

# Regulations of 15 January 2016 No. 35 on the manufacturing and the placing on the market of recreational craft and personal watercraft

**Legal basis:** Laid down by the Norwegian Maritime Authority on 15 January 2016 under the Act of 11 June 1976 No. 79 relating to the control of products and consumer services (Product Control Act), sections 4 and 8, and the Act of 16 June 1994 No. 20 relating to notified bodies responsible for carrying out conformity assessments, cf. Formal Delegation 7 September 1990 No. 730, Formal Delegation of 9 May 2003 No. 567 and Formal Delegation of 22 September 2003 No. 1924.

**EEA references:** EEA Agreement Annex II Chapter XXXI point 2 (Directive 2013/53/EU) and Annex XX Chapter III No. 21ar (Directive 2001/81/EC).

**Amendments:** Amended by Regulations of 5 April 2017 No. 447 and 8 October 2019 No. 1357.

**Corrections:** 29.01.2016 (section 7 fifth paragraph of Annex 1 point 2.1, table head), 05.02.2016 (Annex 1B, table 3).

## Chapter 1. General provisions

### Section 1. *Scope of application*

(1) These Regulations shall apply to the following products which will be used or made available on the EEA market for sports and leisure purposes:

- a) recreational craft and partly completed recreational craft of hull length from 2.5 m to 24 m;
- b) personal watercraft and partly completed personal watercraft of less than 4 m in hull length;
- c) components placed on the market separately;
- d) propulsion engines for recreational craft and personal watercraft.

(2) These Regulations shall apply to recreational craft, personal watercraft and propulsion engines that will be subject to a major conversion.

(3) These Regulations shall also apply to recreational craft and personal watercraft used for charter or for sports or leisure training.

### Section 2. *Exemptions*

(1) The design and manufacturing requirements do not apply to:

- a) recreational craft and personal watercraft intended solely for racing, including racing boats and training rowing boats, labelled as such by the manufacturer;
- b) canoes, kayaks, gondolas and pedalos propelled solely by human power;
- c) surfboards designed solely to be propelled by wind and to be operated by a person or persons standing;
- d) surfboards;
- e) experimental watercraft, provided that they will be not made available or used on the EEA market;
- f) watercraft built for own use, provided that they are not subsequently placed on the EEA market during a period of five years from being put into service;
- g) submersibles, air cushion vehicles, hydrofoils;
- h) external combustion steam powered watercraft, fuelled by coal, coke, wood, oil or gas;
- i) amphibious vehicles.

(2) The exhaust and noise emission requirements do not apply to:

- a) propulsion engines which are installed or specifically intended for installation on the following products:
  - i) recreational craft or personal watercraft intended solely for racing and labelled as such by the manufacturer;
  - ii) experimental watercraft, provided that they are not subsequently placed on the EEA market;

- iii) submersibles, air cushion vehicles, hydrofoils;
  - iv) amphibious vehicles;
  - b) propulsion engines or watercraft built for own use, provided that they are not subsequently placed on the EEA market during a period of five years from being put into service.
- (3) These Regulations shall not apply to:
- a) original historical recreational craft or personal watercraft and individual replicas thereof designed before 1950, built predominantly with the original materials and labelled as such by the manufacturer;
  - b) original and individual replicas of historical propulsion engines, which are based on a pre-1950 design, not produced in series and fitted on recreational craft or personal watercraft referred to in the first paragraph (f) or third paragraph (a).

### Section 3. Definitions

For the purposes of these Regulations, the following definitions shall apply:

- a) *placing on the market* means the first making available of a product on the EEA market;
- b) *distributor* means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the EEA market;
- c) *watercraft built for own use* means a recreational craft or personal watercraft predominantly built by its future user for his or her own use;
- d) *means of propulsion* means the method by which the recreational craft or personal watercraft is propelled;
- e) *propulsion engine* means any spark or compression ignition, internal combustion engine used directly or indirectly for propulsion purposes;
- f) *making available on the market* means any supply of a product for distribution, consumption or use on the EEA market in the course of a commercial activity, whether in return for payment or free of charge;
- g) *importer* means any natural or legal person established within the EEA who places a product manufactured outside the EEA on the EEA market;
- h) *economic operators* means the manufacturer, the representative, the importer and the distributor;
- i) *engine family* means the manufacturer's grouping of engines which, through their design, have similar exhaust and noise emission characteristics;
- j) *private importer* means any natural or legal person established within the EEA who imports in the course of a non-commercial activity a product manufactured outside the EEA into the EEA with the intention of putting it into service for his own use;
- k) *manufacturer* means any natural or legal person who manufactures a product or has such a product designed or manufactured, and markets that product under his or her name or trademark;
- l) *conformity assessment* means the process demonstrating whether the requirements of these Regulations relating to a product have been fulfilled;
- m) *major craft conversion* means a conversion which
  1. changes the means of propulsion of the recreational craft or personal watercraft;
  2. involves a major engine modification; or

3. alters the recreational craft or personal watercraft to such an extent that it may not meet the applicable essential safety and environmental requirements laid down in these Regulations;
- n) *major engine modification* means the modification of a propulsion engine which could potentially cause the engine to exceed the emission limits set out in Part B of Annex 1 or increases the rated power of the engine by more than 15%;
- o) *hull length* means the length of the hull measured in accordance with the harmonised standard;
- p) *putting into service* means the first use of a product in the EEA by its end-user;
- q) *notified body* means an independent body designated pursuant to the Act of 16 June 1994 No. 20 relating to notified bodies that performs conformity assessment activities, including calibration, testing, certification and inspection of products manufactured by others;
- r) *recall* means any measure aimed at achieving the return of a product that has already been made available to the end-user;
- s) *withdrawal* means any measure aimed at preventing a product in the supply chain from being made available on the market;
- t) *personal watercraft* means a watercraft intended for sports and leisure purposes of less than 4 m in hull length which uses a propulsion engine having a water jet pump as its primary source of propulsion and designed to be operated by a person or persons sitting, standing or kneeling on the hull.

#### **Section 4. Essential requirements**

- (1) The products referred to in section 1 may be made available or put into service only if they
- do not endanger the health and safety of persons, property or the environment when correctly maintained and used in accordance with their intended purpose;
  - meet the applicable essential requirements set out in Annex I.
- (2) The requirements of the first paragraph shall be deemed to be satisfied if the product is in conformity with the national standards implementing harmonised standards.

#### **Section 5. The making available on the market or putting into service of products**

- (1) Recreational craft and personal watercraft which are CE marked pursuant to the requirements of these Regulations may be made available on the market or put into service in the EEA in accordance with the declaration referred to in section 8.
- (2) Partly completed recreational craft and personal watercraft may be made available on the market where the manufacturer or the importer declares, in accordance with Annex 3, that the products are intended to be completed by others.
- (3) Components which are CE marked pursuant to the requirements of these Regulations may be made available on the market or put into service in accordance with the declaration referred to in section 8.
- (4) Propulsion engines, whether or not installed in watercraft, which are CE marked pursuant to the requirements of these Regulations, may be made available on the market or put into service in the EEA in accordance with the declaration referred to in section 8.
- (5) The following propulsion engines may be made available on the market or put into service:
- engines installed in recreational craft and personal watercraft and type-approved in accordance with the Regulations of 20 May 2009 No. 544 on machines, which are in compliance with stage III A, stage III B or stage IV emission limits for CI engines used in other applications than propulsion of inland waterway vessels, locomotives and railcars. Installed engines must comply with these Regulations, with the exception of the exhaust emission requirements set out in Part B of Annex 1;

- b) engines installed in recreational craft and personal watercraft and type-approved in accordance with the Regulations on 4 October 1994 No. 918 on technical requirements and approval of vehicles, parts and equipment (Motor Vehicle Regulations). Installed engines must comply with these Regulations, with the exception of the exhaust emission requirements set out in Part B of Annex 1.
- (6) The person adapting the engine referred to the fifth paragraph for installation in recreational craft or personal watercraft shall take account of the data and other information available from the engine manufacturer to ensure that, when installed in accordance with the installation instructions provided by the person adapting the engine, the engine will meet the exhaust emission requirements of the Regulations of 20 May 2009 No. 544 on machines or the Motor Vehicle Regulations, as declared by the engine manufacturer. The person adapting the engine shall declare, as referred to in section 8, the engine will meet the exhaust emission requirements of the Regulations of 20 May 2009 No. 544 on machines or the Motor Vehicle Regulations, as declared by the engine manufacturer, when installed in accordance with the installation instructions.

### **Section 6. *Product exhibition***

Products which do not satisfy the requirements for CE marking pursuant to these Regulations, may be shown at trade fairs, exhibitions, demonstrations and similar events, provided that the exhibitor ensures that the products are clearly marked, indicating that they cannot be made available or put into service.

### **Section 7. *Form and affixing of the CE marking***

- (1) The CE marking shall be affixed by the manufacturer or his or her representative according to Annex 19 before the recreational craft, personal watercraft, components and propulsion engines may be made available on the market or put into service.
- (2) Products bearing the CE marking are presumed to comply with these Regulations and indicate that the manufacturer assumes responsibility for the product's compliance with all requirements set out in these Regulations.
- (3) The CE marking shall be the only marking confirming that the product complies with the requirements of these Regulations. The CE marking shall be affixed visibly, legibly and indelibly.
- (4) On recreational craft and personal watercraft, the CE marking shall be shown on the watercraft builder's plate mounted separately from the watercraft identification number. In the case of a propulsion engine, the CE marking shall be affixed on the engine. In the case of components, where affixing of the CE marking is not possible or not warranted on account of the size or nature of that product, it may be affixed to the packaging and to the accompanying documents.
- (5) The CE marking shall be followed by the identification number of the notified body, where that body is involved in the production control phase or in the post-construction assessment. The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his or her representative, or by the person referred to in section 16 second, third and fourth paragraph.
- (6) The CE marking, and the identification number referred to in the fifth paragraph, may be followed by a pictogram or any other mark indicating a special risk or use.
- (7) The affixing to a product of markings, signs or inscriptions likely to mislead third parties regarding the meaning or form of the CE marking shall be prohibited. Any other marking may be affixed to the product provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.

