

Translation: Only the Danish document has legal validity

Notice from the Danish Maritime Authority L – the Construction and Equipment, etc. of Recreational Craft

Appendix 1(3)

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, as amended by Directive 2003/44/EC of the European Parliament and of the Council of 16 June 2003 of 1 October 2006

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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.

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.

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.

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

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.

- 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.

Annex XIII – Technical documentation supplied by the manufacturer

The technical documentation referred to in Annexes V, VII, VIII, IXD, 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:

1. a general description of the type,
2. conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
3. description and explanations necessary for the understanding of said drawings and schemes and the operation of the product,
4. 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,
5. results of design calculations made, examinations carried out, etc.,
6. 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.),
7. **M** exhaust emissions test reports demonstrating compliance with section 1 of the Essential Requirements (Annex I.B),
8. **M** sound emissions test reports or reference boat data demonstrating compliance with section 1 of the Essential Requirements (Annex I.C).

Annex XIV – Minimum criteria to be taken into account by member States for the notification of bodies

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.
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.

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) **M** 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:
 - (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. **M** 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.

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.

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.

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 CE 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.
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 and 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.

Annex XVII – Conformity of production assessment for exhaust and noise emissions

1. **M** 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. **M** 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:

$$X + K \cdot S < L$$

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 > 20 then k = 0.860/√n.