No. NB/0161

MARINE EQUIPMENT CERTIFICATION AGREEMENT

(Module B; F and D of the Council Directive 2014/90/EU of Marine Equipment and Implementing Regulation (EU) 2024/1975)

Responsibilities of the applicant:

Knowing and understanding my responsibilities and those of the certification body[4] detailed below, I pledge to:

- Comply with the certification requirements[1] including implementation of appropriate changes when certification body[4] announces them.
- If the certification applies to the production in progress, the certified product continues to meet the product[2] requirements.
- Take the necessary measures for:
  - Carrying out evaluation[6] monitoring (if required), including measures to examine the documentation and records, and to have access to the equipment, locations, areas, the staff and the subcontractors of the client[3] that are relevant.
  - Investigating complaints;
  - The participation of observers, if applicable.
- To make statements on the certification consistent with the scope of the certification[7].
- To not use the product certification in a way that puts the certification body[4] into ill repute, and not to make any statement regarding its product certification that the certification body may consider misleading or unauthorised.
- Immediately after suspending, withdrawing or completing the certification, to stop using it in all publicity material that contains any reference to it, and to undertake the actions required by the certification scheme[5] (for example, the return of the certification documents) and any other measure that may be required.
- To provide copies of the certification documents to others, reproduce them in their entirety or as specified by the accreditation scheme[5].
- When referring to the product certification in communication media such as documents, brochures or advertising, to comply with the requirements of the certification body or those specified by the certification scheme[5].
- To comply with all the requirements the certification scheme[5] may stipulate with regard to use of conformity marks and the information related to the product.
- To keep a record of all known complaints with respect to the fulfilment of the requirements of the certification[1] and make such records available to the certification body[4] when requested, and:

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- To take appropriate action with respect to such complaints and to the deficiencies found in the products that affect the conformity with the certification[1] requirements.
- To document the actions carried out.

- To inform the Certification Body[4],without delay about changes that may affect the ability to comply with the certification[1] requirements. (Examples of changes may include the following: The legal, commercial, organisational or property conditions. Organisation and management (for example, key directives, staff that make decisions or technical staff). Changes in the product or production method. Contact addresses and production sites. Major changes in the quality management system).

- Not to use incorrect references to the certification scheme, or make misleading use of licenses, certificates, conformity marks or anything else that indicates that the product is certified, that is in the documentation and/or other advertising, knowing that this may include actions by the Certification Body[4] such as: corrective actions, the withdrawal of the certificate, publication of the transgression and, if necessary, legal action.

- To check the Certification Regulations that the Certification Body has made available to the public and which details the information relating to the certification schemes, assessment procedures and rules for granting, maintaining, extending and reducing the scope of certification, or to suspend, withdraw or deny, the rights and duties of applicants and clients, with requirements, restrictions, or limitations on the use of the name of the Certification body and the brand, or how to refer to the certification granted.

Obligations of the manufacturers

- On affixing the “wheelmark”, the manufacturers will assume the responsibility of ensuring that the marine equipment bearing the brand has been designed and manufactured according to the technical specifications and standards applied in accordance with article 35, paragraph 2, as well as the obligations referred to in paragraphs 2 to 9 of this article.
- The manufacturer shall establish the technical documentation required and carry out the conformity assessment procedures applicable.
- When the fulfilment of the requirements for marine equipment has been demonstrated by the conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity in accordance with article 16 and affix the “wheelmark” in accordance with articles 9 and 10.
- Manufacturers shall retain the technical documentation and the EU declaration of conformity referred to in Article 16 for a period of at least ten years from the fixing of the “wheelmark” and under no circumstances for less than the expected useful life of the marine equipment concerned.
- The manufacturer shall establish procedures for series production to maintain compliance. Due account shall be taken of the changes in the design or the characteristics of the marine equipment and the changes in the requirements referred to in the international instruments referred to in article 4, on which the declaration of conformity of the equipment is based.

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When necessary and in accordance with annex II, manufacturers will carry out a new conformity assessment.