### **Section 8. *EU declaration of conformity and declaration in accordance with Annex 3***

- (1) The EU declaration of conformity shall state that the product complies with the requirements specified in these Regulations.
- (2) The EU declaration of conformity shall have the model structure set out in Annex 20 to these Regulations, shall contain the elements specified in the relevant modules set out in Annexes 5 to 17, and shall be continuously updated. The declaration shall be written in Norwegian or, if there is no risk of misunderstandings, in Swedish or Danish.

(3) By drawing up the EU declaration of conformity, the manufacturer, private importer or the person adapting the engine referred to in section 5 fifth paragraph, assumes responsibility for the product being in compliance with the Regulations.

(4) The EU declaration of conformity referred to in the third paragraph shall accompany the following products when they are made available on the market or put into service:

- a) recreational craft or personal watercraft;
- b) components when placed on the market separately;
- c) propulsion engines.

(5) The declaration by the manufacturer or the importer set out in Annex 3 for partly completed recreational craft of personal watercraft shall contain the elements specified in that Annex and shall accompany partly completed recreational craft of personal watercraft. The declaration shall be written in Norwegian or, if there is no risk of misunderstandings, in Swedish or Danish.

## **Chapter 2. Obligations of manufacturers, representatives, importers, distributors and private importers**

### **Section 9. *Obligations of manufacturers***

(1) When placing their products on the market, manufacturers shall ensure that the products have been designed and manufactured in accordance with the requirements set out in these Regulations.

(2) Manufacturers shall draw up technical documentation in accordance with section 22 and carry out conformity assessment or have it carried out pursuant to sections 16 to 19 and section 21.

(3) Where compliance of a product with the applicable requirements has been demonstrated, manufacturers shall affix the CE marking to the product, cf. section 7, and draw up a declaration as referred to in section 8.

(4) Manufacturers shall keep the technical documentation and a copy of the declaration as referred to in section 8 for 10 years after the product has been placed on the market.

(5) Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in product design or characteristics and changes in the harmonised standards to which the product's declaration of conformity refers shall be taken into account.

(6) When deemed appropriate with regard to the risks presented by a product, manufacturers shall, to protect the health and safety of consumers:

- a) carry out sample testing of products made available on the market;
- b) investigate, and, if necessary, keep a register of complaints, of non-conforming products and of product recalls, and keep distributors informed of any such monitoring.

(7) Manufacturers shall ensure that their products bear a type, batch or serial number or other element allowing their identification. Where the size or nature of the components does not allow such identification, the required information shall be provided on the packaging or in a document accompanying the product.

(8) Manufacturers shall indicate their name, company or registered trade mark and contact address on the product. For products where that is not possible, the information shall be provided on the packaging or in a document accompanying the product. The address shall indicate a single point at which the manufacturer can be contacted.

(9) Manufacturers shall ensure that the product is accompanied by instructions and safety information in the owner's manual in Norwegian or, if there is no risk of misunderstandings, in Swedish or Danish.

(10) Manufacturers who have reason to believe that a product which they have placed on the market is not in compliance with these Regulations, shall immediately take the necessary corrective measures to bring that product into compliance with the Regulations or, if necessary, to withdraw or recall it.

(11) Where the product presents a risk, manufacturers shall immediately inform the competent national authorities of the EEA Member States in which they made the product available to that effect. In particular, details shall be given of the product's non-compliance and of any corrective measures taken.

(12) Manufacturers shall, further to a reasoned request from the market surveillance authorities, provide them with all the information and documentation necessary to demonstrate the conformity of the product, in a language which can be easily understood by that authority. The manufacturers shall cooperate with that authority, at its request, on any action taken to eliminate the risks associated with products which they have placed on the market.

### **Section 10. *Representative***

(1) Any natural or legal person established within the EEA who has received a written mandate from the manufacturer to act on his or her behalf in relation to specified tasks, may act as representative.

(2) The obligations laid down in section 9 first paragraph and the drawing up of technical documentation shall not form part of the representative's mandate.

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

- a) keep a copy of the declaration as referred to in section 8, and the technical documentation at the disposal of the market surveillance authorities for 10 years after the product has been placed on the market;
- b) further to a reasoned request from the market surveillance authorities, provide them with all the information and documentation necessary to demonstrate a product's compliance with these Regulations;
- c) cooperate with the market surveillance authorities, at their request, on any action taken to eliminate the risks associated with products covered by their mandate.

### **Section 11. *Obligations of importers***

(1) Importers shall place only products that are in compliance with the Regulations on the EEA market.

(2) Before placing a product on the market, importers shall ensure that:

- a) the appropriate conformity assessment procedure has been carried out by the manufacturer;
- b) the manufacturer has drawn up the technical documentation;
- c) products as referred to in section 7 (1) bear the CE marking;
- d) the product is accompanied by the documents required in accordance with section 8 and Annex 1 Part A point 2.5, Part B point 4 and Part C point 2;
- e) the manufacturer has satisfied the requirements set out in section 9 seventh and eighth paragraphs.

(3) Where an importer has reason to believe that a product does not satisfy the requirements set out in these Regulations, he or she shall not place the product on the market until it has been brought into compliance. Where the product presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

(4) Importers shall indicate their name, company or registered trade mark and the contact address on the product. In the case of components where that is not possible, the information shall be provided on the packaging or in a document accompanying the product.

(5) Importers shall ensure that the product is accompanied by instructions and safety information in the owner's manual in Norwegian or, if there is no risk of misunderstandings, in Swedish or Danish.

(6) Importers shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in these Regulations.

(7) When deemed appropriate with regard to the risks presented by a product, importers shall, to protect the health and safety of consumers:

- a) carry out sample testing of products made available on the market;
- b) investigate, and, if necessary, keep a register of complaints, of non-conforming products and of product recalls, and shall keep distributors informed of such monitoring.

(8) Importers who have reason to believe that a product which they have placed on the market is not in compliance with these Regulations shall immediately take the necessary corrective measures to bring that product into compliance with the Regulations or, if necessary, to withdraw or recall it.

(9) Where the product presents a risk, importers shall immediately inform the competent national authorities of the EEA Member States in which they made the product available to that effect. In particular, details shall be given of the product's non-compliance and of any corrective measures taken.

(10) Importers shall, for a period of 10 years after the product has been placed on the market, keep a copy of the declaration as referred to in section 8 and keep the technical documentation available. This documentation shall upon request be made available to the market surveillance authorities.

(11) Importers shall, further to a reasoned request from the market surveillance authorities, provide them with all the information and documentation necessary to demonstrate a product's compliance these Regulations, in a language which can be easily understood by that authority. The importers shall cooperate with that authority, at its request, on any action taken to eliminate the risks associated with products which they have placed on the market.

## **Section 12. *Obligations of distributors***

(1) When making a product available on the market, distributors shall act with due care in relation to the requirements of these Regulations.

(2) Before making a product available on the market, distributors shall verify that:

- a) the product bears the CE marking pursuant to section 7;
- b) the product is accompanied by the documents required in section 8 and section 9 ninth paragraph, cf. Annex 1, Part A point 2.5, Part B point 4 and Part C point 2;
- c) the manufacturer and the importer have complied with the requirements set out in section 9 seventh and eighth paragraph and section 11 fourth paragraph.

(3) Where a distributor has reason to believe that a product is not in compliance with the requirements set out in these Regulations, the product shall not be made available on the market until it has been brought into compliance. Where the product presents a risk, the distributor shall inform the manufacturer or the importer, as well as the market surveillance authorities, to that effect.

(4) Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise the product's compliance with the requirements set out in these Regulations.

(5) Distributors who have reason to believe that a product which they have made available on the market is not in compliance with these Regulations, shall make sure that necessary corrective measures are taken in order to bring that product into compliance with the Regulations or, if necessary, to withdraw or recall it.

(6) Where the product presents a risk, distributors shall immediately inform the competent national authorities of the EEA Member States in which they made the product available on the market to that effect. In particular, details shall be given of the product's non-compliance and of any corrective measures taken.

(7) Distributors shall, further to a reasoned request from the market surveillance authorities, provide them with all the information and documentation necessary to demonstrate the product's compliance with these Regulations. The distributors shall cooperate with that authority, at its request, on any action taken to eliminate the risks associated with products which they have made available on the market.

## **Section 13. *Cases in which obligations of manufacturers apply to importers and distributors***

An importer or distributor shall be considered a manufacturer and shall be subject to the obligations of the manufacturer pursuant to section 9, where the importer or distributor places a product on the market under his or her own name or trademark or modifies a product already placed on the market in such a way that compliance with the requirements of these Regulations may be affected.

## **Section 14. *Obligations of private importers***

(1) If the manufacturer does not fulfil the responsibilities for the compliance of the product with these Regulations, a private importer, before putting the product into service, shall ensure that it has been designed and manufactured in accordance with the requirements set out in these Regulations and shall carry out or fulfil the obligations of the manufacturer or ensure that they are fulfilled, as set out in section 9 second, third, fourth, ninth and eleventh paragraphs.

- (2) If the required technical documentation is not available from the manufacturer, the private importer shall have it drawn up using appropriate expertise.
- (3) The private importer shall ensure that the name and address of the notified body which has carried out the conformity assessment of the product is marked on the product

**Section 15. Identification of manufacturers, representatives, importers and distributors**

- (1) The manufacturer, representative, importer and distributor shall, on request, identify the following to the market surveillance authorities:
- a) any economic operator who has supplied them with a product referred to in section 1;
  - b) any economic operator to whom they have supplied a product.
- (2) Economic operators shall be able to present the information referred to in the first paragraph for a period of 10 years after they have been supplied with the product and for a period of 10 years after they have supplied the product.
- (3) Private importers shall, on request, identify to the market surveillance authorities the economic operators who have supplied them with the product.
- (4) Private importers shall be able to present the information referred to in the third paragraph for a period of 10 years after they have been supplied with the product.

