Certification Guidelines for Marine Equipment Directive 2014/90/EC

1. Service Description

This Guidelines describes conformity assessment body EAIC certification process to the Marine Equipment Directive 2014/90/EC (hereinafter - MED). The Document defines Customer and EAIC contractual obligations and responsibilities, conditions of certification and terms for issuing the certificate.

2. General conditions

EAIC will, according to notifications, carry out following conformity assessment procedures described in MED:

Module B – EC-Type examination;
Module F – product verification
Module G – unit verification

If the requirements of MED do not provide sufficient guidance, EAIC has rights for using recommendations from MED Co-ordinating Group, which are accepted by notified bodies.

EAIC will not provide consultancy services aiming to facilitate the certification. All related to the product information received by EAIC for implementing conformity assessment is treated as confidential.

3. EAIC Certification Process

A manufacturer wishing a Notified Body certification service shall submit an application, which is available on the EAIC website. If requested by the customer, the Notified Body provides general information on the service fees and will prepare quotation and the project of the Contract.

Applicant agreement is justified by signed Contract and provision of required documentation for conformity assessment.

The manufacturer shall ensure access to the production facilities for EAIC employers and approved subcontractors.

After completion of required by MED works and achieving satisfactory result the decision on the issuing of Certificate will be made. The responsibility of EAIC is to prepare all necessary certification documents.

4. Refusal of Certification

If the product or quality system are not comply with MED requirements, a written refusal will be sent to the manufacturer. Manufacturer will be given information regarding appeal procedure.

Information regarding refusal of certification will be made available to other Notified Bodies, members of MED

5. maintaining the Certificate

The manufacturer is responsible, at all times, ensure that products and quality system are comply with requirements, set out in the Directive and to undergo periodic EAIC assessments. EAIC conformity assessments does not release manufacturer from sole responsibility for the compliance of the product and quality system. The corrective actions regarding detected nonconformities shall be implemented within the set time limit.

The manufacturer shall ensure EAIC access to production premises for carrying out special visits if there have been changes in the requirements of the Directive or if there are clear and justified doubts about compliance of the product or quality system.

Payment for the services shall be in accordance with the specified conditions of the Contract between the customer and the EAIC.

The manufacturer is required to retain all complaints related to the certified product. EAIC performs assessment of implementation of corrective actions related to complaint during the planned assessments.

EAIC must be informed of any sub-suppliers for main parts of the product to be certified.

EAIC has the rights to report the following information to the notifying authority:

- Any refusal, restriction, suspension or withdrawal of certificates;
- Any circumstances affecting the scope and conditions for notification;
- Any request for information on conformity assessment activities performed which EAIC has received from market surveillance authorities;
- On request, conformity assessment activities performed within the scope of notification and other activities performed, including cross-border activities and subcontracting;
- Any complaints received from third parties regarding products or the certification.

EAIC has the rights to disclose information about products or certification to the relevant market surveillance authorities.

6. Changes in Standards

EAIC carry out conformity assessments in accordance with latest versions of standards related to the product. Therefore, it is responsibility of manufacturer to keep himself informed about latest versions of standards or changes in MED and inform EAIC

regarding any required modifications to the product. EAIC is not responsible for informing customer regarding any changes to the applicable requirements.

7. Changes by the Manufacturer.

Manufacturer shall provide information regarding modifications or changes related to the design or production (including changes in organisation, ownership, new product modifications, production methods, changes in quality system, locations etc), which may have effect on the certified product to the EAIC within reasonable time and preferably before execution of change.

EAIC will make a decision regarding necessity of special surveillance visit for assessment of changes.

8. Suspension or withdrawal of Certificate

EAIC may decide to suspend or withdraw the certificate and, in such cases, the manufacturer will be informed as soon as practicable.

Manufacturer may appeal dis decision.

The reasons for suspension or withdrawal may be:

- Termination of Contract between customer and EAIC;
- Misuse of certificate or certification mark;
- Not fulfilment of MED requirements;
- Manufacturer changed the product and did not inform EAIC;
- Not fulfilment of requirements for product or quality system;
- The product is no longer covered by Directive;
- The product is not comply with Directive requirements and there are no corrective actions implemented regarding raised by EAIC nonconformities;
- The product has substantial defects which came to light during operation;
- Violation of terms of payment of fees or refusal to access to periodic, planned or special assessments;
- Planned assessments are not completed;
- Periodic surveillance is not completed;
- Manufacturer voluntarily requesting temporary suspension.

Suspension of certificate is considered as a first step, followed by a withdrawal if the problems are not solved within defined period. However, depends on seriousness of the problem, EAIC may decide a direct withdrawal of the certificate.

EAIC shall inform manufacturer regarding decision of suspension or withdrawal of the certificate and that product is not allowed to put in the market in the suspension period.

The manufacturer shall delete any reference to a non-valid certificate in public documentation as marketing materials, websits, advertising, etc.

EAIC shall make relevant information regarding suspension of the certificate to other Notified Bodies, MED members.

9. Cancelling of the Certificate by the Manufacturer

Manufacturer may cancel the certificate at any time if relevant information is submitted to EAIC at least 60 days before the cancellation takes place and authorize EAIC to invoice all activities up to date.

10. Complaints and Appeals

All complaints are taken seriously, and EAIC takes full responsibility to perform as expected. An acknowledgement of received complaint will be sent without delay.

The complaint shall include as minimum:

- Name and position of person filing the complaint;
- Company name (if relevant);
- Postal address or e-mail address;
- The reason for complaint.

A written complaint may be filed by mail and e-mail. Complaints regarding our customers will be forwarded to receive their response. All complaints shall be maintained and the person responsible, whose task is to resolve the complaint, will be designated. The responsible persons' task is to manage complaint, analyse and organize activities for immediate or corrective actions. Written reply to the complaint will be submitted to the complainant. The information regarding the opportunity to broaden the appeal in case of an unsatisfactory response will be sent to the complainant.

11. Use of the Certificate and Certification Mark (The EAIC logo)

Certification mark of EAIC may only be used, if the conformity assessment is performed (Modules D + F, G). Manufacturer have the rights to use the valid certificate and certification mark in standard size for the purposes for which the certificate is intended, including on letters, documents and other promotional material.

The certification Mark may be shown on manufacturer's public relation material, provided it is directly related to the certified product and with precise explanatory text.

The certification mark, together with the instructions on use, will be sent to the manufacturer, on request.

12. Mark of conformity («wheelmark»)

EAIC Certification Mark and Conformity mark "wheelmark" shall not be mixed, according to the MED! Conformity mark shall be used by the manufacturer in accordance with MED.

13. Publishing of Certificates

Copies of MED certificates issued by EAIC are published on the EAIC website and listed on the MarED website.