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► **B** **DIRECTIVE 94/25/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**
of 16 June 1994

on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft

(OJ L 164, 30.6.1994, p. 15)

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► <u>M2</u>	Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003	L 284	1	31.10.2003
► <u>M3</u>	Regulation (EC) No 1137/2008 of the European Parliament and of the Council of 22 October 2008	L 311	1	21.11.2008

Corrected by:

- **C1** Corrigendum, OJ L 127, 10.6.1995, p. 27 (94/25/EC)
- **C2** Corrigendum, OJ L 41, 15.2.2000, p. 20 (94/25/EC)



**DIRECTIVE 94/25/EC OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL**

of 16 June 1994

**on the approximation of the laws, regulations and administrative
provisions of the Member States relating to recreational craft**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE
EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and
in particular Article 100a thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the Economic and Social Committee ⁽²⁾,

Acting in accordance with the procedure laid down in Article 189b of
the Treaty ⁽³⁾,

Whereas the internal market is to comprise an area without internal
frontiers in which the free movement of goods, persons, services and
capital is ensured;

Whereas the laws, regulations and administrative provisions in force in
the various Member States relating to the safety characteristics of
recreational craft differ in scope and content; whereas such disparities
are liable to create barriers to trade and unequal conditions of compe-
tition within the internal market;

Whereas harmonization of national legislation is the only way in which
to remove these barriers to free trade; whereas this objective cannot be
satisfactorily achieved by the individual Member States; whereas this
Directive merely lays down the requirements vital to freedom of
movement for recreational craft;

Whereas this Directive should cover only recreational craft of a
minimum length of 2,5 m and a maximum length of 24 m, derived
from the ISO standards;

Whereas the removal of technical barriers in the field of recreational
craft and their components, to the extent that they cannot be removed by
mutual recognition of equivalence among all the Member States, should
follow the new approach set out in the Council resolution of 7 May
1985 ⁽⁴⁾ which calls for the definition of essential requirements on
safety and other aspects which are important for the general well-
being; whereas paragraph 3 of Article 100a provides that, in its
proposals, concerning health, safety, environmental protection and
consumer protection, the Commission will take as a base a high level
of protection; whereas the essential requirements constitute the criteria
with which recreational craft, partly completed craft and their
components when separate and when installed must comply;

Whereas, therefore, this Directive sets out essential requirements only;
whereas, in order to facilitate the task of proving compliance with the
essential requirements, harmonized European standards are necessary for
recreational craft and their components as referred to in Annex II;

⁽¹⁾ OJ No C 123, 15. 5. 1992, p. 7.

⁽²⁾ OJ No C 313, 30. 11. 1992, p. 38.

⁽³⁾ Opinion of the European Parliament of 16 November 1992 (OJ No C 337,
21. 12. 1992, p. 17); Council common position of 16 December 1993 (OJ No
C 137, 19. 5. 1994, p. 1); Decision of the European Parliament of 9 March
1994 (OJ No C 91, 28. 3. 1994).

⁽⁴⁾ OJ No C 136, 4. 6. 1985, p. 1.

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whereas harmonized European standards are drawn up by private bodies and must retain their non-mandatory status; whereas, for this purpose, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are recognized as the bodies competent to adopt harmonized standards which follow the general guidelines for cooperation between the Commission and those two bodies, signed on 13 November 1984; whereas, for the purposes of this Directive, a harmonized standard is a technical specification (European Standard or harmonization document) adopted by one or other of those bodies, or by both, at the prompting of the Commission pursuant to Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations⁽¹⁾ and pursuant to the general guidelines referred to above;

Whereas, in view of the nature of the risks involved in the use of recreational craft and their components, it is necessary to establish procedures applying to the assessment of compliance with the essential requirements of the Directive; whereas these procedures must be devised in the light of the level of risk which may be inherent in recreational craft and their components; whereas, therefore, each category of conformity must be supplemented by an appropriate procedure or a choice between several equivalent procedures; whereas the procedures adopted comply with Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking which are intended to be used in the technical harmonization Directives⁽²⁾;

Whereas the Council has provided for the affixing of the CE marking by either the manufacturer or his authorized representative within the Community; whereas that mark means that the recreational craft and components comply with all the essential requirements and assessment procedures provided for by the Community law applying to the product;

Whereas it is appropriate that the Member States, as provided for by Article 100a (5) of the Treaty, may take provisional measures to limit or prohibit the placing on the market and the use of recreational craft or constituent products thereof in cases where they present a particular risk to the safety of persons and, where appropriate, domestic animals or property, provided that the measures are subject to a Community control procedure;

Whereas the recipients of any decision taken as part of this Directive must be aware of the reasons behind that decision and the means of appeal open to them;

Whereas it is necessary to provide for a transitional arrangement enabling recreational craft and their components manufactured in compliance with the national regulations in force at the date of adoption of this Directive to be marketed and placed in service;

Whereas this Directive does not contain any provisions directed towards limiting the use of the recreational craft after it has been put into service;

Whereas the construction of recreational craft may have an impact on the environment to the extent that the craft may discharge polluting substances; whereas it is therefore necessary to include provisions on the protection of the environment in the Directive, in so far as those provisions concern the construction of recreational craft from the point of view of its direct impact on the environment;

Whereas the provisions of this Directive should not affect Member States' entitlement to lay down, in accordance with the Treaty, such

⁽¹⁾ OJ No L 109, 26. 4. 1983, p. 8. Directive as last amended by Directive 88/182/EEC (OJ No L 81, 26. 3. 1988, p. 75).

⁽²⁾ OJ No L 220, 30. 8. 1993, p. 23.

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requirements as they may deem necessary concerning navigation on certain waters for the purpose of protection of the environment, the fabric of waterways and ensuring safety on waterways, provided that this does not mean that the recreational craft is modified in a way not specified in this Directive,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

▼M1*Article 1***Scope and definitions**

1. This Directive shall apply:
 - (a) with regard to design and construction, to:
 - (i) recreational craft and partly completed boats;
 - (ii) personal watercraft;
 - (iii) components referred to in Annex II when placed on the Community market separately and when intended for installation;
 - (b) with regard to exhaust emissions, to:
 - (i) propulsion engines which are installed or specifically intended for installation on or in recreational craft and personal watercraft;
 - (ii) propulsion engines installed on or in these craft that are subject to a 'major engine modification';
 - (c) with regard to noise emissions, to:
 - (i) recreational craft with stern drive engines without integral exhausts or inboard propulsion engine installations;
 - (ii) recreational craft with stern drive engines without integral exhausts or with inboard propulsion installations which are subject to a major craft conversion and subsequently placed on the Community market within five years following conversion;
 - (iii) personal watercraft;
 - (iv) outboard engines and stern drive engines with integral exhausts intended for installation on recreational craft;
 - (d) for products falling under (a)(ii), (b) and (c), the provisions of this Directive shall only apply from the first placing on the market and/or putting into service after the date of entry into force of this Directive.
2. The following shall be excluded from the scope of this Directive:
 - (a) with regard to paragraph 1(a):
 - (i) craft intended solely for racing, including rowing racing boats and training rowing boats, labelled as such by the manufacturer;
 - (ii) canoes and kayaks, gondolas and pedalos;
 - (iii) sailing surfboards;
 - (iv) surfboards, including powered surfboards;