**Chapter 3. Conformity assessment**

**Section 16. Conformity assessment procedures**

- (1) The manufacturer shall apply the procedures set out in the modules referred to in sections 17, 18 and 19 before placing on the market products referred to in section 1 if the manufacturer has not carried out the conformity assessment for the product concerned.
- (2) The private importer shall apply the procedure referred to in section 20 before putting into service a product referred to in section 1.
- (3) Any person placing on the market or putting into service a propulsion engine, recreational craft or a personal watercraft after a major engine modification or craft conversion, or any person changing the intended purpose of a recreational craft of personal watercraft not covered by these Regulations in a way that it falls under the scope of the Regulations, shall apply the procedure referred to section 20 before placing the product on the market or putting it into service.
- (4) Any person placing on the market a watercraft built for own use before the end of the five-year period referred to in section 2 (1) (f), shall apply the procedure referred to in section 20 before placing the product on the market.

**Section 17. Design and production**

- (1) With regard to design and production of recreational craft, one of the following modules shall apply:

<i>Design category</i>	<i>Available modules</i>	
	$2.5\text{ m} \leq \text{hull length} < 12\text{ m}$	$12\text{ m} \leq \text{hull length} \leq 24\text{ m}$
A	A1 or B + C or B + D or B + E or B + F or G or H	B + C or
B		B + D or B + E or B + F or G or H
C	If harmonised standard for stability and buoyancy are complied with (Annex 1 Part A point 3.2 and 3.3)	A or A1 or B + C or B + D or B + E or B + F or G or H



	If harmonised standard for stability and buoyancy are complied with (Annex 1 Part A point 3.2 and 3.3)	A1 or B + C or B + D or B + E or B + F or G or H	
D	A or A1 or B + C or B + D or B + E or B + F or G or H		

(2) With regard to design and production of personal watercraft, one of the following modules shall apply:

- a) Module A (internal production control);
- b) Module A1 (internal production control plus supervised product testing);
- c) Module B (EU type-examination) together with Module C, D, E or F;
- d) Module G (conformity based on unit verification);
- e) Module H (conformity based on full quality assurance).

(3) With regard to design and production of components, one of the following modules shall apply:

- a) Module B (EU type-examination) together with Module C, D, E or F;
- b) Module G (conformity based on unit verification);
- c) Module H (conformity based on full quality assurance).

### Section 18. Exhaust emissions

With regard to exhaust emissions for engines referred to in section 1 first paragraph (d) and section 1 second paragraph, the engine manufacturer shall apply the following procedures:

- a) where tests are conducted using the harmonised standard, one of the following modules shall be applied:
  - i) Module B (EU type-examination) together with Module C, D, E or F;
  - ii) Module G (conformity based on unit verification);
  - iii) Module H (conformity based on full quality assurance);
- b) where tests are conducted without using the harmonised standard, one of the following modules shall be applied:
  - i) Module B (EU type-examination) together with Module C 1;
  - ii) Module G (conformity based on unit verification).

### Section 19. Noise emissions

(1) With regard to noise emissions for recreational craft with stern drive propulsion engines without integral exhausts or inboard propulsion engine installations and for recreational craft with stern drive propulsion engines without integral exhausts or with inboard propulsion engine installations which are subject to major craft conversion and subsequently placed on the market within five years following conversion, the manufacturer shall apply the following procedures:

- a) where tests are conducted using the harmonised standard for noise measurement, one of the following modules:
  - i) Module A1 (internal production control plus supervised product testing);
  - ii) Module G (conformity based on unit verification);
  - iii) Module H (conformity based on full quality assurance);
- b) where tests are conducted without using the harmonised standard for noise measurement, Module G (conformity based on unit verification) shall be applied;
- c) where the Froude number and power displacement ratio method is used for assessment, one of the following modules shall be applied:
  - i) Module A (intern production control);
  - ii) Module G (conformity based on unit verification);

- iii) Module H (conformity based on full quality assurance);
- (2) With regard to noise emissions for personal watercraft and outboard propulsion engines and stern drive propulsion engines with integral exhausts intended for installation on recreational craft, the personal watercraft or engine manufacturer shall apply the following procedures:
- a) where tests are conducted using the harmonised standard for noise measurement, one of the following modules shall be applied:
    - i) Module A1 (internal production control plus supervised product testing);
    - ii) Module G (conformity based on unit verification);
    - iii) Module H (conformity based on full quality assurance);
  - b) where tests are conducted without using the harmonised standard for noise measurement, Module G (conformity based on unit verification) shall be applied.

### **Section 20. *Post-construction assessment***

The post-construction assessment referred to in section 16 second, third and fourth paragraphs shall be carried out as set out in Annex 17.

### **Section 21. *Supplementary requirements for conformity assessment***

- (1) A production type referred to in Module B may cover several versions of the product, provided that:
- a) the differences between the versions do not affect the level of safety and the other requirements concerning the performance of the product; and
  - b) versions of the product are referred to in the corresponding EU-type examination certificate, if necessary through amendments to the original certificate.
- (2) When Module A1 is used, the product checks shall be carried out on one or several recreational craft or personal watercraft representing the production of the manufacturer, and the supplementary requirements set out in Annex 7 shall apply.
- (3) When Module F is used, the procedure described in Annex 18 shall apply for the assessment of conformity with the exhaust emission requirements.
- (4) When Module C is used, with regard to the assessment of conformity with the exhaust emission requirements of these Regulations and if the manufacturer is not working under a relevant quality system as described in Module H, a notified body chosen by the manufacturer shall carry out the product checks or have them carried out at random intervals determined by that body, in order to verify the quality of the internal checks on the product. When the quality level appears unsatisfactory or when it seems necessary to verify the validity of the data presented by the manufacturer, the procedure set out in Annex 10 to these Regulations shall apply.

### **Section 22. *Technical documentation***

- (1) The technical documentation referred to in section 9 (2) shall contain all relevant data and details of the methods used by the manufacturer to ensure that the product complies with the requirements set out in these Regulations. It shall, in particular, contain the relevant documents listed in Annex 4.
- (2) The technical documentation shall ensure that the design, production, operation and assessment of conformity may be clearly understood.

## **Chapter 4. Notified body**

### **Section 23. *Requirements relating to notified bodies***

- (1) A notified body shall be a third-party body independent of the organisation or the product it assesses.
- (2) A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, may, on

condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

(3) A notified 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 products which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the notified body or the use of such products for personal purposes.

(4) A notified body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacturing, marketing, installation, use or maintenance of those products, or represent 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 in particular apply to consultancy services.

(5) Notified bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

(6) Notified 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 financial, 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.

(7) A notified body shall be capable of carrying out all the conformity assessment tasks assigned to it by sections 16 to 21 and in relation to which it has have been notified, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility.

(8) At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have at its disposal:

- a) the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- b) descriptions of procedures for the conformity assessment ensuring the transparency and ability of reproduction of those procedures;
- c) appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
- d) 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 technology of the product in question and the mass or serial nature of the production process.

(9) It 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 or facilities.

(10) The personnel responsible for carrying out the conformity assessment activities shall have:

- a) sound technical and vocational training covering all the conformity assessment activities in relation to which the notified body has been notified;
- b) satisfactory knowledge of the requirements of the assessments they carry out and the necessary authority to carry out those assessments;
- c) appropriate knowledge and understanding of the essential requirements, the applicable harmonised standards, the relevant EEA harmonisation legislation and the relevant national legislation;
- d) the necessary qualifications to draw up certificates, records and reports demonstrating that assessments have been carried out.

(11) The impartiality of the notified bodies, their top level management and of the assessment personnel shall be ensured.

(12) The remuneration of the top level management and assessment personnel of a notified body shall not depend on the number of assessments carried out or on the results of those assessments.

(13) Notified bodies shall take out liability insurance unless liability is assumed by the EEA Member State in accordance with its national law, or the EEA Member State itself is directly responsible for the conformity assessment.

(14) The personnel of a notified body shall observe professional secrecy with regard to all information obtained in carrying out their tasks pursuant to sections 16 to 21, except in relation to the competent authorities of the Member State in which its activities are carried out.

(15) Notified bodies shall participate in, or see to that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group, and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

#### **Section 24. *Presumption of conformity***

Where a notified body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set out in section 23 in-so-far as the applicable harmonised standards cover those requirements.

#### **Section 25. *Subsidiaries of and subcontracting by notified bodies***

(1) 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 section 23 and shall inform the notifying authority accordingly.

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

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

(4) Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them pursuant to sections 16 to 21.

#### **Section 26. *Application for notification as notified body***

(1) A notified body shall submit an application for notification to the notifying authority of the EEA Member State in which it is established.

(2) The application referred to in the first paragraph shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the product or products for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the notified body fulfils the requirements laid down in section 23.

(3) Where the notified body cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular supervision of its compliance with the requirements laid down in section 23.

#### **Section 27. *Changes to notifications as notified body***

(1) Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in section 23, or that it is failing to fulfil its obligations, the notifying authority 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 immediately inform the European Commission and the other EEA Member States accordingly.

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

#### **Section 28. *Operational obligations of notified bodies***

(1) Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in sections 16 to 21.

(2) Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators and private importers. Notified bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process. In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the product with these Regulations.

(3) Where a notified body finds that the requirements laid down in these Regulations or in corresponding harmonised standards have not been met by a manufacturer or a private importer, it shall require that manufacturer or private importer to take appropriate corrective measures and shall not issue a conformity certificate.

(4) Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a product is no longer in compliance with these Regulations, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

(5) Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

### **Section 29. Information obligation on notified bodies**

(1) Notified bodies shall inform the notifying authority of the following:

- a) any refusal, restriction, suspension or withdrawal of a certificate;
- b) any circumstances affecting the scope of and 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.

(2) Notified bodies shall provide the other bodies carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

## **Chapter 5. EEA market surveillance and control of products entering the EEA market**

### **Section 30. Supervision**

(1) The Norwegian Maritime Authority is the market surveillance authority and supervises the compliance with these Regulations.

