

Comparison table between COUNCIL DIRECTIVE 96/98/EC on marine equipment (current MED) and DIRECTIVE 2014/90/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on marine equipment and repealing Council Directive 96/98/EC (new MED) regarding changes of the requirements to Module B

	COUNCIL DIRECTIVE 96/98/EC on marine equipment	DIRECTIVE 2014/90/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on marine equipment and repealing Council Directive 96/98/EC	
	EC TYPE-EXAMINATION (MODULE B)	I. MODULE B: EC TYPE-EXAMINATION	
	1. A notified body must ascertain and attest that a specimen, representative of the production envisaged, complies with the provisions of the international instruments that apply to it.	<i>1. EC type-examination is the part of a conformity assessment procedure in which a notified body examines the technical design of marine equipment and verifies and attests that the technical design of the marine equipment meets the relevant requirements</i>	
		<p>2. EC type-examination may be carried out in either of the following manners:</p> <ul style="list-style-type: none"> <li>— examination of a specimen, representative of the production envisaged, of the complete product (production type);</li> <li>— <i>assessment of the adequacy of the technical design of the marine equipment through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the product (combination of production type and design type).</i></li> </ul>	There will be a Recommendation issued by Mared, until such time interpretation is that <i>all items listed in the MED have testing standards, which clearly state how and what tests should be carried out and NB should follow it.</i>
	2. The application for the EC type-examination must be lodged by the manufacturer or his authorized representative established within the Community with a	<i>3. The manufacturer shall lodge an application for EC type-examination with a single notified body of its choice.</i>	

	notified body of his choice.- included in para 10 of 2014/90/EC		
	The application <b>must</b> include:	<i>The application <b>shall</b> include:</i>	
	— the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address as well,	<i>— the name and address of the manufacturer and, if the application is lodged by the authorised representative, its name and address as well;</i>	
	— a written declaration that the same application has not been lodged simultaneously with any other notified body,	<i>— a written declaration that the same application has not been lodged with any other notified body;</i>	
	— the technical documentation as described in point 3.	— the technical documentation.	
	<p><i>Appendix to Annex B</i></p> <p><i>Technical documentation to be supplied by the manufacturer to the notified body</i></p> <p><i>The provisions set down in this Appendix apply to all modules of Annex B.</i></p> <p><i>The technical documentation referred to in Annex B must comprise all relevant data and means used by the manufacturer to ensure that equipment complies with the essential requirements relating to it.</i></p> <p><i>The technical documentation <b>must</b> make it possible to understand the design, manufacture and operation of the product, and must make it possible to assess compliance with the requirements of the relevant international instruments.</i></p> <p><i>The documentation <b>must</b>, so far as they are relevant to</i></p>	<p><i>The technical documentation <b>shall</b> make it possible to <b>assess the conformity of the marine equipment with the applicable requirements of the international instruments as referred to in Article 4, and <u>shall include an adequate analysis and assessment of the risk(s).</u></b> The technical documentation shall specify the applicable requirements and shall cover, as far as relevant for the assessment, the design, manufacture and operation of the marine equipment.</i></p> <p><i>The technical documentation <b>shall</b> contain, wherever</i></p>	<p>Appendix to Annex B has been incorporated to the text of the 2014/90/EC</p> <p>“adequate analysis and assessment of the risk” – there will be a Recommendation issued by Mared, until such time interpretation is that essential standards/requirements are clearly established and therefore it would be expected that the risk is</p>

	<p><i>assessment, include:</i></p> <ul style="list-style-type: none"> <li>— a general description of the <i>type</i>,</li> <li>— conceptual-design, build standard and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,</li> <li>— descriptions and explanations necessary for the understanding of those drawings and schemes, including the operation of the product,</li> <li>— the results of design calculations made, <i>impartial</i> examinations carried out, etc.,</li> <li>— <i>impartial</i> test reports,</li> <li>— <i>manuals for installation, use and maintenance.</i></li> </ul>	<p><i>applicable, at least the following elements:</i></p> <ul style="list-style-type: none"> <li>(a) a general description of the <i>marine equipment</i>;</li> <li>(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;</li> <li>(c) descriptions and explanations necessary for the understanding of those drawings and schemes and of the operation of the marine equipment;</li> <li>(d) a list of the requirements and testing standards which are applicable to the marine equipment concerned in accordance with this Directive, together with a description of the solutions adopted to meet those requirements;</li> <li>(e) results of design calculations made, examinations carried out, etc.; and</li> <li>(f) test reports;</li> <li>— the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme</li> <li>— the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used. The supporting evidence shall include, where necessary, the results of tests carried out by the</li> </ul>	<p>included.</p> <p>As per requirements of Annex III of the 2014/90/EU NB shall ensure that testing laboratories used for conformity assessment purposes meet the requirements of standard EN ISO/IEC 17025:2005.</p>
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	<p><i>Where appropriate, the design documentation must contain the following:</i></p> <ul style="list-style-type: none"> <li><i>— attestations relating to the equipment incorporated in the appliance,</i></li> <li><i>— attestations and certificates relating to the methods of manufacture and/or inspection and/or monitoring of the appliance,</i></li> <li><i>— any other document that makes it possible for the notified body to improve its assessment.</i></li> </ul> <p>The applicant must 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 the test programme.</p>	<p><i>appropriate laboratory of the manufacturer, or by another testing laboratory on the manufacturer's behalf and under its responsibility.</i></p>	
	<p>3. The technical documentation must make it possible to assess the product's compliance with the requirements of the relevant international instruments. It must, as far as is relevant for such assessment, cover the design, the building standard, manufacture, installation and functioning of the product in accordance with the description of technical documentation set down in the Appendix to this Annex.</p>		
	<p>4. The notified body <b>must</b>:</p>	<p>4. The notified body <b>shall</b>:</p>	
	<p>4.1. examine the technical documentation and verify</p>	<p><i>For the marine equipment:</i> 4.1. examine the technical documentation <b>and</b></p>	