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- (v) original historical craft and individual replicas thereof designed before 1950, built predominantly with the original materials and labelled as such by the manufacturer;
 - (vi) experimental craft, provided that they are not subsequently placed on the Community market;
 - (vii) craft built for own use, provided that they are not subsequently placed on the Community market during a period of five years;
 - (viii) craft specifically intended to be crewed and to carry passengers for commercial purposes, without prejudice to paragraph 3(a), in particular those defined in Council Directive 82/714/EEC of 4 October 1982 laying down technical requirements for inland waterway vessels ⁽¹⁾, regardless of the number of passengers;
 - (ix) submersibles;
 - (x) air cushion vehicles;
 - (xi) hydrofoils;
 - (xii) External combustion steam powered craft, fuelled by coal, coke, wood, oil or gas;
- (b) with regard to paragraph 1(b):
- (i) propulsion engines installed or specifically intended for installation on the following:
 - craft intended solely for racing and labelled as such by the manufacturer,
 - experimental craft, provided that they are not subsequently placed on the Community market,
 - craft specifically intended to be crewed and to carry passengers for commercial purposes, without prejudice to paragraph 3(a), in particular those defined in Directive 82/714/EEC, regardless of the number of passengers,
 - submersibles,
 - air cushion vehicles,
 - hydrofoils;
 - (ii) original and individual replicas of historical propulsion engines, which are based on a pre-1950 design, not produced in series and fitted on craft referred to in paragraph 2(a)(v) and (vii);
 - (iii) propulsion engines built for own use provided that they are not subsequently placed on the Community market during a period of five years;
- (c) with regard to paragraph 1(c):
- all craft referred to in point (b) of this paragraph,
 - craft built for own use, provided that they are not subsequently placed on the Community market during a period of five years.
3. For the purposes of this Directive the following definitions shall apply:
- (a) 'recreational craft': any boat of any type intended for sports and leisure purposes of hull length from 2,5 m to 24 m, measured according to the harmonised standard, regardless of the means of propulsion; the fact that the same boat could be used for charter or for recreational boating training shall not prevent it being covered

⁽¹⁾ OJ L 301, 28.10.1982, p. 1. Directive as amended by the 1994 Act of Accession.

▼ M1

by this Directive when it is placed on the Community market for recreational purposes;

- (b) 'personal watercraft': a vessel less than 4 m in length which uses an internal combustion 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, rather than within the confines of, a hull;
- (c) 'propulsion engine': any spark or compression ignition, internal combustion engine used for propulsion purposes, including two-stroke and four-stroke inboard, stern-drive with or without integral exhaust and outboard engines;
- (d) 'major engine modification': the modification of an engine which:
 - could potentially cause the engine to exceed the emission limits set out in Annex I.B. excluding routine replacement of engine components that do not alter the emission characteristics, or
 - increases the rated power of the engine by more than 15 %;
- (e) 'major craft conversion': a conversion of a craft which:
 - changes the means of propulsion of the craft,
 - involves a major engine modification,
 - alters the craft to such an extent that it is considered a new craft;
- (f) 'means of propulsion': the mechanical method by which the craft is driven, in particular marine propellers or waterjet mechanical drive systems;
- (g) 'engine family': the manufacturer's grouping of engines which, through their design, are expected to have similar exhaust emission characteristics and which comply with the exhaust emissions requirements of this Directive;
- (h) 'manufacturer': any natural or legal person who designs and manufactures a product covered by this Directive or who has such a product designed and/or manufactured with a view to placing it on the market on his own behalf;
- (i) 'authorised representative': any natural or legal person established in the Community who has received a written mandate from the manufacturer to act on his behalf with regard to the latter's obligation under this Directive.

▼ B*Article 2***Placing on the market and putting into service**

1. Member States shall take all necessary measures to ensure that the products referred to in Article 1 (1) may be placed on the market and put into service for use in accordance with their intended purpose only if they do not endanger the safety and health of persons, property or the environment when correctly constructed and maintained.

2. The provisions of this Directive shall not prevent Member States from adopting, in compliance with the Treaty, provisions concerning navigation on certain waters for the purpose of protection of the environment, the fabric of waterways, and ensuring safety of waterways, providing that this does not require modification to craft conforming to this Directive.

▼B*Article 3***Essential requirements**

The products referred to in Article 1 (1) shall meet the essential safety, health, environmental protection and consumer protection requirements set out in Annex I.

▼M1*Article 4***Free movement of the products referred to in Article 1(1)**

1. Member States shall not prohibit, restrict or impede the placing on the market and/or putting into service in their territory of products referred to in Article 1(1) bearing the CE marking referred to in Annex IV, which indicates their conformity with all the provisions of this Directive, including the conformity procedures set out in Chapter II.
2. Member States shall not prohibit, restrict or impede the placing on the market of partly-completed boats where the builder or his authorised representative established in the Community or the person responsible for the placing on the market declares, in accordance with Annex IIIa, that they are intended to be completed by others.
3. Member States shall not prohibit, restrict or impede the placing on the market and/or putting into service of components referred to in Annex II and bearing the CE marking referred to in Annex IV which indicates their conformity with the relevant essential requirements where these components are accompanied by a written declaration of conformity as provided for in Annex XV and are intended to be incorporated into recreational craft, in accordance with the declaration, referred to in Annex IIIb, of the manufacturer, his authorised representative established in the Community or, in the case of imports from a third country, of any person who places those components on the Community market.
4. Member States shall not prohibit, restrict or impede the placing on the market and/or putting into service of:
 - inboard engines and stern drive propulsion engines without integral exhaust,
 - engines type-approved according to Directive 97/68/EC ⁽¹⁾ which are in compliance with stage II provided for in section 4.2.3 of Annex I to that Directive and of,
 - engines type-approved according to Directive 88/77/EEC ⁽²⁾;
 where the manufacturer or his authorised representative established in the Community declares in accordance with Annex XV.3 that the engine will meet the exhaust emission requirements of this Directive, when installed in a recreational craft or personal watercraft in accordance with the manufacturer's supplied instructions.
5. At trade fairs, exhibitions, demonstrations, etc., Member States shall not create any obstacles to the showing of the products referred

⁽¹⁾ Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 59, 27.2.1998, p. 1). Directive as amended by Commission Directive 2001/63/EC (OJ L 227, 23.8.2001, p. 41).

⁽²⁾ Council Directive 88/77/EEC of 3 December 1987 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous and particulate pollutants from compression ignition engines for use in vehicles, and the emission of gaseous pollutants from positive ignition engines fuelled with natural gas or liquefied petroleum gas for use in vehicles (OJ L 36, 9.2.1988, p. 33). Directive as last amended by Commission Directive 2001/27/EC (OJ L 107, 18.4.2001, p. 10).

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to in Article 1(1) which do not comply with this Directive, provided that a visible sign clearly indicates that such products may not be marketed or put into service until they have been made to comply.

6. Where the products referred to in Article 1(1) are subject to other Directives covering other aspects and which provide for the affixing of the CE marking, the latter shall indicate that such products are also presumed to conform to the provisions of those other Directives. The CE marking shall indicate conformity with the applicable Directives or relevant parts thereof. In this case, the particulars of the said Directives applied by the manufacturer, as published in the *Official Journal of the European Union*, must be given in the documents, declaration of conformity or instructions required by the Directives and accompanying such products.

▼ B*Article 5*

Member States shall presume compliance with the essential requirements referred to in Article 3 of products referred to in Article 1 (1) which meet the relevant national standards adopted pursuant to the harmonized standards the references of which have been published in the *Official Journal of the European Communities*; Member States shall publish the references of such national standards.

Article 6

1. Where a Member State or the Commission is of the opinion that the harmonized standards referred to in Article 5 do not fully meet the essential requirements referred to in Article 3, the Commission or the Member State shall notify the committee set up under Directive 83/189/CEE, setting out its reasons. The committee shall deliver an urgent opinion.