(2) Market surveillance shall ensure that the product does not compromise health and safety when properly installed, used and maintained. and that a non-conforming product is prohibited, restricted or withdrawn from the market. The public shall have access to such information.

(3) The Norwegian Maritime Authority may require economic operators to make necessary documentation and information available. When necessary and justified, the Norwegian Maritime Authority shall be given access to enter the premises of economic operators and take the necessary samples of products. Where the Norwegian Maritime Authority deems it necessary, they may require a product presenting a serious risk to be destroyed or otherwise rendered inoperable.

### **Section 31. Procedure for dealing with products presenting a risk**

(1) Where the Norwegian Maritime Authority has sufficient reason to believe that a product presents a risk to the health or safety of persons, to property or to the environment, they shall carry out an evaluation of the

product in relation to the requirements laid down in these Regulations. The relevant economic operators or the private importer shall cooperate with the Norwegian Maritime Authority.

(2) If the product does not comply with the requirements, the Norwegian Maritime Authority shall, following an evaluation, without delay require the relevant economic operator to take corrective action, to withdraw the product from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as the Norwegian Maritime Authority may prescribe.

(3) Where, in the course of that evaluation, the Norwegian Maritime Authority finds that a product imported by a private importer does not comply with the requirements, the private importer shall be informed without delay of the appropriate corrective action to be taken to bring the product into compliance with those requirements. Commensurate with the nature of the risk, suspension of the use of the product may be required. The Norwegian Maritime Authority shall inform the relevant notified body accordingly.

(4) The Norwegian Maritime Authority shall ensure any measure taken pursuant to the second and third paragraphs to prohibit or restrict the product being made available, to withdraw the product from that market or to recall it is proportionate to the purpose and states the exact grounds on which it is based.

(5) The economic operator shall ensure that the appropriate corrective action is taken in respect of all similar products that the economic operator has made available on the EEA market.

(6) The private importer shall ensure that the appropriate corrective action is taken in respect of the product that he or she has imported to the EEA for his or her own use.

(7) Where the relevant economic operator does not take adequate corrective action within the period referred to in the second paragraph, the Norwegian Maritime Authority shall take the necessary measures to prohibit or restrict the availability of the product, to withdraw the product or to recall it.

(8) Where the private importer does not take adequate corrective action, the Norwegian Maritime Authority shall take the necessary measures to prohibit the putting into service of the product, or prohibit or restrict the use of the product.

### **Section 32. *Formal non-compliance***

(1) The Norwegian Maritime Authority shall require the relevant economic operator or the private importer to rectify the non-compliance with the Regulations if:

- a) the CE marking has been affixed in violation of section 7;
- b) the CE marking, as referred to in section 7, has not been affixed;
- c) the EU declaration of conformity or the declaration referred to in Annex 3 has been drawn up incorrectly or not at all;
- d) the technical documentation is either not available or not complete;
- e) the information set out in section 9 (8) or section 11 (4) is absent, false or incomplete;
- f) any other requirement set out in section 9 or 11 is not fulfilled.

(2) Where the non-compliance referred to in the first paragraph persists, the Norwegian Maritime Authority shall take all appropriate measures to prohibit or restrict the availability of the product, to withdraw the product or to recall it. In the case of a product imported by a private importer for his or her own use, the use of the product shall be prohibited or restricted.

### **Section 33. *Appeals***

Decisions made pursuant to these Regulations may be appealed. The Ministry of Climate and Environment is the administrative appeal body for decisions concerning environmental requirements, and the Ministry of Trade, Industry and Fisheries is the administrative appeal body for other decisions.

### **Section 34. *Penalties***

In the event of violation of these Regulations or decisions made in pursuance thereof, the provisions of section 12 of the Product Control Act concerning penalties apply.

**Section 35. *Coercive fines***

In the event of violation of decisions made in pursuance of these Regulations, the provisions of section 13 of the Product Control Act concerning coercive fines apply.

**Section 36. *Entry into force, amendments to other regulations and transitional provisions***

(1) These Regulations enter into force on 18 January 2016.

(2) As from the same date, the Regulations of 20 December 2004 No. 1820 on the production and the placing on the market of recreational craft, etc. are repealed.

(3) The following products may be made available on the market or put into service within the following deadlines, even though the requirements of the current Regulations are not satisfied, when the products meet the requirements set out in the provisions in force on 17 January 2016:

- a) products referred to in section 1, up to and including 17 January 2017;
- b) outboard spark-ignition propulsion engines with power equal to or less than 15 kW which comply with the stage I exhaust emission limits laid down in point 2.1 of Part B of Annex 1 and which were manufactured by small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC, up to and including 17 January 2020.

## Annex 1. Essential requirements

### A. Essential requirements for the design and construction of products referred to in section 1

#### 1. *Design categories for recreational craft and personal watercraft*

<i>Design category</i>	<i>Wind force (Beaufort scale)</i>	<i>Significant wave height (<math>H \frac{1}{3}</math>, metres)</i>
A	exceeding 8	exceeding 4
B	up to, and including, 8	up to, and including, 4
C	up to, and including, 6	up to, and including, 2
D	up to, and including, 4	up to, and including, 0.3

#### *Explanatory notes:*

- A. A recreational craft given design category A is considered to be designed for winds that may exceed wind force 8 (Beaufort scale) and significant wave height of 4 m and above but excluding abnormal conditions, such as storm, violent storm, hurricane, tornado and extreme sea conditions or rogue waves.
- B. A recreational craft given design category B is considered to be designed for a wind force up to, and including, 8 and significant wave height up to, and including, 4 m.
- C. A recreational craft or personal watercraft given design category C is considered to be designed for a wind force up to, and including, 6 and significant wave height up to, and including, 2 m.
- D. A recreational craft or personal watercraft given design category D is considered to be designed for a wind force up to, and including, 4 and significant wave height up to, and including, 0.3 m, with occasional waves of 0.5 m maximum height.

Recreational craft or personal watercraft in each design category shall be designed and constructed to withstand the wind force and significant wave height in respect of stability, buoyancy, and other relevant essential requirements listed in Annex 1, and to have good handling characteristics.

#### 2. *General requirements*

##### 2.1 *Watercraft identification*

The EEA Agreement Annex II Chapter XXXI point 3 (Regulation (EU) 2017/1) on procedures for watercraft identification under Directive 2013/53/EU of the European Parliament and of the Council on recreational craft and personal watercraft applies as regulation with the adaptations that follow from Annex XIII, Protocol 1 to the Agreement and the Agreement in general.

A watercraft identification number (WIN) shall include the following information, in this order:

- (a) country code of the manufacturer, indicating where the manufacturer is established;
- (b) unique code of the manufacturer assigned by the national authority of the Member State; however, the same character combination, which constitutes a unique code and is generated by a national authority or a national body in one Member State, may also be generated by a national authority or a national body in another Member State, with a distinctive part which is the manufacturer's country code;
- (c) unique serial number assigned by the manufacturer for identification of the watercraft, and which is used only once by this manufacturer; however, the same character combination may also be used by another manufacturer, with a distinctive part which is the combination of the unique manufacturer code and the manufacturer's country code;
- (d) month and year of production;



(e) model year, corresponding to the year the watercraft is to be placed on the market.

Detailed requirements for the identification number referred to in the first paragraph are set out in the relevant harmonised standard.

## 2.2. *Watercraft builder's plate*

Each recreational craft and personal watercraft shall carry a permanently affixed plate mounted separately from the watercraft identification number, containing at least the following information:

- a) manufacturer's name, company or registered trade mark, as well as contact address;
- b) CE marking, as provided for in section 7;
- c) watercraft design category in accordance with point 1;
- d) manufacturer's maximum recommended load derived from point 3.6 excluding the weight of the contents of the fixed tanks when full;
- e) number of persons recommended by the manufacturer for which the watercraft was designed.

In the case of post-construction assessment, the contact details and the requirements referred to in point (a) shall include those of the notified body which has carried out the conformity assessment.

## 2.3. *Protection from falling overboard and means of reboarding*

Recreational craft and personal watercraft shall be designed to minimise the risks of falling overboard and to facilitate reboarding. Means of reboarding shall be accessible to or deployable by a person in the water unaided.

## 2.4. *Visibility from the main steering position*

For recreational craft, the main steering position shall give the operator, under normal conditions of use (speed and load), good all-round visibility.

## 2.5. *Owner's manual*

Each product shall be provided with an owner's manual in accordance with section 9(9) and section 11(5). That manual shall provide all the information necessary for safe use of the product. Particular attention shall be paid to set up, maintenance, regular operation, prevention of risks and risk management.

## 3. *Integrity and structural requirements*

### 3.1. *Structure*

The choice and combination of materials and its construction shall ensure that the recreational craft or personal watercraft is strong enough in all respects. Special attention shall be paid to the design category in accordance with point 1, and the manufacturer's maximum recommended load in accordance with point 3.6.

### 3.2. *Stability and freeboard*

The recreational craft or personal watercraft shall have sufficient stability and freeboard considering its design category in accordance point 1 and the manufacturer's maximum recommended load in accordance with point 3.6.

### 3.3. *Buoyancy and flotation*

The recreational craft or personal watercraft shall be constructed as to ensure that it has buoyancy characteristics appropriate to its design category in accordance with point 1 and the manufacturer's maximum recommended load in accordance with point 3.6. All habitable multihull recreational craft susceptible of inversion shall have sufficient buoyancy to remain afloat in the inverted position.

Watercraft of less than 6 metres in hull length that are susceptible to swamping when used in accordance with their design category shall be provided with appropriate means of flotation so that the watercraft remains afloat in the swamped condition.

#### 3.4. *Openings in hull, deck and superstructure*

Openings in hull, deck(s) and superstructure shall not impair the structural integrity of the recreational craft of personal watercraft or its weathertight integrity when closed.

Windows, port lights, doors and hatch covers shall withstand the water pressure likely to be encountered in their specific position, as well as point loads applied by the weight of persons moving on deck.

