SUBSIDIARY LEGISLATION 427.60

CONFORMITY ASSESSMENT OF MARINE EQUIPMENT REGULATIONS

18th September, 2016*

LEGAL NOTICE 275 of 2016,as amended by Legal Notices 428 of 2018 and 53 of 2022.

Citation and scope.

1. (1) The title of these regulations is the Conformity Assessment of Marine Equipment Regulations.

(2) These regulations transpose the conformity assessment procedures of Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC.

(3) The objective of these regulations is to enhance safety at sea and to prevent marine pollution through the uniform application of the relevant international instruments relating to marine equipment to be placed on board EU ships, and to ensure the free movement of such equipment within the Union.

Commencement.

2. These regulations shall apply as from 18th September 2016.

Applicability.

3. (1) These regulations shall apply to equipment placed or to be placed on board an EU ship and for which the approval of the flag State administration is required by the international instruments, regardless of whether the ship is situated in the Union at the time when it is fitted with the equipment.

(2) Notwithstanding the fact that the equipment referred to in sub-regulation (1) may also fall within the scope of instruments of Union law other than Directive 2014/90/EU, that equipment shall, for the purpose set out in regulation 1(3), be subject only to the national regulations transposing Directive 2014/90/EU.

Definitions.

4. For the purpose of these regulations, the following definitions shall apply:

"accreditation" means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;

"authorised representative" means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks;

"conformity assessment" means the process carried out by the notified bodies, in accordance with regulation 13, demonstrating whether marine equipment complies with the requirements laid down in these regulations;

"conformity assessment body" means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

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* see regulation 2.

"distributor" means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes marine equipment available on the market;

"economic operators" means the manufacturer, the authorised representative, the importer and the distributor;

"EU declaration of conformity" means a statement issued by the manufacturer in accordance with regulation 14;

"EU ship" means a ship flying the flag of a Member State and falling within the scope of the international conventions;

"importer" means any natural or legal person established within the Union who places marine equipment from a third country on the Union market;

"international conventions" means the following conventions, together with their protocols and codes of mandatory application, adopted under the auspices of the International Maritime Organization (IMO), which have entered into force and which lay down specific requirements for the approval by the flag State of equipment to be placed on board ships:

- the 1972 Convention on the International Regulations for Preventing Collisions at Sea (Colreg);
- the 1973 International Convention for the Prevention of Pollution from Ships (Marpol);
- the 1974 International Convention for the Safety of Life at Sea (Solas);

"international instruments" means the international conventions, together with the resolutions and circulars of the IMO giving effect to those conventions in their up-to-date version, and the testing standards;

"making available on the market" means any supply of marine equipment on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

"manufacturer" means any natural or legal person who manufactures marine equipment or has marine equipment designed or manufactured, and markets that equipment under its name or trademark;

"marine equipment" means equipment falling within the scope of these regulations in accordance with regulation 3;

"national accreditation body" means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;

"National Accreditation Board (Malta)" means the National Accreditation Board (Malta) established in terms of regulation 3 of the National Accreditation Board (Malta) (Establishment) Regulations; S.L. 419.07

"notified body" means an organisation designated by the Technical Regulations Division in accordance with regulation 15(1);

"placed on board" means installed or placed on board a ship;

"placing on the market" means the first making available of marine equipment on the Union market;

"product" means an item of marine equipment;

"recall" means any measure aimed at achieving the return of marine equipment that has already been placed on board EU ships or purchased with the intention of being placed on board EU ships;

"testing standards" means the testing standards for marine equipment set by:

- the International Maritime Organization (IMO);
- the International Organization for Standardization (ISO);
- the International Electrotechnical Commission (IEC);
- the European Committee for Standardization (CEN);
- the European Committee for Electrotechnical Standardization (Cenelec);
- the International Telecommunication Union (ITU);
- the European Telecommunications Standards Institute (ETSI);
- the Commission; in accordance with Article 8 and Article 27(6) of Directive 2014/90/EU;
- the regulatory authorities recognised in the mutual recognition agreements to which the Union is a party;

"Registrar-General" has the same meaning as is assigned to it by article 2 of the Merchant Shipping Act; Cap. 234.