In the light of the opinion of the committee, the Commission shall inform Member States if the standards concerned should be withdrawn from the publications referred to in Article 5.

2. The Commission may adopt any appropriate measure with a view to ensuring that this Directive is applied practically in a uniform manner in pursuance of paragraph 3.

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3. The Commission shall be assisted by a standing committee (hereinafter referred to as 'the Committee').

Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC ⁽¹⁾ shall apply, having regard to the provisions of Article 8 thereof.

The Committee shall adopt its rules of procedure.

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4. The Standing Committee may, in addition, examine any question concerning the application of this Directive and raised by its chairman, either at the chairman's initiative or at the request of a Member State.

▼ M3*Article 6a*

The Commission may make amendments which are necessary in the light of the progress of technical knowledge and in the light of new scientific evidence to the requirements of Annex I.B.2 and Annex I.C.1,

⁽¹⁾ Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).

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excluding direct or indirect modifications to exhaust or noise emission values and to the Froude and P/D ratio values. Such amendments may include reference fuels and the standards to be used for exhaust and noise emissions testing.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 6b(2).

Article 6b

1. The Commission shall be assisted by the Committee set up pursuant to Article 6(3).

2. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

▼B*Article 7***Safeguard clause****▼M1**

1. Where a Member State ascertains that products falling within the scope of Article 1 and bearing the CE marking referred to in Annex IV, when correctly designed, constructed, installed where appropriate, maintained and used in accordance with their intended purpose may endanger the safety and health of persons, property or the environment, it shall take all appropriate interim measures to withdraw them from the market or prohibit or restrict their being placed on the market and/or put into service.

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The Member State shall immediately inform the Commission of any such measure, indicating the reasons for its decision, in particular where non-conformity is the result of:

- (a) failure to comply with the essential requirements referred to in Article 3;
- (b) incorrect application of the standards referred to in Article 5, in so far as it is claimed that those standards have been applied;
- (c) shortcomings in the standards referred to in Article 5 themselves.

2. The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that:

- the measures are justified, it shall immediately so inform the Member State which took the initiative and the other Member States; where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the Commission shall, after consulting the parties concerned, bring the matter before the Committee referred to in Article 6 (1) within two months, if the Member State which has taken the decision intends to maintain it, and shall initiate the procedure referred to in Article 6 (1),
- the measures are unjustified, it shall immediately so inform the Member State which took the initiative and the manufacturer or his authorized representative established in the Community.

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3. Where a non-complying product referred to in Article 1 bears the CE marking, the appropriate measures shall be taken by the Member State which has authority over whomsoever affixed the marking; that Member State shall inform the Commission and the other Member States thereof.

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4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

CHAPTER II

Conformity assessment**▼M1***Article 8*

1. Before placing on the market, and/or putting into service, products referred to in Article 1(1) the manufacturer or his authorised representative established within the Community shall apply the procedures referred to in paragraphs 2, 3 and 4 of this Article.

In the case of post-construction assessment for recreational craft, if neither the manufacturer nor his authorised representative established within the Community fulfils the responsibilities for the product's conformity to this Directive, these can be assumed by any natural or legal person established within the Community who places the product on the market, and/or puts it into service, under his own responsibility. In such a case, the person who places the product on the market or puts it into service must lodge an application for a post-construction report with a notified body. The person who places the product on the market and/or puts it into service must provide the notified body with any available document and technical file referring to the first placing on the market of the product in the country of origin. The notified body shall examine the individual product and carry out calculations and other assessment to ensure its equivalent conformity with the relevant requirements of the Directive. In this case, the Builder's plate described in Annex I, 2.2 shall include the words ('Post-construction certificate'). The notified body shall draw up a report of conformity concerning the assessment carried out and shall inform the person who places the product on the market and/or puts it into service of his obligations. That person shall draw up a declaration of conformity (see Annex XV) and affix, or cause to be affixed, the CE mark accompanied by the distinguishing number of the relevant notified body on the product.

2. With regard to design and construction of products referred to in Article 1(1)(a), the boat manufacturer or his authorised representative established in the Community shall apply the following procedures for boat design categories A, B, C and D as referred to in section 1 of Annex I.A:

(a) for categories A and B:

- (i) for boats from 2,5 m to 12 m hull length: the internal production control plus tests (module Aa) referred to in Annex VI, or the EC type-examination (module B) as described in Annex VII, supplemented by conformity to type (module C) referred to in Annex VIII, or any of the following modules: B+D, or B+E, or B+F, or G or H;
- (ii) for boats from 12 m to 24 m hull length: the EC type-examination (module B) referred to in Annex VII supplemented by conformity to type (module C) referred to in Annex VIII, or any of the following modules: B+D, or B+E, or B+F, or G or H;

(b) for category C:

- (i) for boats from 2,5 m to 12 m hull length:
 - where the harmonised standards relating to Sections 3.2 and 3.3 of Annex I.A are complied with: the internal production control (module A), referred to in Annex V, or internal production control plus tests (module Aa) referred to in Annex VI, or the EC type-examination (module B) as described in Annex VII, supplemented by conformity to

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type (module C) referred to in Annex VIII, or any of the following modules: B+D, or B+E, or B+F, or G, or H,

- where the harmonised standards relating to Sections 3.2 and 3.3 of Annex I.A are not complied with: the internal production control plus tests (module Aa) referred to in Annex VI, or the EC type-examination (module B) as described in Annex VII, supplemented by conformity to type (module C) referred to in Annex VIII, or any of the following modules: B+D, or B+E, or B+F, or G, or H;

- (ii) for boats from 12 m to 24 m hull length: the EC type-examination (module B) referred to in Annex VII followed by conformity to type (module C) referred to in Annex VIII, or any of the following modules: B+D, or B+E, or B+F, or G or H;

- (c) for category D:

for boats from 2,5 m to 24 m hull length: the internal production control (module A) referred to in Annex V, or the internal production control plus tests (module Aa) referred to in Annex VI, or the EC type-examination (module B) as described in Annex VII, supplemented by conformity to type (module C) referred to in Annex VIII, or any of the following modules: B+D, or B+E, or B+F or G or H;

- (d) for personal watercraft:

the internal production control (module A) referred to in Annex V, or the internal production control plus tests (module Aa) referred to in Annex VI, or the EC type-examination (module B) as described in Annex VII followed by conformity to type (module C) referred to in Annex VIII, or any of the following modules: B+D, or B+E, or B+F, or G or H;

- (e) for components referred to in Annex II: any of the following modules: B+C, or B+D, or B+F, or G or H.

3. With regard to exhaust emissions:

for products referred to in Article 1(1)(b), the engine manufacturer or his authorised representative established in the Community shall apply the EC type-examination (module B) as described in Annex VII followed by conformity to type (module C) referred to in Annex VIII, or any of the following modules: B+D, or B+E, or B+F, or G or H.

4. With regard to noise emissions:

- (a) for products referred to in Article 1(1)(c)(i) and (ii), the boat manufacturer or his authorised representative established in the Community shall apply:

- (i) where tests are conducted using the harmonised standard ⁽¹⁾ for noise measurement: either internal production control plus tests (module Aa) referred to in Annex VI, or unit verification (module G) referred to in Annex XI, or full quality assurance (module H) referred to in Annex XII;

- (ii) where the Froude number and power displacement ratio method is used for assessment: either the internal production control (module A) referred to in Annex V, or the internal production control plus tests (module Aa) referred to in Annex VI, or unit verification (module G) referred to in Annex XI, or full quality assurance (module H) referred to in Annex XII;

- (iii) where certified reference boat data, established in accordance with point (i), is used for assessment: either internal production

⁽¹⁾ EN ISO 14509.