- Manufacturers shall ensure that their products bear a type, batch and/or serial number or any other element allowing their identification or, if the size or the nature of the product does not allow it, that the information required is included in the packaging or in a document accompanying the product or, in their case, in both.
- Manufacturers shall indicate their name, their registered trade name or trademark and their contact address on the product or, where this is not possible, on the packaging or on an accompanying document or, in their case, on both. A single point where the manufacturer can be contacted should be indicated in the address.
- The manufacturers shall ensure that the product is accompanied by instructions and all the necessary information to install it on board and use it in safe conditions, including the limitations of use, where appropriate, that will be easily understood by users, along with the rest of the documentation required by the international instruments or testing standards.
- Manufacturers who believe or have reason to believe that a product which bears the “wheelmark” is not in accordance with the applicable requirements of design, construction and performance, and with the testing standards applied in accordance with article 35, paragraphs 2 and 3, shall immediately take the necessary corrective measures to bring it into conformity, withdraw it from the market or request its return, if applicable. In addition, when the product involves some risk, they shall immediately inform the competent national authorities of the Member States and give details, in particular, on the non-conformity and the remedial action taken.
- At the request of the competent authority, manufacturers shall provide without delay all the information and documentation necessary to demonstrate the conformity of the product, in easily understandable language or that which the authority can accept, allow access to their facilities to carry out market surveillance activities in accordance with article 19 of Regulation (EC) No 765/2008 and provide samples or access to them in accordance with article 25, paragraph 4, of this Directive. They shall cooperate with the competent authority, upon request, in terms of any action intended to prevent the risks posed by the products that have been introduced to the market.

Authorised representative

- Manufacturers not established in the territory of at least one member State shall, by written mandate, designate an authorised representative for the European Union and indicate in this mandate the name of the authorised representative and the address where they can be contacted.
- The fulfilment of the obligations laid down in article 12, paragraph 1, and the drafting of the technical documentation shall not form part of the of the authorised representative mandate.
- The authorised representative shall carry out the tasks specified in the mandate received from the manufacturer. The terms of reference shall allow the authorised representative to undertake the following tasks as a minimum:

  a) maintain the EU declaration of conformity and the technical documentation at the disposal of the national monitoring authorities for a period of at least ten years from the

placement of the "wheelmark", and in no case for less than the expected useful life of the marine equipment concerned;

b) at the request of the competent authority, provide the authority with all the information and documentation necessary to demonstrate the conformity of the product;

c) cooperate with the competent authorities, upon request, with any action aimed to eliminate the risks involving the products covered by their mandate.

Other economic agents

1. The importers shall indicate their name, their registered trade name or trademark and their contact address on the product or, when not possible, on its original packaging or in an accompanying document or, in their case, in both.
2. At the request of the competent authority, importers and distributors will provide all the information and documentation necessary to demonstrate the conformity of the product, in easily understandable language or that which the authority can accept. They shall cooperate with the competent authority, upon request, in terms of any action intended to prevent the risks posed by the products that have been introduced to the market.
3. For the purposes of this Directive, the manufacturer shall be deemed and shall be subject to the manufacturer's obligations under article 12, for an importer or distributor when they introduce marine equipment to the market or install it onboard an EU vessel with their name or brand on it, or modify marine equipment that has already been introduced to the market in such a way that it can affect compliance with the applicable requirements
4. For a period of at least ten years from the placement of the "wheelmark", and in no case less than the expected useful life of the marine equipment concerned, economic agents shall disclose upon request, to the market surveillance authorities:

   a) any economic agent that has supplied them with a product;

   b) any economic agent to whom they have supplied a product.

Responsibilities of the certifying body O.N. 0161:

- The certifying body shall verify compliance with the retention of the known complaints records, with respect to the fulfilment of the requirements of the certification[1] and will request them, as well as the documentation of the actions taken with respect to such complaints or deficiencies found in the products that affect conformity with the certification requirements[1].
- Regarding the use of the license, certificates and conformity marks

  The certification body shall exercise the control specified by the certification scheme[5] on ownership, use and display of licenses, certificates and conformity marks or any other mechanism to indicate that the product is certified.

  Incorrect references to the certification scheme, or misleading use of licenses, certificates, conformity marks or any other mechanism to indicate that the product is certified, that are in the documentation and/or other advertising should be dealt with by the appropriate action,

which may include corrective action, the withdrawal of the certificate, publication of the transgression and, if necessary, legal action.