"Technical Regulations Division" means the Technical Regulations Division within the Malta Competition and Consumer Affairs Authority as established by the Malta Competition and Consumer Affairs Authority Act;

"Union" means the European Union;

"wheel mark" means the symbol referred to in regulation 7 and set out in Schedule I or, as appropriate, the electronic tag referred to in regulation 9;

"withdrawal" means any measure aimed at preventing marine equipment in the supply chain from being made available on the market.

Requirements for marine equipment.

5. (1) Marine equipment that is placed on board an EU ship on or after 18th September 2016 shall meet the design, construction and performance requirements of the international instruments as applicable at the time when that equipment is placed on board.

(2) Compliance of marine equipment with the requirements referred to in sub-regulation (1) shall be demonstrated solely in accordance with the testing standards and by means of the conformity assessment procedures referred to in regulation 13.

(3) The international instruments shall apply, without prejudice to the conformity checking procedure set out in Article 5 of Regulation (EC) No 2099/2002 of the European Parliament and of

the Council.

(4) The requirements and standards referred to in sub-regulations (1) and (2) shall be implemented in a uniform manner, in accordance with Article 35(2) of Directive 2014/90/EU.

(5) Without prejudice to sub-regulation (4), until the implementing acts referred to in Article 35(2) of Directive 2014/90/EU are published by the European Commission, the requirements and testing standards stipulated in Annex A of Directive 96/98/EC of 20 December 1996 on marine equipment shall remain applicable.

Functioning of the EU internal market.

6. The Technical Regulations Division and the Registrar-General shall not prohibit the placing on the market or the placing on board an EU ship of marine equipment which complies with these regulations.

The wheel mark.

7. (1) Marine equipment the compliance of which with the requirements laid down in these regulations has been demonstrated in accordance with the relevant conformity assessment procedures shall have the wheel mark affixed to it.

(2) The wheel mark shall not be affixed to any other product.

(3) The form of the wheel mark to be used shall be as set out in Schedule I.

(4) Use of the wheel mark shall be subject to the general principles set out in paragraphs 1 and 3 to 6 of Article 30 of Regulation (EC) No 765/2008, where any reference to the CE marking shall be construed as a reference to the wheel mark.

Rules and conditions for affixing the wheel mark.

8. (1) The wheel mark shall be affixed visibly, legibly and indelibly to the product or to its data plate and, where relevant, embedded in its software. Where that is not possible or not warranted on account of the nature of the product, it shall be affixed to the packaging and to the accompanying documents.

(2) The wheel mark shall be affixed at the end of the production phase.

(3) The wheel mark shall be followed by the identification number of the notified body, where that body is involved in the production control phase, and by the year in which the mark is affixed.

(4) The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or the manufacturer's authorised representative.

Electronic tag.

9. (1) In order to facilitate market surveillance and prevent the counterfeiting of specific items of marine equipment, identified by means of delegated acts issued in accordance with Article 37 of Directive 2014/90/EU by the European Commission, manufacturers may use an appropriate and reliable form of electronic tag instead of, or in addition to, the wheel mark. In such a case, regulations 7 and 8 shall, *mutatis mutandis*, apply, as appropriate.

(2) For the specific items of marine equipment referred to in sub-regulation (1), the wheel mark may, within three years after the date of adoption of the appropriate technical criteria referred to in Article 11(4) of Directive 2014/90/EU, be supplemented by an appropriate and reliable form of electronic tag.

(3) For the specific items of marine equipment referred to in sub-regulation (1), the wheel mark may, five years after the date of adoption of the appropriate technical criteria referred to in Article 11(4) of Directive 2014/90/EU, be replaced by an appropriate and reliable form of electronic tag.

Obligations of manufacturers.

10. (1) By affixing the wheel mark, manufacturers shall take on responsibility for guaranteeing that the marine equipment to which the mark is affixed has been designed and manufactured in accordance with the technical specifications and standards referred to in regulation 5 and shall assume the obligations laid down in sub-regulations (2) to (9).

(2) Manufacturers shall draw up the required technical documentation and have the applicable conformity assessment procedures carried out.

(3) Where the compliance of marine equipment with the applicable requirements has been demonstrated by the conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity in accordance with regulation 14 and affix the wheel mark in accordance with regulations 7 and 8.