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control (module A) referred to in Annex V, or internal production control plus supplementary requirements (module Aa) referred to in Annex VI, or unit verification (module G) referred to in Annex XI, or full quality assurance (module H) referred to in Annex XII;

- (b) for products referred to in Article 1(1)(c)(iii) and (iv), the personal watercraft/engine manufacturer or his authorised representative established in the Community shall apply: internal production control plus supplementary requirements referred to in Annex VI (module Aa) or module G or H.

▼B*Article 9***Notified bodies**

1. Member States shall notify the Commission and other Member States of the bodies which they have appointed to carry out the tasks pertaining to the conformity assessment procedures referred to in Article 8, together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.

The Commission shall publish a list of the notified bodies, together with the identification numbers it has allocated to them and the tasks for which they have been notified, in the *Official Journal of the European Communities*. It shall ensure that the list is kept up to date.

2. Member States shall apply the criteria laid down in Annex XIV in assessing the bodies to be indicated in such notification. Bodies meeting the assessment criteria laid down in the relevant harmonized standards shall be presumed to fulfil those criteria.

3. A Member State shall withdraw its approval from such a body if it is established that the latter no longer satisfies the criteria referred to in Annex XIV. It shall inform the Commission and the other Member States of its action forthwith.

CHAPTER III

CE Marking*Article 10***▼M1**

1. When the following products are placed on the market, they shall bear the CE marking of conformity:

- (a) recreational craft, personal watercraft and components referred to in Annex II, which are regarded as meeting the corresponding essential requirements set out in Annex I;
- (b) outboard engines which are regarded as meeting the essential requirements set out in Annex I.B and I.C.;
- (c) stern drive engines with integral exhaust which are regarded as meeting the essential requirements set out in Annex I.B. and I.C.

2. The CE marking of conformity, as shown in Annex IV, must appear in a visible, legible and indelible form on the craft and the personal watercraft as in point 2.2 of Annex I.A, on components, as referred to in Annex II and/or on their packaging, and on outboard engines and stern drive engines with integral exhaust as in point 1.1 of Annex I.B.

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The CE marking shall be accompanied by the identification number of the body responsible for implementation of the procedures set out in Annexes IX, X, XI, XII, and XVI.

3. The affixing of markings or inscriptions on products covered by this Directive which are likely to mislead third parties with regard to the meaning or the form of the CE marking shall be prohibited. Any other markings may be affixed to products covered by this Directive and/or on their packaging provided that the visibility and legibility of the CE marking is not thereby reduced.

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4. Without prejudice to Article 7:

- (a) where a Member State establishes that the CE marking has been affixed wrongly, the manufacturer or his authorized representative established in the Community shall be obliged to end the infringement under conditions laid down by the Member State;
- (b) where non-compliance continues, the Member State shall take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market, in accordance with the procedure laid down in Article 7.

CHAPTER IV

Final provisions*Article 11*

Detailed grounds shall be given for any decision taken pursuant to this Directive leading to a restriction on the marketing and putting into service of products referred to in Article 1 (1). The party concerned shall be informed of the decision as soon as possible together with the means of redress available under the laws in force in the Member State concerned and the periods within which appeals must be lodged.

Article 12

The Commission shall take the necessary measures to ensure that data affecting all pertinent decisions concerning the management of this Directive are made available.

Article 13

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive not later than 16 December 1995. They shall immediately inform the Commission thereof.

Member States shall apply these provisions from 16 June 1996.

The Standing Committee referred to in Article 6 (3) may assume its tasks from the date of the entry into force of this Directive. Member States may take the measures referred to in Article 9 of such date.

When Member States adopt the provisions referred to in the first subparagraph, these shall contain a reference to this Directive or shall be accompanied by such a reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field governed by this Directive.

▼B

3. Member States shall accept the placing on the market and putting into service of products referred to in Article 1 (1) which comply with the rules in force in their territory on the date of adoption of this Directive during a period of four years from that date.

Article 14

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 15

This Directive is addressed to the Member States.

▼ M1

ANNEX I

ESSENTIAL REQUIREMENTS

PRELIMINARY OBSERVATION

For the purposes of this Annex the term 'craft' shall cover recreational craft and personal watercraft.

A. Essential safety requirements for the design and construction of craft

▼ B

1. BOAT DESIGN CATEGORIES

▼ M1

Design category	Wind force (Beaufort scale)	Significant wave height (H 1/3, metres)
A - 'Ocean'	exceeding 8	exceeding 4
B - 'Offshore'	up to, and including, 8	up to, and including, 4
C - 'Inshore'	up to, and including, 6	up to, and including, 2
D - 'Sheltered waters'	up to, and including, 4	up to, and including, 0,3

▼ B

Definitions:

▼ M1

A. OCEAN: Designed for extended voyages where conditions may exceed wind force 8 (Beaufort scale) and significant wave heights of 4 m and above but excluding abnormal conditions, and vessels largely self-sufficient.

▼ B

B. OFFSHORE: Designed for offshore voyages where conditions up to, and including, wind force 8 and significant wave heights up to, and including, 4 m may be experienced.

C. INSHORE: Designed for voyages in coastal waters, large bays, estuaries, lakes and rivers where conditions up to, and including, wind force 6 and significant wave heights up to, and including, 2 m may be experienced.

▼ M1

D. SHELTERED WATERS: Designed for voyages on sheltered coastal waters, small bays, small lakes, rivers and canals when conditions up to, and including, wind force 4 and significant wave heights up to, and including, 0,3 m may be experienced, with occasional waves of 0,5 m maximum height, for example from passing vessels.

Craft in each Category must be designed and constructed to withstand these parameters in respect of stability, buoyancy, and other relevant essential requirements listed in Annex I, and to have good handling characteristics.

▼ B

2. GENERAL REQUIREMENTS

▼ M1

Products falling under Article 1(1)(a) shall comply with the essential requirements in so far as they apply to them.

▼ B2.1. ► M1 Craft identification ◀▼ M1

Each craft shall be marked with an identification number including the following information:

▼ B

— manufacturer's code,

▼B

- country of manufacture,
- unique serial number,
- year of production,
- model year.

The relevant harmonized standard gives details of these requirements.

2.2. Builder's plate

Each craft shall carry a permanently affixed plate mounted separately from the boat hull identification number, containing the following information:

- manufacturer's name,
- CE marking (see Annex IV),
- boat design category according to section 1,

▼M1

- manufacturer's maximum recommended load derived from section 3.6 excluding the weight of the contents of the fixed tanks when full,

▼B

- number of persons recommended by the manufacturer for which the boat was designed to carry when under way.

2.3. Protection from falling overboard and means of reboarding

Depending on the design category, craft shall be designed to minimize the risks of falling overboard and to facilitate reboarding.

2.4. Visibility from the main steering position

For motor boats, 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 craft shall be provided with an owner's manual in the official Community language or languages which may be determined by the Member State in which it is marketed in accordance with the Treaty. This manual should draw particular attention to risks of fire and flooding and shall contain the information listed in sections 2.2, 3.6 and 4 as well as the unladen weight of the craft in kilograms.

3. INTEGRITY AND STRUCTURAL REQUIREMENTS**3.1. Structure**

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

3.2. Stability and freeboard

The craft shall have sufficient stability and freeboard considering its design category according to section 1 and the manufacturer's maximum recommended load according to section 3.6.

3.3. Buoyancy and flotation

The craft shall be constructed to ensure that it has buoyancy characteristics appropriate to its design category according to section 1.1, and the manufacturer's maximum recommended load according to section 3.6. All habitable multihull craft shall be so designed as to have sufficient buoyancy to remain afloat in the inverted position.