Through-hull fittings designed to allow water passage into the hull or out of the hull, below the waterline corresponding to the manufacturer's maximum recommended load in accordance with point 3.6, shall be fitted with a means of shutoff which shall be readily accessible.

#### 3.5. *Flooding*

All recreational craft and personal watercraft shall be designed so as to minimise the risk of sinking.

Where appropriate, particular attention shall be paid to:

- a) cockpits and wells, which shall be self-draining or have other means of keeping water out of the watercraft interior;
- b) ventilation fittings;
- c) removal of water by pumps or other means.

#### 3.6. *Manufacturer's maximum recommended load*

The manufacturer's maximum recommended load (fuel, water, provisions, miscellaneous equipment and people (in kilograms)) for which the recreational craft of personal watercraft was designed, shall be determined in accordance with the design category (point 1), stability and freeboard (point 3.2) and buoyancy and flotation (point 3.3).

#### 3.7. *Liferaft stowage*

All recreational craft of design categories A and B, and recreational craft of design categories C and D of more than 6 metres in hull length shall be provided with one or more stowage points for a liferaft (liferafts) large enough to hold the number of persons the recreational craft was designed to carry as recommended by the manufacturer. Liferaft stowage point(s) shall be readily accessible at all times.

#### 3.8. *Escape*

All habitable multihull recreational craft susceptible of inversion shall be provided with viable means of escape in the event of inversion. Where there is a means of escape provided for use in the inverted position, it shall not compromise the structure (point 3.1), the stability (point 3.2) or buoyancy (point 3.3) whether the recreational craft is upright or inverted.

Every habitable recreational craft shall be provided with viable means of escape in the event of fire.

#### 3.9. *Anchoring, mooring and towing*

All recreational craft of personal watercraft, taking into account their design category and their characteristics, shall be fitted with one or more strong points or other means capable of safely accepting anchoring, mooring and towing loads.

#### 4. *Handling characteristics*

The manufacturer shall ensure that the handling characteristics of the watercraft are satisfactory with the most powerful propulsion engine for which the watercraft is designed and constructed. For all propulsion engines, the maximum rated engine power shall be declared in the owner's manual.

## 5. *Installation requirements*

### 5.1. *Engines and engine compartments*

#### 5.1.1. *Inboard engine*

All inboard mounted engines shall be placed within an enclosure separated from living quarters and installed so as to minimise the risk of fires or spread of fires as well as hazards from toxic fumes, heat, noise or vibrations in the living quarters.

Engine parts and accessories that require frequent inspection and/or servicing shall be readily accessible.

The insulating materials inside the engine compartment shall not sustain combustion.

#### 5.1.2. *Ventilation*

The engine compartment shall be ventilated. The ingress of water into the engine compartment through openings shall be minimised.

#### 5.1.3. *Exposed parts*

Unless the engine is protected by a cover or its own enclosure, exposed moving or hot parts of the engine that could cause personal injury shall be effectively shielded.

#### 5.1.4. *Outboard propulsion engine starting*

Every outboard propulsion engine fitted on any recreational craft of personal watercraft shall have a device to prevent the engine being started in gear, except:

- a) when the engine produces less than 500 newtons (N) of static thrust;
- b) when the engine has a throttle limiting device to limit thrust to 500 N at the time of starting the engine.

#### 5.1.5. *Personal watercraft running without driver*

Personal watercraft shall be designed either with an automatic propulsion engine cut-off or with an automatic device to provide reduced speed and circular, forward movement when the driver dismounts deliberately or falls overboard.

#### 5.1.6. *Tiller-controlled outboard propulsion engines shall be equipped with an emergency stopping device which can be linked to the helmsman.*

## 5.2. *Fuel system*

### 5.2.1. *General*

The filling, storage, venting and fuel-supply arrangements and installations shall be designed and installed so as to minimise the risk of fire and explosion.

### 5.2.2. *Fuel tanks*

Fuel tanks, lines and hoses shall be secured and separated or protected from any source of significant heat. The material that the tanks are made of and their method of construction shall be in accordance with their capacity and the type of fuel.

Petrol fuel tank spaces shall be ventilated.

Petrol fuel tanks shall not form part of the hull and shall be:

- a) protected against fire from any engine and from all other sources of ignition;
- b) separated from living quarters.

Diesel fuel tanks may be integral with the hull.

### 5.3. *Electrical system*

Electrical systems shall be designed and installed so as to ensure proper operation of the watercraft under normal conditions of use and shall be such as to minimise risk of fire and electric shock.

All electrical circuits, except engine starting circuits supplied from batteries, shall remain safe when exposed to overload.

Electric propulsion circuits shall not interact with other circuits in such a way that either would fail to operate as intended.

Ventilation shall be provided to prevent the accumulation of explosive gases which might be emitted from batteries. Batteries shall be firmly secured and protected from ingress of water.

### 5.4. *Steering system*

#### 5.4.1. *General*

Steering and propulsion control systems shall be designed, constructed and installed in order to allow the transmission of steering loads under foreseeable operating conditions.

#### 5.4.2. *Emergency arrangements*

Every sailing recreational craft and single-propulsion engine non-sailing recreational craft with remote-controlled rudder steering systems shall be provided with emergency means of steering the recreational craft at reduced speed.

### 5.5. *Gas system*

Gas systems for domestic use shall be of the vapour-withdrawal type and shall be designed and installed so as to avoid leaks and the risk of explosion and be capable of being tested for leaks. Materials and components shall be suitable for the specific gas used and shall withstand the stresses and exposures found in the marine environment.

Each gas appliance intended by the manufacturer for the application for which it is used shall be so installed in accordance with the manufacturer's instructions. Each gas-consuming appliance shall be supplied by a separate branch of the distribution system, and it shall be possible to control each appliance by a separate closing device. Adequate ventilation shall be provided to prevent hazards from leaks and products of combustion.

All watercraft with a permanently installed gas system shall be fitted with an enclosure to contain all gas cylinders. The enclosure shall be separated from the living quarters, accessible only from the outside and ventilated to the outside so that any escaping gas drains overboard.

All permanently installed gas system shall be tested after installation.

### 5.6. *Fire protection*

#### 5.6.1. *General*

The type of equipment installed and the layout of the watercraft shall take account of the risk and spread of fire. Special attention shall be paid to the surroundings of open flame devices, hot areas or

engines and auxiliary machines, oil and fuel overflows, uncovered oil and fuel pipes and routing of electrical wiring in particular away from heat sources and hot areas.

#### 5.6.2. *Fire-fighting equipment*

Recreational craft shall be supplied with fire-fighting equipment appropriate to the fire hazard, or the position and capacity of fire-fighting equipment appropriate to the fire hazard shall be indicated. The craft shall not be put into service until the appropriate fire-fighting equipment is in place. Petrol engine compartments shall be protected by a fire extinguishing system that avoids the need to open the compartment in the event of fire. Where fitted, portable fire extinguishers shall be readily accessible and one shall be so positioned that it can easily be reached from the main steering position of the recreational craft.

#### 5.7. *Navigation lights, shapes and sound signals*

Where navigation lights, shapes and sound signals are fitted, they shall comply with the Regulations of 1 December 1975 No. 5 for preventing collisions at seas (COLREG) or CEVNI (European Code for Interior Navigations for inland waterways) as appropriate.

#### 5.8. *Discharge prevention and installations facilitating the delivery ashore of waste*

Recreational craft and personal watercraft shall be constructed so as to prevent the accidental discharge of pollutants (oil, fuel, etc.) overboard.

Any toilet fitted in a recreational craft shall be connected solely to a holding tank system or water treatment system.

Recreational craft with installed holding tanks shall be fitted with a standard discharge connection to enable pipes of reception facilities to be connected with the recreational craft discharge pipeline.

In addition, any through-the-hull pipes for human waste shall be fitted with valves which are capable of being secured in the closed position.

Amended by Regulation of 5 April 2017 No. 447.

## **B. Essential requirements for exhaust emissions from propulsion engines**

Propulsion engines shall comply with the essential requirements for exhaust emissions set out in this Part.

### 1. *Propulsion engine identification*

1.1. Each engine shall be clearly marked with the following information:

- a) engine manufacturer's name, company or registered trade mark and contact address; and, if applicable, the name and contact address of the person adapting the engine;
- b) engine type, and engine family, if applicable;
- c) a unique engine serial number;
- d) CE marking, as provided for in section 7.

1.2. The marks referred to in point 1.1 shall be durable for the normal life of the engine and shall be clearly legible and indelible. If labels or plates are used, they shall be attached in such a manner that the fixing is durable for the normal life of the engine, and the labels/plates cannot be removed without destroying or defacing them.

1.3. The marks shall be secured to an engine part necessary for normal engine operation and not normally requiring replacement during the engine life.

1.4. The marks shall be located so as to be readily visible after the engine has been assembled with all the components necessary for engine operation.

## 2. Exhaust emission requirements

Propulsion engines shall be designed, constructed and assembled so that when correctly installed and in normal use, emissions shall not exceed the limit values obtained from point 2.1, Table 1 and point 2.2, Tables 2 and 3:

2.1 Values applying for the purposes of section 36 (3) (b) and Table 2 of point 2.2:

Table 1

Type	Carbon monoxide $CO = A + B/P_N^n$			Hydrocarbons $HC = A + B/P_N^n$			Nitrogen oxides $NO_x$	(g/kWh) Particulates PT
	A	B	n	A	B	n		
	Two-stroke spark ignition	150.0	600.0	1.0	30.0	100.0		
Four-stroke spark ignition	150.0	600.0	1.0	6.0	50.0	0.75	15.0	Not applicable
Compression ignition	5.0	0	0	1.5	2.0	0.5	9.8	1.0

where A, B and n are constants in accordance with the table,  $P_N$  is the rated engine power in kW.