(4) Manufacturers shall keep the technical documentation and the EU declaration of conformity referred to in regulation 14 for at least ten years after the wheel mark has been affixed and in no case for a period shorter than the expected life of the marine equipment concerned.

(5) Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in marine equipment design or characteristics and changes in the requirements in the international instruments as referred to in regulation 5, on the basis of which conformity of marine equipment is declared, shall be taken into account. When necessary in accordance with Schedule II, manufacturers shall have a new conformity assessment carried out.

(6) Manufacturers shall ensure that their products bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product or both, as appropriate.

(7) Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product or both, as appropriate. The address must indicate a single point at which the manufacturer can be contacted.

(8) Manufacturers shall ensure that the product is accompanied by instructions and all necessary information for safe installation

on board and safe use of the product, including limitations of use, if any, that can be easily understood by the users, together with any other documentation required by the international instruments or testing standards.

(9) Manufacturers who consider or have reason to believe that a product to which they have affixed the wheel mark is not in conformity with the applicable design, construction and performance requirements and with the testing standards referred to in regulation 5, shall immediately take the necessary corrective measures to bring that product into conformity, to withdraw it or to recall it, if appropriate. In addition, where the product presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States, giving details, in particular, of the non-compliance and of any corrective measures taken.

(10) Manufacturers shall, further to a reasoned request from a competent authority, promptly provide it with all the information and documentation necessary to demonstrate the conformity of the product, in a language which can be easily understood by or is acceptable to that authority, grant that authority access to their premises for market surveillance purposes in accordance with Article 19 of Regulation (EC) No 765/2008 and provide samples or access to samples in accordance with regulation 17(4). They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

Authorised representatives.

11. (1) A manufacturer who is not located in the territory of at least one Member State shall, by a written mandate, appoint an authorised representative for the Union and shall indicate in the mandate the name of the authorised representative and the address at which it can be contacted.

(2) Fulfilment of the obligations laid down in regulation 10(1) and the drawing-up of technical documentation shall not form part of the authorised representative's mandate.

(3) An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(*a*) keep the EU declaration of conformity and the technical documentation at the disposal of national surveillance authorities for at least ten years after the wheel mark has been affixed and in no case for a period shorter than the expected life of the marine equipment concerned;

(*b*) further to a reasoned request from a competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a product;

(*c*) cooperate with the competent authorities, at their request, on any action taken to eliminate the risks

posed by products covered by its mandate.

Other economic operators.

12. (1) Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product or both, as appropriate.

(2) Importers and distributors shall, further to a reasoned request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product in a language which can be easily understood by, or is acceptable to, that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market. The competent authorities for products imported into Malta shall be the Technical Regulations Division and the Registrar-General and the necessary information documentation shall be provided to such authorities in at least the Maltese or the English language.

(3) An importer or distributor shall be considered a manufacturer for the purposes of these regulations and shall be subject to the obligations of the manufacturer under regulation 10, where it places marine equipment on the market or on board an EU ship under its name or trademark or modifies marine equipment already placed on the market in such a way that compliance with the applicable requirements may be affected.

(4) For a period of at least ten years after the wheel mark has been affixed and in no case for a period shorter than the expected life of the marine equipment concerned, economic operators shall, on request, identify the following to the market surveillance authorities, which in Malta are the Technical Regulations Division and the Registrar-General:

(*a*) any economic operator who has supplied them with a product;

(*b*) any economic operator to whom they have supplied a product.

Conformity assessment procedures.

13. (1) The conformity assessment procedures shall be as set out in Schedule II.

(2) The Technical Regulations Division, in collaboration with the Registrar-General, shall ensure that the manufacturer or the manufacturer's authorised representative has the conformity assessment carried out, through a notified body, for a specific item of marine equipment, by using one of the options provided by means of implementing acts adopted by the Commission in accordance with the examination procedure referred to in Article 38(2) of Directive 2014/90/EU, from among one of the following procedures:

(*a*) where the EC type-examination (module B) is to be used, before being placed on the market, all marine equipment shall be subject to:

(i) production-quality assurance (module D); or

(ii) product-quality assurance (module E); or

(iii) product verification (module F);

(*b*) where sets of marine equipment are produced individually or in small quantities and not in series or in mass, the conformity assessment procedure may be the EC unit verification (module G).