Boats of less than six metres in length that are susceptible to swamping when used in their design category shall be provided with appropriate means of flotation in the swamped condition.

▼B**3.4. Openings in hull, deck and superstructure**

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

Windows, portlights, doors and hatchcovers shall withstand the water pressure likely to be encountered in their specific position, as well as pointloads 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 according to section 3.6, shall be fitted with shutoff means which shall be readily accessible.

3.5. Flooding

All craft shall be designed so as to minimize the risk of sinking.

Particular attention should be paid where appropriate to:

- cockpits and wells, which should be self-draining or have other means of keeping water out of the boat interior,
- ventilation fittings,
- 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 boat was designed ►**MI** ◀ shall be determined according to the design category (section 1), stability and freeboard (section 3.2) and buoyancy and flotation (section 3.3).

3.7. Liferaft stowage

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

3.8. Escape

All habitable multihull craft over 12 metres long shall be provided with viable means of escape in the event of inversion.

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

3.9. Anchoring, mooring and towing

All craft, 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 craft are satisfactory with the most powerful engine for which the boat is designed and constructed. For all recreational marine engines, the maximum rated engine power shall be declared in the owner's manual in accordance with the harmonized standard.

5. INSTALLATION REQUIREMENTS**5.1. Engines and engine spaces****5.1.1. Inboard engine**

All inboard mounted engines shall be placed within an enclosure separated from living quarters and installed so as to minimize 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.

▼B

The insulating materials inside engine spaces shall be non-combustible.

5.1.2. *Ventilation*

The engine compartment shall be ventilated. The dangerous ingress of water into the engine compartment through all inlets must be prevented.

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 engines starting*

All boats with outboard engines shall have a device to prevent starting the engine 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.

▼M15.1.5. *Personal watercraft running without driver*

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

▼B5.2. **Fuel system**5.2.1. *General*

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

▼M15.2.2. *Fuel tanks*

Fuel tanks, lines and hoses shall be secured and separated or protected from any source of significant heat. The material the tanks are made of and their method of construction shall be according to their capacity and the type of fuel. All tank spaces shall be ventilated.

Petrol fuel shall be kept in tanks which do not form part of the hull and are:

- (a) insulated from the engine compartment and from all other source of ignition;
- (b) separated from living quarters;

Diesel fuel may be kept in tanks that are integral with the hull.

▼B5.3. **Electrical system**

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

Attention shall be paid to the provision of overload and short-circuit protection of all circuits, except engine starting circuits, supplied from batteries.

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

▼B**5.4. Steering system****5.4.1. General**

Steering 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

Sailboat and single-engined inboard powered motor boats with remote-controlled rudder steering systems shall be provided with emergency means of steering the 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 to withstand the stresses and exposures found in the marine environment.

Each appliance shall be equipped with a flame failure device effective on all burners. Each gas-consuming appliance must be supplied by a separate branch of the distribution system, and each appliance must be controlled by a separate closing device. Adequate ventilation must be provided to prevent hazards from leaks and products of combustion.

All craft 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. Any permanent 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 craft 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 avoiding electrical wiring above hot areas of machines.

▼M1**5.6.2. Fire-fighting equipment**

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 enclosures shall be protected by a fire extinguishing system that avoids the need to open the enclosure 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 craft.

▼B**5.7. Navigation lights**

Where navigation lights are fitted, they shall comply with the 1972 Colreg or CEVNI regulations, as appropriate.

▼M1**5.8. Discharge prevention and installations facilitating the delivery ashore of waste**

Craft shall be constructed so as to prevent the accidental discharge of pollutants (oil, fuel, etc.) overboard.

Craft fitted with toilets shall have either:

- (a) holding tanks, or
- (b) provision to fit holding tanks.

▼ **M1**

Craft with permanently installed holding tanks shall be fitted with a standard discharge connection to enable pipes of reception facilities to be connected with the 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.

B. Essential requirements for exhaust emissions from propulsion engines

Propulsion engines shall comply with the following essential requirements for exhaust emissions.

1. *ENGINE IDENTIFICATION*

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

- engine manufacturer's trademark or trade-name,
- engine type, engine family, if applicable,
- a unique engine identification number,
- CE marking, if required under Article 10.

1.2. These marks must be durable for the normal life of the engine and must be clearly legible and indelible. If labels or plates are used, they must 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. These marks must be secured to an engine part necessary for normal engine operation and not normally requiring replacement during the engine life.

1.4. These marks must be located so as to be readily visible to the average person 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 the following table:

Table 1

Type	Carbon monoxide $CO = A + B/P_N^n$			Hydrocarbons $HC = A + B/P_N^n$			Nitrogen oxides NO_x	Particulates PT
	A	B	n	A	B	n		
Two-stroke spark ignition	150,0	600,0	1,0	30,0	100,0	0,75	10,0	Not applicable
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 and the exhaust emissions are measured in accordance with the harmonised standard ⁽¹⁾.

For engines above 130 kW either E3 (IMO) or E5 (recreational marine) duty cycles may be used.

The reference fuels to be used for the emissions test for engines fuelled with petrol and diesel shall be as specified in Directive 98/69/EC (Annex IX, Tables 1 and 2), and for those engines fuelled with Liquefied Petroleum Gas as specified in Directive 98/77/EC.

3. *DURABILITY*

The manufacturer of the engine shall supply engine installation and maintenance instructions, which if applied should mean that the

⁽¹⁾ EN ISO 8178-1: 1996.

▼ **M1**

engine in normal use will continue to comply with the above limits 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 component fatigue so that the necessary maintenance instructions may be prepared by the manufacturer and issued with all new engines when first placed on the market.

The normal life of the engine is considered to mean:

- (a) inboard or stern drive engines with or without integral exhaust: 480 hours or 10 years, whichever occurs first;
- (b) personal watercraft engines: 350 hours or five years, whichever occurs first;
- (c) outboard engines: 350 hours or 10 years, whichever occurs first.

4. *OWNER'S MANUAL*

Each engine shall be provided with an owner's manual in the Community language or languages, which may be determined by the Member State in which the engine is to be marketed. This manual shall:

- (a) provide instructions for the installation and maintenance needed to assure the proper functioning of the engine to meet the requirements of paragraph 3, (Durability);
- (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 following essential requirements for noise emissions.

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 measured in accordance with tests defined in the harmonised standard ⁽¹⁾ shall not exceed the limit values in the following table:

Table 2

Single engine power In kW	Maximum Sound Pressure Level = L_{pASmax} In dB
$P_N \leq 10$	67
$10 < P_N \leq 40$	72
$P_N > 40$	75

where P_N = rated engine power in kW 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 these noise requirements if they have a Froude number of $\leq 1,1$ and a power displacement ratio of ≤ 40 and where the engine and exhaust system are installed in accordance with the engine manufacturer's specifications.

⁽¹⁾ EN ISO 14509.

▼ **M1**

- 1.3. 'Froude number' shall be calculated by dividing the maximum boat speed V (m/s) by the square root of the waterline length lwl (m) multiplied by a given gravitational constant, ($g = 9,8 \text{ m/s}^2$)

$$Fn = \frac{V}{\sqrt{(g \cdot Lwl)}}$$

'Power displacement ratio' shall be calculated by dividing the engine power P (kW) by the boat's displacement $D(\tau) = \frac{P}{D}$

- 1.4. As a further alternative to sound measurement tests, recreational craft with inboard or stern drive engine configurations without integral exhaust, shall be deemed to comply with these noise requirements if their key design parameters are the same as or compatible with those of a certified reference boat to tolerances specified in the harmonised standard.
- 1.5. 'Certified reference boat' shall mean a specific combination of hull/inboard engine or stern drive engine without integral exhaust that has been found to comply with the noise emission requirements, when measured in accordance with section 1.1, and for which all appropriate key design parameters and sound level measurements have been included subsequently in the published list of certified reference boats.