- The certification body is impartial and does not permit commercial, financial or other pressure, which could compromise their impartiality.
- The certification service is accessible to all applicants whose activities are within the scope of their operations.
- The Certification body reserves the right to accept an application or to maintain a contract with a customer, based on proven or substantiated reasons, and to decline in cases such as: client participation in illegal activities, a history of repeated non-compliance with the product or certification requirements, or similar issues.
- The Certification Body is responsible for safeguarding and guarantees through this legal agreement the absolute confidentiality of the management of all the information obtained or created during the performance of the certification activities. With the exception of the information that the customer makes available to the public, or when there is an agreement between the certification body and the client (for example, for the purpose of responding to complaints), all the information is considered private information and therefore confidential. The Certification Body shall inform the customer, in advance, on the information that it seeks to make available to the public. When required by the Certification Body, by law or authorisation of the contractual provisions, the disclosure of confidential information shall be notified to the client or person involved in the information provided, except as prohibited by law. The information relating to the client, obtained from sources other than from the client (for example, from a complaint or from regulatory authorities) will be treated as confidential information.
- Product Certification Body No. 0161 shall inform the notifying authority of any denial, restriction, suspension or withdrawal of certificates, of any circumstances that affect the scope and conditions of notification; of any request for information about the conformity assessment activities carried out that it has received from the market surveillance authorities; on request, of conformity assessment activities carried out within the scope of their notification and of any other activity carried out, including cross-border outsourcing and subcontracting activities.
- The Certification Body will make available to the public on its website: www.aitex.es in the document referred to as the Certification Regulations, information relating to the certification schemes, assessment procedures and rules for granting, maintaining, extending and reducing the scope of certification, or to suspend, withdraw or deny the rights and responsibilities of applicants and clients, with requirements, restrictions, or limitations of the use of the name of the Certification body and the brand, or how to make reference to the certification granted.
- Before the suspension of a certification, the certification body[4] will formulate and notify the customer of the necessary actions to complete the suspension and re-certification of products in accordance with the certification scheme and any other action required by the accreditation scheme.

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- The certification body[4] will acknowledge receipt of a complaint or a formal appeal. They will meet and verify all the information necessary to reach a decision (revised and approved by the personnel involved) on the subject of the complaint or appeal.
- Whenever possible, the certification Body[4] will request a formal notification of the result and completion of the appeal process to the appellant.
- The Certification Body[4] shall inform the customer advance about the outsourced activities in order to give the client the opportunity to object.
- The Certification Body[4] shall inform the customer[3] about all non conformities, and if the customer expresses interest in continuing the certification process, the Certification Body[4] will provide information with respect to the additional evaluation[6] work necessary to verify that the nonconformities have been corrected. In the event that the client agrees to complete the additional evaluation work, the certification process will be restarted from the initial stage.
- The Certification Body shall notify customers of the decision not to grant certification, as well as identify the reasons for such a decision.
- The Certification Body has provided the customer, along with the present agreement, with the certification Regulation.
- The notified bodies will conduct or carry out conformity assessments in accordance with the procedures established in Article 15.L 257/160 Official Journal of the European Union, 28.8.2014.
- If a notified body finds that a manufacturer does not comply with the obligations laid down in Article 12, they shall request that the manufacturer adopts without delay the corrective measures and shall not issue the certificate of conformity.
- If, in the course of the follow-up of the conformity subsequent to the issuance of the certificate, a notified body finds that the product no longer conforms, they will insist the manufacturer adopts without delay the corrective measures and, if necessary, suspend or withdraw the certificate. If corrective measures are not taken or they do not have the necessary effect, the notified body shall restrict, suspend or withdraw the certificate, as appropriate.

DEFINITIONS AND TERMS USED IN THE AGREEMENT

1. **Certification requirement**: the specified requirement, including the product requirements[2], which the customer'[3] meets as a condition of obtaining or maintaining certification. The certification requirements include customer requirements imposed by the certification body[4] (usually through certification agreement, in order to comply with ISO/IEC 17065:2012 and may also include the customer requirements[3] imposed by the certification scheme[5]. The certification requirements, do not include the certification body requirements for the certification scheme[5]. For example, the following are certification requirements that are not product requirements: to formalise the certification agreement; to pay charges; to provide

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information about the changes to the certified product; to provide access to certified products for surveillance activities.

2. **Product requirement**: Requirement which directly refers to a product, as specified in standards or other normative documents identified in the certification scheme (regulations, technical standards and specifications).
3. **Client**: organisation or person responsible to a certification Body[4] to ensure that they comply with certification requirements[1], including the product requirements[2]. Whenever the term "Customer" is used it applies to both the "applicant" and the "customer", unless otherwise specified.

4. **The certification body**: Conformity assessment body of third party certification schemes. (O.N. AITEX 0161).

5. **The certification scheme**: certification system applied to certain products, to which the same specified requirements, specific rules and procedures are applied.

6. **Evaluation**: Combination of the functions of selection and determination in the activity of conformity assessment.

7. **Scope of the certification**: Identification of the products for which certification is granted, the applicable certification scheme and the standards and other normative documents, including the date of publication, with regard to which the product is deemed to be in accordance with.