2.2. Values applying from 18 January 2016:

Table 2  
Exhaust emission limits for compression ignition (CI) engines\*\*

Slagvolum SV (L/syl)	Motorens nominelle effekt $P_N$ (kW)	Partikler PT (g/kWh)	Hydrokarboner + nitrogenoksider HC + $NO_x$ (g/kWh)
SV < 0,9	$P_N < 37$	Verdiene nevnt i tabell 1	
	$37 \leq P_N < 75^{(*)}$	0,30	4,7
	$75 \leq P_N < 3700$	0,15	5,8
$0,9 \leq SV < 1,2$	$P_N < 3700$	0,14	5,8
$1,2 \leq SV < 2,5$		0,12	5,8
$2,5 \leq SV < 3,5$		0,12	5,8
$3,5 \leq SV < 7,0$		0,11	5,8

\* Alternatively, compression-ignition engines with rated engine power at or above 37 kW and below 75 kW and with a swept volume below 0.9 L/cyl shall not exceed a PT emission limit of 0.20 g/kWh and a combined HC +  $NO_x$  emission limit of 5.8 g/kWh.

\* Any compression-ignition engine shall not exceed a carbon monoxide (CO) emission limit of 5.0 g/kWh.

\*

*Table 3*  
Exhaust emission limits for spark ignition (SI) engines

<i>Type of engine</i>	<i>Rated Engine Power P<sub>N</sub> (kW)</i>	<i>Carbon monoxide CO (g/kWh)</i>	<i>Hydrocarbons + Nitrogen Oxides HC + NO<sub>x</sub> (g/kWh)</i>
Stern-drive and inboard engines	P <sub>N</sub> < 373	75	5
	373 < P <sub>N</sub> ≤ 485	350	16
	P <sub>N</sub> > 485	350	22
Outboard engines and PWC engines	P <sub>N</sub> ≤ 4.3	500 - (5.0 × P <sub>N</sub> )	30
	4.3 < P <sub>N</sub> ≤ 40	500 - (5.0 × P <sub>N</sub> )	$15.7 + \left( \frac{50}{P_{N^{0.9}}} \right)$
	P <sub>N</sub> > 40	300	$15.7 + \left( \frac{50}{P_{N^{0.9}}} \right)$

### 2.3. Test cycles:

Test cycles and weighting factors to be applied:

The following requirements of ISO standard 8178-4:2007 shall be used, taking into account the values set out in the table below.

For variable speed CI engines test cycle E1 or E5 shall be applied or alternatively, above 130 kW, test cycle E3 may be applied. For variable speed SI engines test cycle E4 shall be applied.

<i>Cycle E1, Mode number</i>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<i>Speed</i>	<i>Rated speed</i>		<i>Intermediate speed</i>		<i>Low-idle speed</i>
Torque, %	100	75	75	50	0
Weighting factor	0.08	0.11	0.19	0.32	0.3
<i>Cycle E3, Mode number</i>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	
Speed, %	100	91	80	63	
Power, %	100	75	50	25	
Weighting factor	0.2	0.5	0.15	0.15	
<i>Cycle E4, Mode number</i>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
Speed, %	100	80	60	40	Idle
Torque, %	100	71.6	46.5	25.3	0
Weighting factor	0.06	0.14	0.15	0.25	0.40
<i>Cycle E5, Mode number</i>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
Speed, %	100	91	80	63	Idle
Power, %	100	75	50	25	0
Weighting factor	0.08	0.13	0.17	0.32	0.3

Notified bodies may accept tests carried out on the basis of other tests cycles as specified in a harmonised standard and as applicable for the engine duty cycle.

### 2.4. Application of the propulsion engine family and choice of parent propulsion engine

The engine manufacturer shall be responsible for defining those engines from his range which are to be included in an engine family.

A parent engine shall be selected from an engine family in such a way that its emissions characteristics are representative for all engines in that engine family. The engine incorporating those features that are expected to result in the highest specific emissions (expressed in g/kWh), when measured on the applicable test cycle, should normally be selected as the parent engine of the family.

### 2.5. Test fuels

The test fuel used for exhaust emission testing shall meet the following characteristics:

#### Petrol Fuels

<i>Property</i>	<i>RF-02-99 Unleaded</i>		<i>RF-02-03 Unleaded</i>	
	<i>min</i>	<i>max</i>	<i>min</i>	<i>max</i>
Research Octane Number (RON)	95	-	95	-
Motor Octane Number (MON)	85	-	85	-
Density at 15°C (kg/m <sup>3</sup> )	748	762	740	754
Initial boiling point (°C)	24	40	24	40
Mass fraction of sulphur (mg/kg)	-	100	-	10
Lead content (mg/l)	-	5	-	5
Reid vapour pressure (kPa)	56	60	-	-
Vapour pressure (DVPE) (kPa)	-	-	56	60

#### Diesel Fuels

<i>Property</i>	<i>RF-06-99</i>		<i>RF-06-03</i>	
	<i>min</i>	<i>max</i>	<i>min</i>	<i>max</i>
Cetane number	52	54	52	54
Density at 15°C (kg/m <sup>3</sup> )	833	837	833	837
Final boiling point (°C)	-	370	-	370
Flash point (°C)	55	-	55	-
Mass fraction of sulphur (mg/kg)	To be reported	300 (50)	-	10
Mass fraction of ash (%)	To be reported	0.01	-	0.01

Notified bodies may accept tests carried out on the basis of other tests fuel as specified in a harmonised standard.

### 3. Durability

The manufacturer of the engine shall prepare engine installation and maintenance instructions to be issued with all new engines when first placed on the market. If these instructions are followed, it should mean that the engine in normal use will continue to comply with the limits set out in points 2.1 and 2.2 throughout the normal life of the engine and under normal conditions of use.

This information shall be obtained by the engine manufacturer by use of prior endurance testing, based on normal operating cycles, and by calculation of wear and tear / component fatigue.

The normal life of the engine is as follows:

- a) for CI engines: 480 hours of operation or 10 years, whichever occurs first;
- b) for SI inboard or stern drive engines with or without integral exhaust:
  - i) for the engine category  $P_N \leq 373$  kW: 480 hours of operation or 10 years, whichever occurs first;
  - ii) for engines in the category  $373 < P_N \leq 485$  kW: 150 hours of operation or 3 years, whichever occurs first;
  - iii) for the engine category  $P_N > 485$  kW: 50 hours of operation or 1 year, whichever occurs first;
- c) for personal watercraft engines: 350 hours of operation or 5 years, whichever occurs first;
- d) for outboard engines: 350 hours of operation or 10 years, whichever occurs first.

### 4. Owner's manual



Each engine shall be provided with an owner’s manual in Norwegian or, if there is no risk of misunderstandings, in Swedish or Danish.

The owner’s manual shall:

- a) provide instructions for the installation, use and maintenance needed to assure the proper functioning of the engine to meet the requirements of point 3;
- b) specify the power of the engine when measured in accordance with the harmonised standard.

## C. Essential requirements for noise emissions

Recreational craft with inboard or stern drive engines without integral exhaust, personal watercraft and outboard engines and stern drive engines with integral exhaust shall comply with the essential requirements for noise emissions set out in this Part.

### 1. Noise emission levels

- 1.1. Recreational craft with inboard or stern drive engines without integral exhaust, personal watercraft and outboard engines and stern drive engines with integral exhaust shall be designed, constructed and assembled so that noise emissions shall not exceed the limit values in the following table:

<b>Rated Engine Power (single engine) in kW</b>	<b>Maximum Sound Pressure Level = <math>L_{pASmax}</math> in dB</b>
$P_N \leq 10$	67
$10 < P_N \leq 40$	72
$P_N > 40$	75

where  $P_N$  = rated engine power in kW of a single engine at rated speed and  $L_{pASmax}$  = maximum sound pressure level in dB.

For twin-engine and multiple-engine units of all engine types an allowance of 3 dB may be applied.

- 1.2. As an alternative to sound measurement tests, recreational craft with inboard engine configuration or stern drive engine configuration, without integral exhaust, shall be deemed to comply with the noise requirements set out in point 1.1 if they have a Froude number of  $\leq 1.1$  and a Power to Displacement ratio of  $\leq 40$  and where the engine and exhaust system are installed in accordance with the engine manufacturer’s specifications.
- 1.3. ‘Froude number’  $F_n$  shall be calculated by dividing the maximum recreational craft speed  $V$  (m/s) by the square root of the waterline length  $lwl$  (m) multiplied by a given gravitational acceleration constant,  $g$ , of  $9.8 \text{ m/s}^2$ .

$$F_n = \frac{V}{\sqrt{(g \times lwl)}}$$

‘Power to Displacement ratio’ shall be calculated by dividing the rated engine power  $P_N$  (in kW) by the recreational craft’s displacement  $D$  (in tonnes).

$$\text{Effekt/deplasement-forhold} = \frac{P_N}{D}$$

### 2. Owner’s manual

For recreational craft with inboard engine or stern drive engines without integral exhaust and personal watercraft, the owner’s manual required under point 2.5 of Part A shall include information necessary to

maintain the recreational craft and exhaust system in a condition that, insofar as is practicable, will ensure compliance with the specified noise limit values when in normal use.

For outboard engines and stern drive engines with integral exhaust, the owner's manual required under point 4 of Part B shall provide the instructions necessary to maintain the engine in a condition that, insofar as is practicable, will ensure compliance with the specified noise limit values when in normal use.

### 3. *Durability*

The provisions on the durability in point 3 of Part B shall apply *mutatis mutandis* to the compliance with the requirements on noise emissions set out in point 1 of this Part.

## **Annex 2. Components of recreational craft and personal watercraft**

- 1) Ignition-protected equipment for inboard and stern drive petrol engines and petrol tank spaces;
- 2) Start-in-gear protection devices for outboard engines;
- 3) Steering wheels, steering mechanisms and cable assemblies;
- 4) Fuel tanks intended for fixed installations and fuel hoses;
- 5) Prefabricated hatches, and port lights.

## **Annex 3. Declaration by the manufacturer or the importer of the partly completed recreational craft and personal watercraft**

The declaration by the manufacturer or the importer established in the EEA referred to in section 5(2) shall contain the following:

- a) the name and address of the manufacturer;
- b) the name and address of the representative of the manufacturer established in the EEA or, if appropriate, of the person responsible for placing the watercraft on the market;
- c) a description of the partly completed watercraft;
- d) a statement that the partly completed watercraft complies with the essential requirements that apply at this stage of construction. This shall include references to the relevant harmonised standards used, or references to the specifications in relation to which compliance is declared at this stage of construction; furthermore, that the partly completed watercraft is intended to be completed by other legal or natural persons in full compliance with these Regulations.