2. *OWNER'S MANUAL*

For recreational craft with inboard engine or stern drive engines with or without integral exhaust and personal watercraft, the owner's manual required under Annex I.A Section 2.5, shall include information necessary to maintain the 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, the owner's manual required under Annex I.B.4 shall provide instructions necessary to maintain the outboard engine in a condition, that insofar as is practicable, will ensure compliance with the specified noise limit values when in normal use.

▼B

ANNEX II

COMPONENTS

1. Ignition-protected equipment for inboard and stern drive engines.
2. Start-in-gear protection devices for outboard engines.
3. Steering wheels, steering mechanisms and cable assemblies.

▼M1

4. Fuel tanks intended for fixed installations and fuel hoses.

▼B

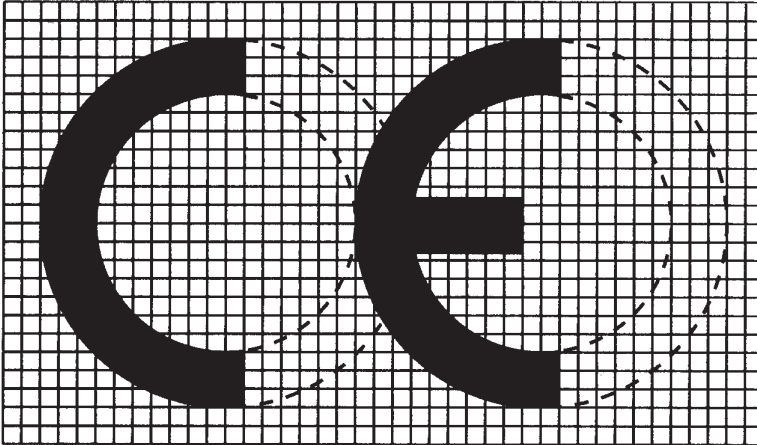
5. Prefabricated hatches and portlights.

*ANNEX III***DECLARATION BY THE BUILDER OR HIS AUTHORIZED REPRESENTATIVE ESTABLISHED IN THE COMMUNITY OR THE PERSON RESPONSIBLE FOR PLACING ON THE MARKET****(Article 4 (2) and (3))**

- (a) The declaration by the builder or his authorized representative established in the Community referred to in Article 4 (2) (partly completed craft) shall contain the following:
- the name and address of the builder,
 - the name and address of the representative of the builder established in the Community or, if appropriate, of the person responsible for the placing on the market,
 - a description of the partly completed craft,
 - a statement that the partly completed craft is intended to be completed by others and that it complies with the essential requirements that apply at this stage of construction.
- (b) The declaration by the builder, his authorized representative established in the Community or the person responsible for placing on the market referred to in Article 4 (3) (components) shall contain the following:
- the name and address of the builder,
 - the name and address of the representative of the builder established in the Community or, if appropriate, of the person responsible for the placing on the market,
 - a description of the component,
 - a statement that the component complies with the relevant essential requirements.

▼B*ANNEX IV***CE MARKING**

The CE conformity marking must consist of the initials 'CE' taking the following form:



If the marking is reduced or enlarged, the proportions given in the above graduated drawing must be respected.

The various elements of the CE marking must have about the same vertical dimension, which shall not be less than 5 mm.

▼C1

The CE marking is followed by the identification number of the notified body if it intervenes in the control of production.

*ANNEX V***INTERNAL PRODUCTION CONTROL****(module A)**

1. The manufacturer or his authorized representative established within the Community, who carries out the obligations laid down in point 2, ensures and declares that the products concerned satisfy the requirements of the Directive that apply to them. The manufacturer or his authorized representative established within the Community shall affix the CE marking to each product and draw up a written declaration of conformity (see Annex XV).
2. The manufacturer shall establish the technical documentation described in paragraph 3 and he or his authorized representative established within the Community shall keep it for a period ending at least 10 years after the last product has been manufactured at the disposal of the relevant national authorities for inspection purposes.

Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the product on the Community market.

3. Technical documentation shall enable the conformity of the products with the requirements of the Directive to be assessed. It shall, as far as relevant for such assessment, cover the design, manufacture and operation of the product (see Annex XIII).
4. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity with the technical documentation.
5. The manufacturer shall take all measures necessary in order that the manufacturing process shall ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the Directive that apply to them.

▼ M1*ANNEX VI***INTERNAL PRODUCTION CONTROL PLUS TESTS (Module Aa, option 1)**

This module consists of module A, as referred to in Annex V, plus the following supplementary requirements:

A. Design and construction

On one or several boats 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 behalf:

- (a) test of stability according to section 3.2 of the Essential Requirements (Annex IA);
- (b) test of buoyancy characteristics according to section 3.3 of the Essential Requirements (Annex IA).

Provisions common to both variations:

These tests or calculations or control shall be carried out under the responsibility of a notified body chosen by the manufacturer.

B. Noise emissions

For recreational craft fitted with inboard or stern drive engines without integral exhaust and for personal watercraft:

On one or several craft representing the production of the craft manufacturer, the sound emission tests defined in Annex I.C shall be carried out by the craft manufacturer, or on his 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 sound emission tests defined in Annex I.C shall be carried out by the engine manufacturer, or on his 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 XVII shall be applied to ensure conformity of the sample.



ANNEX VII

EC TYPE-EXAMINATION

(module B)

1. A notified body ascertains and attests that a specimen, representative of the production envisaged, meets the provisions of the Directive that apply to it.
2. The application for the EC type-examination shall be lodged by the manufacturer or his authorized representative established within the Community with a notified body of his choice.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address in addition,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation, as described in point 3.

The applicant shall place at the disposal of the notified body a specimen, representative of the production envisaged and hereinafter called 'type' ⁽¹⁾.

The notified body may request further specimens if needed for carrying out the test programme.

3. The technical documentation shall enable the conformity of the product with the requirements of the Directive to be assessed. It shall, as far as relevant for such assessment, cover the design, manufacture and functioning of the product (see Annex XIII).
4. The notified body shall:
 - 4.1. examine the technical documentation, verify that the type has been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in Article 5, as well as the components which have been designed without applying the relevant provisions of those standards;
 - 4.2. perform or have performed the appropriate examinations and necessary tests to check whether, where the standards referred to in Article 5 have not been applied, the solutions adopted by the manufacturer meet the Essential Requirements of the Directive;
 - 4.3. perform or have performed the appropriate examinations and necessary tests to check whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied;
 - 4.4. agree with the applicant the location where the examinations and necessary tests shall be carried out.
5. Where the type meets the provisions of the Directive, the notified body shall issue an EC type-examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, conclusions of the examination, conditions for its validity and the necessary data for identification of the approved type.

A list of the relevant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.

If the manufacturer is denied a type certification, the notified body shall provide detailed reasons for such denial.

6. The applicant shall inform the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications to the approved product which must receive additional approval where such changes may affect the conformity with the essential requirements or the prescribed conditions for use of the product. This

⁽¹⁾ A type may cover several versions of the product provided that the differences between the versions do not affect the level of safety and the other requirements concerning the performance of the product.

▼B

additional approval is given in the form of an addition to the original EC type-examination certificate.

7. Each notified body shall communicate to the other notified bodies the relevant information concerning the EC type-examination certificates and additions issued and withdrawn.
8. The other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The annexes to the certificates shall be kept at the disposal of the other notified bodies.
9. The manufacturer or his authorized representative shall keep with the technical documentation copies of EC type-examination certificates and their additions for a period ending at least 10 years after the last product has been manufactured.

Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the product on the Community market.

▼B*ANNEX VIII***CONFORMITY TO TYPE****(module C)**

1. The manufacturer or his authorized representative established within the Community ensures and declares that the products concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of the Directive that applies to them. The manufacturer shall affix the CE marking to each product and draw up a written declaration of conformity (see Annex XV).
2. The manufacturer shall take all measures necessary to ensure that the manufacturing process assures compliance of the manufactured products with the type as described in the EC type-examination certificate and with the requirements of the Directive that apply to them.
3. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity for a period ending at least 10 years after the last product has been manufactured.

Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the product on the Community market (see Annex XIII).

▼M1

4. With regard to the assessment of conformity with the exhaust emission requirements of this Directive and if the manufacturer is not working under a relevant quality system as described in Annex XII, a notified body chosen by the manufacturer may carry out or have carried out product checks at random intervals. When the quality level appears unsatisfactory or when it seems necessary to verify the validity of the data presented by the manufacturer, the following procedure shall be used:

An engine is taken from the series and subjected to the test described in Annex I.B. Test engines shall have been run in, partially or completely, according to the manufacturer's specifications. If the specific exhaust emissions of the engine taken from the series exceed the limit values according to Annex I.B, 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 defined above with the requirements of the Directive, the statistical method described in Annex XVII shall be applied.



ANNEX IX

PRODUCTION QUALITY ASSURANCE

(module D)

1. The manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of the Directive that apply to them. The manufacturer or his authorized representative established within the Community shall affix the CE marking to each product and draw up a written declaration of conformity (see Annex XV). The CE marking shall be accompanied by the distinguishing number of the notified body responsible for the monitoring as specified in point 4.
2. The manufacturer shall operate an approved quality system for production, final product inspection and testing as specified in paragraph 3 and shall be subject to monitoring as specified in point 4.

3. Quality system

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

The application shall include:

- all relevant information for the product category envisaged,
- the documentation concerning the quality system,
- where appropriate, the technical documentation of the approved type (see Annex XIII) and a copy of the EC type-examination certificate.

- 3.2. The quality system shall ensure compliance of the products with the type as described in the EC type-examination certificate and with the requirements of the Directive 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 must permit a consistent interpretation of the quality programmes, plan, manuals and records.

It shall contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,
- the 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 of the personnel concerned, etc.,
- the means to monitor the achievement of the required product quality and the effective operation of the quality system.

- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with these requirements in respect of quality systems that implement the relevant harmonized standard.

The auditing team shall have at least one member with experience of evaluation in the product technology concerned. The evaluation procedure shall include an inspection visit to the manufacturer's premises.

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 uphold it so that it remains adequate and efficient.

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The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a reassessment is required.

It shall notify its decisions 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 entrance for inspection purposes to the locations of manufacture, inspection and testing, and storage 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 of the personnel concerned, etc.
- 4.3. The notified body shall periodically carry out audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.
- 4.4. Additionally the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may carry out, or cause to be carried out, tests to verify that the quality system is functioning correctly, if necessary. The notified body shall provide the manufacturer with a visit report and, if a test has taken place, with a test report.
5. The manufacturer shall, for a period ending at least 10 years after the last product has been manufactured, keep at the disposal of the national authorities:
 - the documentation referred to in the second indent of the second subparagraph of point 3.1,
 - the updating referred to in the second subparagraph of point 3.4,
 - the decision and reports from the notified body which are referred to in the final subparagraph of point 3.4, point 4.3 and point 4.4.
6. Each notified body shall give the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

▼B*ANNEX X***PRODUCT VERIFICATION****(module F)**

1. This module describes the procedure whereby a manufacturer or his authorized representative established within the Community checks and attests that the products subject to the provisions of point 3 are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of the Directive that apply to them.
2. The manufacturer shall take all measures necessary in order that the manufacturing process ensures conformity of the products with the type as described in the EC type-examination certificate and with the requirements of the Directive that apply to them. The manufacturer or his authorized representative established within the Community shall affix the CE marking to each product and shall draw up a declaration of conformity (see Annex XV).
3. The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the product with the requirements of the Directive either by examination and testing of every product as specified in point 4 or by examination and testing of products on a statistical basis, as specified in point 5, at the choice of the manufacturer.
- 3a. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity for a period ending at least 10 years after the last product has been manufactured.
4. **Verification by examination and testing of every product**
 - 4.1. All products shall be individually examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 or equivalent tests shall be carried out in order to verify their conformity with the type as described in the EC type-examination certificate and the requirements of the Directive that apply to them.
 - 4.2. The notified body shall affix, or cause to be affixed, its distinguishing number to each approved product and draw up a written certificate of conformity relating to the tests carried out.
 - 4.3. The manufacturer or his authorized representative shall ensure that he is able to supply the notified body's certificates of conformity on request.
5. **Statistical verification**
 - 5.1. The manufacturer shall present his products in the form of homogeneous lots and shall take all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced.
 - 5.2. All products shall be available for verification in the form of homogeneous lots. A random sample shall be drawn from each lot. Products in a sample shall be individually examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, shall be carried out to ensure their conformity with the requirements of the Directive which apply to them and to determine whether the lot is accepted or rejected.
 - 5.3. The statistical procedure shall use the following elements:
 - the statistical method to be applied,
 - the sampling plan with its operational characteristics.

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For the assessment of conformity with the exhaust emission requirements, the procedure defined in Annex XVII shall be applied.

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- 5.4. In the case of accepted lots, the notified body shall affix, or cause to be affixed, its distinguishing number to each product and shall draw up a written certificate of conformity relating to the tests carried out. All products in the lot may be put on the market except those products from the sample which were found not to be in conformity.

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

The manufacturer may, under the responsibility of the notified body, affix the latter's distinguishing number during the manufacturing process.

- 5.5. The manufacturer or his authorized representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

**B***ANNEX XI***UNIT VERIFICATION****(module G)**

1. This module describes the procedure whereby the manufacturer ensures and declares that the product concerned, which has been issued with the certificate referred to in point 2, conforms to the requirements of the Directive that apply to it. The manufacturer or his authorized representative established within the Community shall affix the CE marking to the product and draw up a declaration of conformity (see Annex XV).
2. The notified body shall examine the individual product and carry out the appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, to ensure its conformity with the relevant requirements of the Directive.

The notified body shall affix, or cause to be affixed, its distinguishing number on the approved product and shall draw up a certificate of conformity concerning the tests carried out.
3. The aim of the technical documentation is to enable conformity with the requirements of the Directive to be assessed and the design, manufacture and operation of the product to be understood (see Annex XIII).



ANNEX XII

FULL QUALITY ASSURANCE

(module H)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of paragraph 2 ensures and declares that the products concerned satisfy the requirements of the Directive that apply to them. The manufacturer or his authorized representative established within the Community shall affix the CE marking to each product and draw up a written declaration of conformity (see Annex XV). The CE marking shall be accompanied by the distinguishing number of the notified body responsible for the surveillance as specified in point 4.

2. The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing 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 quality system with a notified body.

The application shall include:

- all relevant information for the product category envisaged,
- the quality system's documentation.

- 3.2. The quality system shall ensure compliance of the products with the requirements of the Directive 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. This quality system documentation shall ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

- the quality objectives and the organizational 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 standards referred to in Article 5 will not be applied in full, the means that will be used to ensure that the essential requirements of the Directive 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 of the personnel concerned, etc.,
- the means to monitor 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 compliance with these requirements in respect of quality systems that implement the relevant harmonized standard (EN 29001).

