized as notified under several legislative acts of the Union.

3.3 The Commission shall make publicly available the list of the bodies notified under these regulations, including the identification numbers that have been allocated to them and the activities for which they have been notified.

3.4 The Commission shall ensure that that list is kept up to date.".

Substitutes Schedule V to the principal regulations.

6. Schedule V to the principal regulations shall be substituted by the following:-

"Schedule V
REQUIREMENTS TO BE MET BY NOTIFYING AUTHORITIES

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated in such a way as to safeguard the objectivity and impartiality of its activities.

VERŻJONI ELETTRONIKA

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide, on a commercial or competitive basis, any activities that conformity assessment bodies perform or any consultancy services.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.".

Ippubblikat mid-Dipartiment tal-Informazzjoni (doi.gov.mt) — Valletta — ***Published by the Department of Information (doi.gov.mt) — Valletta***
Mitbugħ fl-Istamperija tal-Gvern fuq karta FSC — ***Printed at the Government Printing Press on FSC certified paper***

Prezz/*Price*
€1.17