## **Annex 4. Technical documentation**

The technical documentation referred to in section 9(2) and section 22 shall, as far as it is relevant for the assessment, contain the following:

- a) a general description of the type;
- b) conceptual-design, build standard and manufacturing drawings and schemes of components, sub-assemblies, circuits, and other relevant data;
- c) descriptions and explanations necessary for the understanding of those drawings and schemes, including the operation of the product;
- d) a list of the standards referred to in section 4(2), applied in full or in part, and descriptions of the solutions adopted to fulfil the essential requirements when the standards referred to in section 4(2) have not been applied;
- e) results of design calculations made, examinations carried out and other relevant data;
- f) test reports, or calculations namely on stability in accordance with point 3.2 of Part A of Annex I and on buoyancy in accordance with point 3.3;

- g) exhaust emissions test reports demonstrating compliance with point 2 of Part B of Annex I;
- h) noise emissions test reports demonstrating compliance with point 1 of Part C of Annex I.

## **Annex 5. Internal production control (module A)**

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of these Regulations that apply to them.

### *2. Technical documentation*

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and 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, build standard 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 harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- results of design calculations made, examinations carried out, etc.;
- test reports.

### *3. Manufacturing*

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 Annex and with the essential requirements of these Regulations that apply to them.

### *4. Conformity marking and declaration of conformity*

- 4.1. The manufacturer shall affix the required conformity marking set out in the Regulations to each individual product that satisfies the applicable requirements of the Regulations.
- 4.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market. 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.

### *5. Representative*

The manufacturer's obligations set out in point 4 may be fulfilled by his or her representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

## **Annex 6. Internal production control plus supervised product testing (Module A1)**

1. Internal production control plus supervised product testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4 and 5, and ensures and declares on his or her sole responsibility that the products concerned satisfy the requirements of these Regulations that apply to them.

### *2. Technical documentation*

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and 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, build standard 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 harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- results of design calculations made, examinations carried out, etc.;
- test reports.

### *3. Manufacturing*

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the essential requirements of these Regulations that apply to them.

### *4. Product checks*

For each individual product manufactured, one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his or her behalf, in order to verify conformity with the corresponding requirements of the Regulations. The tests shall be carried out under the responsibility of a notified body chosen by the manufacturer.

The manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number on the product during the manufacturing process.

### *5. Conformity marking and declaration of conformity*

5.1. The manufacturer shall affix the required conformity marking set out in the Regulations to each individual product that satisfies the applicable requirements of the Regulations.

5.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market. 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. *Representative*

The manufacturer's obligations set out in point 5 may be fulfilled by his or her representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

Amended by Regulation of 5 April 2017 No. 447.

## **Annex 7. Supplementary requirements when internal production control plus supervised production tests set out in Module A1 is used**

### *Design and production*

On one or several recreational craft or personal watercraft representing the production of the manufacturer one or more of the following tests, equivalent calculation or control shall be carried out by the manufacturer or on his or her behalf.

- a) test of stability in accordance with point 3.2 of Part A of Annex 1.
- b) test of buoyancy characteristics in accordance with point 3.2 of Part A of Annex 1.

### *Noise emissions*

For recreational craft fitted with inboard or stern drive engines without integral exhaust and for personal watercraft, on one or several watercraft representing the production of the watercraft manufacturer, the noise emission tests defined in Part C of Annex 1 shall be carried out by the watercraft manufacturer, or on his or her behalf, under the responsibility of a notified body chosen by the manufacturer.

For outboard engines and stern drive engines with integral exhaust, on one or several engines of each engine family representing the production of the engine manufacturer, the noise emission tests defined in Part C of Annex I shall be carried out by the engine manufacturer, or on his or her behalf, under the responsibility of a notified body chosen by the manufacturer.

Where more than one engine of an engine family is tested, the statistical method described in Annex 18 shall be applied to ensure conformity of the sample.

## **Annex 8. EC-type examination (Module B)**

1. EC-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of these Regulations that apply to it.
2. EC-type examination shall be carried out by assessment of the adequacy of the technical design of the product 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 his or her choice.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the representative, his or her 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 product conformity with the applicable requirements of these Regulations and shall include an adequate

analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and 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, build standard 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 harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- results of design calculations made, examinations carried out, etc.;
- 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, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full. 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 his or her behalf and under his or her responsibility.

4. The notified body shall:

For the product:

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the product;

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 harmonised standards and/or technical specifications, 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, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and/or technical specifications, these have been applied correctly;

4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential requirements of the Regulations;

4.5. 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 Regulations that apply to the product 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 Regulations, 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. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of the Regulations, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

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 product with the essential requirements of the Regulations 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 market surveillance authorities and the other notified bodies may, on request, obtain a copy of the EC-type examination certificates and/or additions thereto. On request, the market surveillance authorities and 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 10 years after the product has been placed on the market.
10. The manufacturer's 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.

## **Annex 9. Conformity to type based on internal production control (Module C)**

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of these Regulations 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 these Regulations that apply to them.

## 3. *Conformity marking and declaration of conformity*

3.1. The manufacturer shall affix the required conformity marking set out in the Regulations to each individual product that is in conformity with the type described in the EC-type examination certificate and satisfies the applicable requirements of the Regulations.

3.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product 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.

## 4. *Representative*

The manufacturer's obligations set out in point 3 may be fulfilled by his or her representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

## **Annex 10. Supplementary procedure to be applied under conformity to type based on internal production control (Module C)**

In the cases referred to in section 21 fourth paragraph, when the quality level appears unsatisfactory, the following procedure shall apply:

An engine is taken from the series and subjected to the test described in Part B of Annex 1. Test engines shall have been run in, partially or completely, in accordance with the manufacturer's specifications. If the specific exhaust emissions of the engine taken from the series exceed the limit values in accordance with Part B of Annex 1, the manufacturer may ask for measurements to be done on a sample of engines taken from the series and including the engine originally taken. To ensure the conformity of the sample of engines with the requirements of the Regulations, the statistical method described in Annex 18 shall be applied.

## **Annex 11. Conformity to type based on internal production control plus supervised product testing (Module C1)**

1. Conformity to type based on internal production control plus supervised product testing is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his or her sole responsibility that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of these Regulations 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 type described in the EC-type examination certificate and with the requirements of the specific Regulations that apply to them.

## 3. *Product checks*



For each individual product manufactured one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his or her behalf, in order to verify conformity with the corresponding requirements of the Regulations. At the choice of the manufacturer, the tests may be carried out under the responsibility of a notified body chosen by the manufacturer.

Where the tests are carried out by a notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

#### 4. *Conformity marking and declaration of conformity*

4.1. The manufacturer shall affix the required conformity marking set out in the Regulations to each individual product that is in conformity with the type described in the EC-type examination certificate and satisfies the applicable requirements of the Regulations.

4.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product 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.

#### 5. *Representative*

The manufacturer's obligations set out in point 4 may be fulfilled by his or her representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

## **Annex 12. Conformity to type based on quality assurance of the production process (Module D)**

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 his or her sole responsibility that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the Regulations that apply to them.

#### 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 his or her quality system with the notified body of his or her choice, for the products concerned.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the representative, his or her 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 product 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 comply with the requirements of the Regulations 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, include 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.;
- 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 laid down in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specifications.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the Regulations. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1, fifth indent, to verify the manufacturer's ability to identify the relevant requirements of the Regulations 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 examination 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 reassessment is necessary.

The decision shall be notified to the manufacturer. 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 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. 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 required conformity marking set out in the Regulations, 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 satisfies the applicable requirements of the Regulations.

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 10 years after the product has been placed on the market. The declaration of conformity shall identify the product 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, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

- 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. *Representative*

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

## **Annex 13. Conformity to type based on product quality assurance (Module E)**

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 his or her sole responsibility that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the Regulations that apply to them.

## 2. *Manufacturing*

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

## 3. *Quality system*

3.1. The manufacturer shall lodge an application for assessment of his or her quality system with the notified body of his or her choice, for the products concerned.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the representative, his or her 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 product 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 compliance of the products with the type described in the EC-type examination certificate and with the applicable requirements of the Regulations.

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, include 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 laid down in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specifications.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the Regulations. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1, fifth indent, to verify the manufacturer's ability to identify the relevant requirements of the Regulations 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 examination 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 reassessment is necessary.

The decision shall be notified to the manufacturer. 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 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. 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 required conformity marking set out in the Regulations, 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 satisfies the applicable requirements of the Regulations.

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 10 years after the product has been placed on the market. The declaration of conformity shall identify the product 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, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

- 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. *Representative*

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

## **Annex 14. Conformity to type based on product verification (Module F)**

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 his or her 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 satisfy the requirements of the Regulations 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 these Regulations 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 Regulations.

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 appropriate tests set out in the relevant harmonised standard(s) and/or technical specifications, or equivalent tests, shall be carried out in order to verify conformity with the approved type described in the EC-type examination certificate and with the appropriate requirements of the Regulations. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

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 10 years after the product has been placed on the market.

### *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 his products for verification in the form of homogeneous lots.

5.2. A random sample shall be taken from each lot according to the requirements of the Regulations. All products in a sample shall be individually examined, and appropriate tests set out in the relevant harmonised standard(s) and/or technical specifications, or equivalent tests, shall be carried out in order to ensure their conformity with the applicable requirements of the Regulations and to determine whether the

lot is accepted or rejected. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

- 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 10 years after the product has been placed on the market.

- 5.4. If a lot is rejected, the notified body or the competent authority shall take appropriate measures to prevent that lot's 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 required conformity marking set out in the Regulations, 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 type described in the EC-type examination certificate and satisfies the applicable requirements of the Regulations.