The auditing team shall have at least one member experienced as an assessor in the product technology concerned. The evaluation procedure shall include an assessment visit to the manufacturer's premises.

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

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

The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a reassessment is required.

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

4. **EC 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 entrance for inspection purposes to the locations of design, manufacture, inspection and testing, and storage, and shall provide it with all necessary information, in particular:

- the quality system documentation,
- the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc.,
- the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

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

- 4.4. Additionally the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality system where necessary; it shall provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer shall, for a period ending at least 10 years after the last product has been manufactured, keep at the disposal of the national authorities:

- the documentation referred to in the second indent of the second subparagraph of point 3.1,
- the updating referred to in the second subparagraph of point 3.4,
- the decisions and reports from the notified body which are referred to in the final subparagraph of point 3.4, point 4.3 and point 4.4.

6. Each notified body shall forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

▼ M1*ANNEX XIII***TECHNICAL DOCUMENTATION SUPPLIED BY THE MANUFACTURER**

The technical documentation referred to in Annexes V, VII, VIII, IX, XI and XVI must comprise all relevant data or means used by the manufacturer to ensure that components or craft comply with the essential requirements relating to them.

The technical documentation shall enable understanding of the design, manufacture and operation of the product, and shall enable assessment of conformity with the requirements of this Directive.

The documentation shall contain so far as relevant for assessment:

- (a) a general description of the type,
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- (c) descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product,
- (d) a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to fulfil the essential requirements when the standards referred to in Article 5 have not been applied,
- (e) results of design calculations made, examinations carried out, etc.,
- (f) test reports, or calculations namely on stability according to section 3.2 of the Essential Requirements and on buoyancy according to section 3.3 thereof (Annex I.A),
- (g) exhaust emissions test reports demonstrating compliance with section 2 of the Essential Requirements (Annex I.B),
- (h) sound emissions test reports or reference boat data demonstrating compliance with section 1 of the Essential Requirements (Annex I.C).

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ANNEX XIV

MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES FOR THE NOTIFICATION OF BODIES**▼M1**

1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of the products referred to in Article 1 which they inspect, nor the authorised representative of any of these parties. They shall not become either involved directly or as authorised representatives in the design, construction, marketing or maintenance of the said products. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.
- 1a. A notified body must be independent and must not be controlled by the manufacturers or by suppliers.

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2. The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgment or the result of the inspection, especially from persons or groups of persons with an interest in the result of verifications.
3. The body shall have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with verification; it shall also have access to the equipment required for special verification.
4. The staff responsible for inspection shall have:
 - sound technical and professional training,
 - satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,
 - the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.
5. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.
6. The body shall take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.
7. The staff of the body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks (except *vis-à-vis* the competent administrative authorities of the State in which its activities are carried out) under the Directive or any provision of national law giving effect to it.

▼ **M1***ANNEX XV***WRITTEN DECLARATION OF CONFORMITY**

1. The written declaration of conformity to the provisions of the Directive must always accompany:
 - (a) the recreational craft and the personal watercraft and must be included with the owner's manual (Annex I.A section 2.5),
 - (b) the components, as referred to in Annex II,
 - (c) propulsion engines and must be included with the owner's manual (Annex I.B.4).
2. The written declaration of conformity shall include the following ⁽¹⁾:
 - (a) name and address of the manufacturer or his authorised representative established in the Community ⁽²⁾,
 - (b) description of the product defined in point 1 ⁽³⁾,
 - (c) references to the relevant harmonised standards used, or references to the specifications in relation to which conformity is declared,
 - (d) where appropriate, the references of the other Community Directives applied,
 - (e) where appropriate, reference to the EC type-examination certificate issued by a notified body,
 - (f) where appropriate, the name and address of the notified body,
 - (g) identification of the person empowered to sign on behalf of the manufacturer or his authorised representative established within the Community.
3. With regard to:
 - inboard engines and stern drive propulsion engines without integral exhaust,
 - engines type-approved according to Directive 97/68/EC which are in compliance with stage II provided for in section 4.2.3 of Annex I of the latter Directive and,
 - engines type-approved according to Directive 88/77/EEC,

the declaration of conformity shall include in addition to the information of point 2, a statement of the manufacturer that the engine will meet the exhaust emission requirements of this Directive, when installed in a recreational craft, in accordance with the manufacturer's supplied instructions and that this engine must not be put into service until the recreational craft into which it is to be installed has been declared in conformity, if so required, with the relevant provision of the Directive;

⁽¹⁾ Must be drawn up in the language(s) as provided for under section 2.5 of Annex I.A.

⁽²⁾ Business name and full address; the authorised representative must also give the business name and address of the manufacturer.

⁽³⁾ Description of the product make, type, serial number, where appropriate.

▼ M1

ANNEX XVI

PRODUCT QUALITY ASSURANCE (MODULE E)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of the directive that apply to them. The manufacturer or his authorised representative established within the Community must affix the CE mark to each product and draw up a written declaration of conformity. The CE mark must be accompanied by the identification symbol of the notified body responsible for surveillance as specified in point 4.
2. The manufacturer must operate an approved quality system for final product inspection and testing as specified in point 3 and must be subject to surveillance as specified in point 4.
3. Quality system
 - 3.1. The manufacturer must lodge an application for assessment of his quality system for the products concerned, with a notified body of his choice.
The application must include:
 - all relevant information for the product category envisaged,
 - the quality system's documentation,
 - if applicable, the technical documentation of the approved type and a copy of the EC type-examination certificate.
 - 3.2. Under the quality system, each product must be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 or equivalent tests shall be carried out in order to ensure its conformity with the relevant requirements of the directive. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must ensure a common understanding of the quality programmes, plans, manuals and records.
It must contain in particular 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 means to monitor the effective operation of the quality system,
 - quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
 - 3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.
It presumes conformity with these requirements in respect of quality systems that implement the relevant harmonised standard.
The auditing team must have at least one member experienced as an assessor in the product technology concerned. The assessment procedure must include an assessment visit to the manufacturer's premises.
The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.
 - 3.4. The manufacturer must undertake to fulfil the obligations arising from the quality system as approved and to maintain it in an appropriate and efficient manner.
The manufacturer or his authorised representative must keep the notified body which has approved the quality system informed of any intended updating of the quality system.
The notified body must evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements referred to in point 3.2 or whether a reassessment is required.

▼M1

It must notify its decision to the manufacturer. The notification must 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 must allow the notified body entrance for inspection purposes to the locations of inspection, testing and storage and shall provide it with all necessary information, in particular:
 - the quality system documentation,
 - the technical documentation,
 - the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
 - 4.3. The notified body must periodically carry out audits to ensure that the manufacturer maintains and applies the quality system and must provide an audit report to the manufacturer.
 - 4.4. Additionally, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality system where necessary; it must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.
5. The manufacturer must, for a period ending at least 10 years after the last product has been manufactured, keep at the disposal of the national authorities:
 - the documentation referred to in the third indent of the second subparagraph of point 3.1,
 - the updating referred to in the second subparagraph of point 3.4,
 - the decisions and reports from the notified body which are referred to in the final subparagraph of point 3.4, points 4.3 and 4.4.
6. Each notified body must forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

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ANNEX XVII

CONFORMITY OF PRODUCTION ASSESSMENT FOR EXHAUST AND NOISE EMISSIONS

1. For verifying the conformity of an engine family, a sample of engines is 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

x = the individual results of the sample

L = the appropriate limit value

n = the number of engines in the sample

k = statistical factor depending on n (see table)

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 $k = 0,860/\sqrt{n}$. $k = 0,860/\sqrt{2n}$