EU declaration of conformity.

14. (1) The EU declaration of conformity shall state that the fulfilment of the requirements laid down in accordance with regulation 5 has been demonstrated.

(2) The EU declaration of conformity shall follow the model structure set out in Annex III to Decision No 768/ 2008/EC. It shall contain the elements specified in the relevant modules set out in Schedule II and shall be kept up to date.

(3) By drawing up the EU declaration of conformity, the manufacturer shall assume the responsibility and the obligations referred to in regulation 10(1).

(4) A copy of the EU declaration of conformity shall be provided to the notified body or to the bodies which carried out the relevant conformity assessment procedures.

Notification of conformity assessment bodies.

15. (1) The Technical Regulations Division shall, by means of the information system made available by the European Commission for that purpose, notify the European Commission and the other Member States of bodies authorised to carry out conformity assessment tasks under these regulations.

(2) The Technical Regulations Division shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies for the purposes of these regulations, and for the monitoring of notified bodies, including compliance with regulations 16(2) to (5).

(3) Notified bodies shall be monitored at least every two years.

(4) The assessment and monitoring referred to in sub-regulation (2) shall be carried out by the National Accreditation Board (Malta).

(5) The Technical Regulations Division shall take full responsibility for the tasks performed by National Accreditation Board (Malta) and referred to in sub-regulation (4).

(6) The Technical Regulations Division shall comply with the requirements laid down in Schedule V.

(7) The Technical Regulations Division shall, by means of the information system made available by the Commission for that purpose, notify the Commission and the other Member States of bodies authorised to carry out conformity assessment tasks under these regulations.

(8) Where the Technical Regulations Division has ascertained, or has been informed, that a notified body no longer meets the requirements laid down in Schedule III, or that it is failing to fulfil its obligations under these regulations, the Technical Regulations

Division shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall, by means of the information system made available by the European Commission for that purpose, immediately inform the European Commission and the other Member States accordingly.

(9) In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the Technical Regulations Division shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available to the responsible notifying and market surveillance authorities, at their request.

(10) The Technical Regulations Division shall provide the European Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

Requirements for notified bodies.

16. (1) Notified Bodies shall comply with the requirements laid down in Schedule III.

(2) Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Schedule III and shall inform the Technical Regulations Division accordingly.

(3) Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

(4) Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

(5) Notified bodies shall keep at the disposal of the Technical Regulations Division the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by such subcontractor or subsidiary under these regulations.

(6) Notified bodies shall carry out conformity assessments or have them carried out in accordance with the procedures provided for in regulation 13.

(7) Where a notified body finds that the obligations laid down in regulation 10 have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures without delay and shall not issue a conformity certificate.

(8) Where, in the course of monitoring conformity following the issue of a conformity certificate, a notified body finds that a product no longer complies, it shall require the manufacturer to take appropriate corrective measures without delay and shall suspend or withdraw the certificate if necessary. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw the certificate, as appropriate.

(9) Notified bodies shall inform the Technical Regulations Division of the following:

(*a*) any refusal, restriction, suspension or withdrawal of a conformity certificate;

(*b*) any circumstances affecting the scope of, and the conditions for, notification;

(*c*) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(*d*) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

(10) Notified bodies shall provide the European Commission and the Member States, on request, with relevant information concerning issues relating to negative and positive conformity assessment results. Notified bodies shall provide the other notified bodies carrying out conformity assessment activities covering the same products with information concerning negative and, on request, positive conformity assessment results.

(11) Notified bodies shall participate, directly or by means of designated representatives, in the appropriate coordination and cooperation groups for notified bodies organised by the European Commission.

Market surveillance.

17. (1) As regards marine equipment, the Technical Regulations Division and the Registrar-General shall undertake market surveillance in accordance with the EU market surveillance framework laid down in Chapter III of Regulation (EC) No 765/2008, subject to sub-regulations (2) and (3).

(2) Market surveillance infrastructures and programmes shall take into account the specific features of the marine equipment sector, including the various procedures carried out as part of the conformity assessment, and in particular the responsibilities placed on the flag State administration by the international conventions.