	that the type has been manufactured in accordance with the technical documentation;	<i>supporting evidence to assess the adequacy of the technical design of the marine equipment;</i>	
		For the specimen(s): 4.2. <i>verify that the specimen(s) have been manufactured in conformity with the technical documentation</i> , and identify the elements which have been designed in accordance with the applicable provisions of the relevant requirements and testing standards, as well as the elements which have been designed without applying the relevant provisions of those standards;	
	4.2. <i>perform the</i> appropriate examinations and necessary tests or have them performed to check whether the requirements of the relevant international instruments have actually been met;	4.3. <i>carry out appropriate examinations and tests, or have them carried out, in accordance with this Directive;</i>	
	4.3. agree with the applicant the location where the examinations and necessary tests will be carried out.	4.4. <i>agree with the manufacturer on a location where the examinations and tests will be carried out.</i>	
		5. <i>The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.</i>	The evaluation report will have a form of the EC Type Examination (Module B) Certificate
	5. Where the type meets the <i>provisions</i> of the relevant international instruments, the notified body <i>must</i> issue an EC type-examination certificate to the <i>applicant</i> . The certificate <i>must give the name and address of the manufacturer, details of the equipment, the conclusions of the examination, the conditions of its validity and the necessary data for identification of the approved type.</i>	6. <i>Where the type meets the requirements of the specific international instruments that apply to the marine equipment concerned, the notified body shall issue an EC type-examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the</i>	

	<p>A list of the relevant parts of the technical documentation must be annexed to the certificate and a copy kept by the notified body.</p> <p>If a manufacturer is refused a type-certification, the notified body must give detailed reasons for that refusal. Where a manufacturer reapplies for type-approval for equipment for which a type-certificate has been refused, his submission to the notified body must include all relevant documentation, including the original test reports, the detailed reasons for the previous refusal and details of all modifications made to the equipment.</p>	<p><i>approved type. The certificate may have one or more annexes attached.</i></p> <p>The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.</p> <p><i>Where the type does not satisfy the applicable requirements of the international instruments, the notified body shall refuse to issue an EC type-examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.</i></p>	
	<p>6. The applicant must 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 compliance with the requirements or the prescribed conditions for use of the product. Such additional approval must be given in the form of an addition to the original EC type-examination certificate.</p>	<p>7. If the approved type no longer complies with the applicable requirements, the notified body shall determine whether further testing or a new conformity assessment procedure is necessary.</p> <p><i>The manufacturer shall inform the notified body that holds the technical documentation relating to the EC type- examination certificate of all modifications to the approved type that may affect the conformity of the marine equipment with the requirements of the relevant international instruments or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EC type- examination certificate.</i></p>	
	<p>7. Each notified body must, on request, provide flag Member State administrations and the other notified bodies with the relevant information concerning the EC</p>	<p>8. Each notified body shall inform its notifying authorities concerning the EC type-examination certificates and/or any additions thereto which it has</p>	

	type-examination certificates and additions issued and withdrawn.	issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.	
	8. The other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The Annexes to the certificates must be kept at the disposal of the other notified bodies.	Each notified body shall inform the other notified bodies concerning the EC type-examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.	
		The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC type- examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EC type-examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.	
	9. The manufacturer or his authorized representative established within the Community must keep with the technical documentation copies of EC type-examination certificates and their additions for at least 10 years after the last product has been manufactured.	9. The manufacturer shall keep a copy of the EC type-examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for at least 10 years after the wheel mark has been affixed on the last product manufactured and in no case for a period shorter than the expected life of the marine	

		equipment concerned.	
		10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.	<p>According to Art.13 of the 2014/90/EC</p> <p>"1. A manufacturer who is not located in the territory of at least one Member State shall, by a written mandate, appoint an authorised representative for the Union and shall indicate in the mandate the name of the authorised representative and the address at which it can be contacted."</p>