- 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 10 years after the product has been placed on the market. The declaration of conformity shall identify the product 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.

If the notified body referred to in point 3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the products.

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. *Representative*

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

## **Annex 15. Conformity based on unit verification (Module G)**

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 his or her sole responsibility that the product concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of the Regulations that apply to it.

## 2. *Technical documentation*

The manufacturer shall establish 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 conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and 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, build standard 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 harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- results of design calculations made, examinations carried out, etc.;
- test reports.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the product has been placed on the market.

### 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 Regulations.

### 4. *Verification*

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or technical specifications, or equivalent tests, to check the conformity of the product with the applicable requirements of the Regulations, or have them carried out. In the absence of such a harmonised standard and/or technical specification, the notified body concerned shall decide on the appropriate tests to be carried out.

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 10 years after the product has been placed on the market.

### 5. *Conformity marking and declaration of conformity*

5.1. The manufacturer shall affix the required conformity marking set out in the Regulations 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 Regulations.

5.2. The manufacturer shall draw up a written declaration of conformity and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. 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. *Representative*

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



## Annex 16. Conformity based on full quality assurance (Module H)

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his or her sole responsibility that the products concerned satisfy the requirements of the Regulations that apply to them.

### 2. *Manufacturing*

The manufacturer shall operate an approved quality system for design, manufacture and 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 his or her quality system with the notified body of his or her choice, for the products concerned.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the representative, his or her name and address as well;
- the technical documentation for one model of each category of products intended to be manufactured. The technical documentation shall, wherever applicable, contain at least the following elements:
  - a general description of the product;
  - conceptual-design, build standard 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 harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
  - results of design calculations made, examinations carried out, etc.;
  - test reports;
  - the documentation concerning the quality system;
  - a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the products with the requirements of the Regulations 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, include an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;
- the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or technical specifications will not be applied in full, the means that will be used to ensure that the essential requirements of these Regulations that apply to the products will be met:

- the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered;
- 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.;
- the means of monitoring the achievement of the required design and 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.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specifications.

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

The manufacturer or his or her representative shall be notified of the decision.

The notification shall contain the conclusions of the examination 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 reassessment is necessary.

The decision shall be notified to the manufacturer. 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 allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

- the quality system documentation;
- the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.;
- the quality records as provided for by the manufacturing part of the quality system, 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. During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It 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 required conformity marking set out in the Regulations, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that satisfies the applicable requirements of the Regulations.
- 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 10 years after the product has been placed on the market. The declaration of conformity shall identify the product 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, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the national authorities:
- the technical documentation referred to in point 3.1;
  - the documentation concerning the quality system 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. *Representative*

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

## **Annex 17. Equivalent conformity based on post-construction assessment (Module PCA)**

1. If the manufacturer has not assumed the responsibility for the product's conformity with these Regulations, the conformity assessment procedure based on post-construction assessment must be applied to assess equivalent conformity with the requirements of the Regulations. A natural or legal person referred to in section 16 second, third and fourth paragraphs, who is placing the product on the market or putting it into service under his or her own responsibility may assume the responsibility for the equivalent conformity of the product. This person shall fulfil the obligations laid down in points 2 and 4 and ensure and declare on his or her sole responsibility that the product concerned, which has been subject to the provisions of point 3, is in conformity with the applicable requirements of these Regulations.

2. The person who is placing the product on the market or putting it into service shall lodge an application for a post-construction assessment of the product with a notified body and shall provide the notified body with the documents and technical file enabling the notified body to assess the conformity of the product with the requirements of these Regulations and any available information on the use of the product after its first putting into service.

The person who is placing such a product on the market or putting it into service shall keep these documents and information at the disposal of the relevant national authorities for 10 years after the product has been assessed on its equivalent conformity in accordance with the post-construction assessment procedure.

3. The notified body shall examine the individual product and carry out calculations, tests and other assessments, to the extent necessary to ensure that the equivalent conformity of the product with the relevant requirements of these Regulations is demonstrated.

The notified body shall draw up and issue a certificate and a related report of conformity concerning the assessment carried out and shall keep a copy of the certificate and related report of conformity at the disposal of the national authorities for 10 years after it has issued these documents.

The notified body shall affix its identification number next to the CE marking on the approved product or have it affixed under its responsibility.

In case the assessed product is a recreational craft or personal watercraft, the notified body shall also have affixed, under his or her responsibility, the watercraft identification number as referred to in point 2.1 of Part A of Annex 1. The field for the country code of the manufacturer shall be used to indicate the country of establishment of the notified body. The fields for the unique code of the manufacturer assigned by the national authority of the Member State shall be used to indicate the post-construction assessment identification code assigned to the notified body, followed by the serial number of the post-construction assessment certificate. The fields in the watercraft identification number for the month and year of production and for the model year shall be used to indicate the month and year of the post-construction assessment.

#### 4. *CE marking and EU declaration of conformity*

- 4.1. The person who is placing the product on the market or putting it into service shall affix the CE marking and, under the responsibility of the notified body referred to in point 3, the latter's identification number to the product for which the notified body has assessed and certified its equivalent conformity with the relevant requirements of these Regulations.

- 4.2. The person who is placing the product on the market or putting it into service shall draw up an EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the date the post-construction assessment certificate has been issued. The declaration of conformity shall identify the product for which it has been drawn up.

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

- 4.3. In the case the assessed product is a recreational craft or personal watercraft, the person who is placing the watercraft on the market or putting it into service shall affix to the watercraft the builder's plate described in point 2.2 of Part A of Annex I, which shall include the words 'post-construction assessment', and the watercraft identification number described in point 2.1 of Part A of Annex 1, in accordance with the provisions set out in point 3.

5. The notified body shall inform the person who is placing the product on the market or putting it into service of his obligations under this post-construction assessment procedure.

Amended by Regulation of 5 April 2017 No. 447.

## Annex 18. Conformity of production assessment for exhaust and noise emissions

1. For verifying the conformity of an engine family, a sample of engines shall be taken from the series. The manufacturer shall decide the size (n) of the sample, in agreement with the notified body.
2. The arithmetical mean X of the results obtained from the sample shall be calculated for each regulated component of the exhaust and noise emission. The production of the series shall be deemed to conform to the requirements ('pass decision') if the following condition is met:

$$X + k \cdot S \leq L$$

S is standard deviation, where:

$$S^2 = \sum (x - X)^2 / (n - 1)$$

X = the arithmetical mean of the results obtained from the sample

x = the individual results obtained from the sample

L = the appropriate limit value

n = the number of engines in the sample

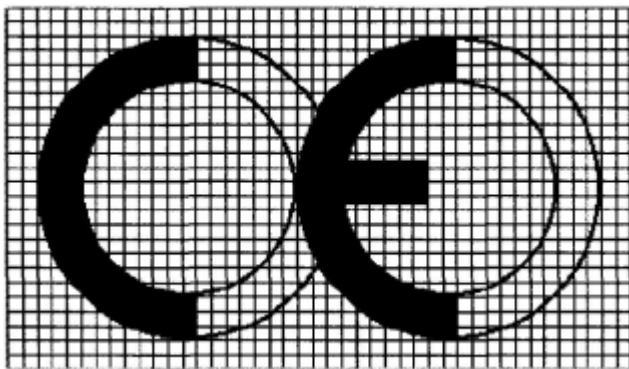
k = statistical factor depending on n (see table below)

n	2	3	4	5	6	7	8	9	10
k	0.973	0.613	0.489	0.421	0.376	0.342	0.317	0.296	0.279
n	11	12	13	14	15	16	17	18	19
k	0.265	0.253	0.242	0.233	0.224	0.216	0.210	0.203	0.198

If  $n \geq 20$ , then  $k = 0.860 / \sqrt{n}$ .

## Annex 19. CE marking

1. The CE marking shall consist of the initials "CE" taking the following form:



2. If the CE marking is reduced or enlarged, the proportions given in the graduated drawing in point 1 shall be respected.
3. The CE marking shall be at least 5 mm high.

## Annex 20. EU declaration of conformity No. xxxxx<sup>1</sup>

1. No. xxxxx (Product: product, batch, type, or serial number).
2. Name and address of the manufacturer or the manufacturer's representative [The representative shall also give the business name and address of the manufacturer] or the private importer.
3. This declaration of conformity is issued under the sole responsibility of the manufacturer or the private importer or the person referred to in section 16 third or fourth paragraph.

4. Object of the declaration (identification of product allowing traceability. It may include a photograph, where appropriate).
5. The object of the declaration described in point 4 is in conformity with the relevant EEA harmonisation legislation.
6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared.
7. Where applicable, the notified body ... (name, number) performed ... (description of intervention) and issued the certificate.
8. Identification of the person empowered to sign on behalf of the manufacturer or his or her representative.
9. Additional information:

The EU declaration of conformity shall include a statement of the propulsion engine manufacturer and that of the person adapting an engine in accordance with section 5 (5):

- a) when installed in a recreational craft or personal watercraft, in accordance with the installation instructions accompanying the engine, the engine will meet:
  - i) the exhaust emission requirements of these Regulations;
  - ii) the limit values of the Regulations of 20 May 2009 No. 544 on machines as regards engines type-approved in accordance with the Regulations of 20 May 2009 No. 544 on machines, which are in compliance with stage III A, stage III B or stage IV emission limits for CI engines used in other applications than propulsion of inland waterway vessels, locomotives and railcars, as provided for in point 4.1.2 of Annex I to the mentioned Directive; or;
  - iii) the limit values of Regulations on 4 October 1994 No. 918 on technical requirements and approval of vehicles, parts and equipment (Motor Vehicle Regulations) as regards engines type-approved in accordance with the mentioned Regulation.

The engine shall not be put into service until the watercraft into which it is to be installed has been declared in conformity with the relevant provision of these Regulations.

If the engine has been placed on the market during the additional transitional period provided for in section 36 (3) (b), the EU declaration of conformity shall contain an indication thereof.

Signed for and on behalf of:

(place and date of issue)

(name, function) (signature)

- 1 It is optional to assign a number to the declaration of conformity.