(3) Market surveillance may include documentary checks as well as checks of marine equipment which bears the wheel mark, whether or not it has been placed on board ships. Checks of marine equipment already placed on board shall be limited to such examination as can be carried out while the equipment concerned remains fully functional on board.

(4) Where the Technical Regulations Division and the Registrar-General intend to carry out sample checks, they may, when it is reasonable and practicable to do so, request the manufacturer to make the necessary samples available or to give on-the-spot access to the samples at the manufacturer's own cost.

(5) Where the Technical Regulations Division and, or the Registrar-General has sufficient reasons to believe that marine equipment covered by these regulations presents a risk to maritime safety, to health or to the environment, they shall carry out an

evaluation in relation to the marine equipment concerned covering all relevant requirements laid down in these regulations. The relevant economic operators shall cooperate as necessary with the Technical Regulations Division and, or the Registrar-General.

(6) Where, in the course of that evaluation, the Technical Regulations Division and, or the Registrar-General find that the marine equipment does not comply with the requirements laid down in these regulations, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the marine equipment into compliance with those requirements, to withdraw the marine equipment from the market, or to recall it within such reasonable period, commensurate with the nature of the risk, as they may prescribe.

(7) The Technical Regulations Division and, or the Registrar-General shall inform the relevant notified body accordingly.

(8) Article 21 of Regulation (EC) No 765/2008 shall apply to the measure referred to in sub-regulation (6).

(9) Where the Technical Regulations Division and, or the Registrar-General considers that non-compliance is not restricted to the Maltese territory or to ships flying the Maltese flag, they shall inform the European Commission and the other Member States, by means of the information system made available by the European Commission for market surveillance purposes, of the results of the evaluation carried out under sub-regulations (5) to (8) and of the actions which they have required the economic operator to take.

(10) The economic operator shall ensure that all appropriate corrective action is taken in respect of all the products concerned that it has made available on the market throughout the Union or, as the case may be, placed or delivered to be placed on board EU ships.

(11) Where the relevant economic operator does not take adequate corrective action within the period prescribed by the Technical Regulations Division and, or the Registrar-General in accordance with sub-regulation (6), or otherwise fails to meet its obligations under these regulations, the Technical Regulations Division and, or the Registrar-General shall take all appropriate provisional measures to prohibit or restrict the marine equipment being made available on the Maltese market or placed on board ships flying the Maltese flag, to withdraw the product from the market or to recall it.

(12) The Technical Regulations Division and, or the Registrar-General shall inform the European Commission and the other Member States, without delay, of those measures.

(13) The information on the measures taken by the Technical Regulations Division and, or the Registrar-General referred to in sub-regulation (11) shall include all available details, in particular the data necessary for the identification of the non-compliant marine equipment, the origin of the product, the nature of the alleged non-compliance and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the economic operator concerned. In particular, the

Technical Regulations Division and, or the Registrar-General shall indicate whether the non-compliance is due to either:

(*a*) failure of the marine equipment to comply with the applicable design, construction and performance requirements as laid down pursuant to regulation 5;

(*b*) non-compliance with the testing standards referred to in regulation 5 during the conformity assessment procedure;

(*c*) shortcomings in those testing standards.

(14) When the procedure under this regulation is initiated by another Member State, the Technical Regulations Division and, or the Registrar-General shall without delay inform the European Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the marine equipment concerned, and, in the event of disagreement with the notified national measure, of their objections.

(15) Where, within four months of receipt of the information concerning the measures taken by the market surveillance authorities, as referred to in sub-regulation (11), no objection has been raised by a Member State or by the European Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

In such cases, the Technical Regulations Division and, or the Registrar-General shall ensure that appropriate restrictive measures in respect of the marine equipment concerned, such as withdrawal of the product from the Maltese market, are taken without delay.

(16) Where, on completion of the procedure set out in sub-regulations (10) and (11), objections are raised against a measure taken by the Technical Regulations Division and, or the Registrar-General, or where the European Commission considers that a national measure may be contrary to European Union legislation, the European Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the European Commission shall decide whether or not the relevant national measure is justified.

If the relevant national measure is considered justified, the Technical Regulations Division and, or the Registrar-General shall take the measures necessary to ensure that the non-compliant marine equipment is withdrawn from the Maltese market, and, where necessary, recalled. They shall inform the European Commission accordingly.

If the relevant national measure is considered unjustified, the national measure shall be withdrawn.

(17) Where, having performed an evaluation under sub-regulation (5), the Technical Regulations Division and, or the Registrar-General find that marine equipment which is in

compliance with these regulations nevertheless presents a risk to maritime safety, to health or to the environment, it shall require the economic operator concerned to take all appropriate measures to ensure that the marine equipment concerned, when placed on the market, no longer presents that risk, to withdraw the marine equipment from the market or to recall it within such reasonable period, commensurate with the nature of the risk, as it may prescribe.

(18) The economic operator shall ensure that corrective action is taken in respect of all the products concerned that it has made available on the market throughout the Union or placed on board EU ships.

(19) The Technical Regulations Division and, or the Registrar-General shall immediately inform the European Commission and the other Member States. The information provided shall include all available details, in particular the data necessary for the identification of the marine equipment concerned, the origin and the supply chain of the marine equipment, the nature of the risk involved and the nature and duration of the national measures taken.

(20) Without prejudice to sub-regulations (5) to (15), where the Technical Regulations Division and, or the Registrar-General make one of the following findings, they shall require the relevant economic operator to put an end to the non-compliance concerned:

(*a*) the wheel mark has been affixed in violation of regulations 7 or 8;

(*b*) the wheel mark has not been affixed;

(*c*) the EU declaration of conformity has not been drawn up;

(*d*) the EU declaration of conformity has not been drawn up correctly;

(*e*) the technical documentation is either not available or not complete;

(*f*) the EU declaration of conformity has not been sent to the ship.

(21) Where the non-compliance referred to in sub-regulation (20) persists, the Technical Regulations Division and, or the Registrar-General shall take all appropriate measures to restrict or to prohibit the marine equipment being made available on the Maltese market or to ensure that it is recalled or withdrawn from the Maltese market.

Penalties.

18. The penalties applicable for the infringement of any of the provisions of these regulations shall be those provided for in Part IV of the Product Safety Act.

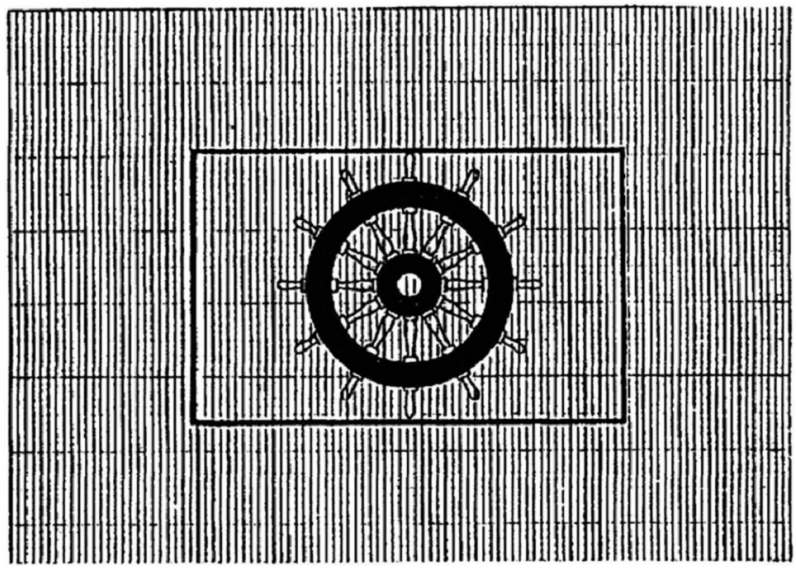
Cap. 427.

Saving. L.N. 241 of 2009.

19. (1) Any references to the Conformity Assessment of Marine Equipment Regulations, 2009, revoked by these regulations, shall be construed as references to these regulations.

(2) Any references in existing laws, regulations and administrative provisions to Directive 96/98/EC shall be construed as references to Directive 2014/90/EU.

Schedule 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.

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 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 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.

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.

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 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:

— 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 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 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:

— 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 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 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 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 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

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.

Amended by:
L.N. 53 of 2022.

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 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.

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 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 17025:2017.

Schedule IV
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 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.

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.

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.