CONFORMITY ASSESSMENT PROGRAM FOR MARINE EQUIPMENT ACCORDING TO DIRECTIVE 2014/90/UE

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1. SUBJECT AND SCOPE OF THE PROGRAM.

1.1 Conformity assessment of products according to Directive 2014/90/EU

The program defines the principles and procedures for assessing the conformity of products to Directive 2014/90/EU, hereinafter referred to as the MED Directive. Directive 2014/90/EU was introduced into Polish legislation by the Act of 2.12.2016 on marine equipment. The program applies when assessing the conformity of marine equipment placed on new or existing convention ships bearing the flag of a member state of the European Union, when the equipment is placed for the first time or replaced with new equipment.

For the purposes of the MED Directive, the current versions of international conventions and testing standards should apply. These are defined in Commission (EU) Implementing Regulations. Currently, Commission Implementing Regulation (EU) 2024/1975 of 19/07/2024 is in force. If new EU regulations become available, they are immediately posted on https://prs.pl/en/certification/products-and-persons-certification/marine-equipment-directive-2014-90-ue-med/.

The recommendations of the International Group of Notified Bodies for the Implementation of the Requirements of the Marine Equipment Directive (MarED) should be taken into account during the conformity assessment of products. They are published on the website https://portal.med.emsa.europa.eu/ and their list can be found in Annex 3/PCW-01/MED *MarED "Approved recommendations".*

1.2 Scope of application of the program

Product Conformity Assessment Program *PCW-01/MED of the* Bureau of Product and Personnel Certification, Polski Rejestr Statków S.A. concerns the assessment of conformity with the requirements specified in the acts of EU harmonization legislation, standards or other normative documents, applicable to this equipment.

Certificates of conformity are issued for all products covered by this conformity assessment program.

The following documents are an integral part of the program:
- PCW-01 Product Certification System - General Principles,
- Principles for the Use of Product Certification Marks.

2. DEFINITIONS

Conformity assessment - a process, carried out on the basis of notification by the government of the Republic of Poland to the European Commission, aimed at confirming compliance with the requirements of European Union directives and issuing appropriate certificates or other documents of conformity specified in the directives.

Certificate - a document issued by a notified body (PRS) confirming that the product, product design or product manufacturing process complies with the requirements.

Non-conformity (N) - failure to meet a requirement

Omission in the described product quality assurance system or failure to meet one or more of the requirements of the MED Directive or the identification of a situation that raises serious doubts

about the ability of the organization's product quality assurance system to achieve its intended results.

Observation (O) - an observation made by the auditor related to opportunities for improvement of the management system (area of improvement), for which the organization is recommended to take preventive or other improvement actions.

3. DESCRIPTION OF THE PROCEEDINGS

3.1 Initiating the certification process

3.1.1 Upon receipt of an order, the manager of the Products and Persons Certification Bureau (CW) reviews it and appoints a competent expert/auditor to carry it out.

3.1.2 In the case of implementation of the conformity assessment process according to Module D or E, the Manager of the Certification of Products and Persons Bureau appoints an auditor or a team of auditors to carry out the audit in the Organization and signs the document "*Appointment of the* audit *team". - Form.13/PCW-01/MED.* The appointment is issued in accordance with Annex 5/PCW-01/MED - Determination of audit time.

3.1.3 The technical documentation of the product, together with the order, the manager gives the expert, and the documentation of the quality system, together with a copy of the order, to the auditor (together with a copy of the order, if it is a person other than the expert). The appointed expert verifies that the scope of the documentation meets the requirements of the directive and confirms the acceptance of the order in accordance with the instructions, at the same time informing the auditor of the need to supplement any deficiencies. Prior to the start of the process, the expert/auditor prepares the *Product Certification / Conformity Assessment Process Plan* (Form. 8/PCW-01). When planning the assessment, he takes into account the results of the evaluation of the review of the submitted documentation. The plan includes information on the designated personnel to carry out each assessment activity and the various elements of the assessment, such as design and documentation review, sampling, testing, inspection and audit.

NOTE:

1. *Conformity assessment according to modules B, F and G is carried out by an expert, and according to modules D and E by an auditor.*
2. *If Polski Rejestr Statków S.A. has a person who is both an expert in the products that are the subject of the order and a quality systems auditor, then in the case of conformity assessment of products according to B+D or B+E modules, the whole process, if possible, is carried out by one person.*

3.2 Conformity assessment according to module B (EC type examination)

EC type examination can be carried out in one of the following ways:

- testing of a sample of a complete product, representative of the expected production (production type),
- Assessment of the adequacy of the technical design of the marine equipment by examining the technical documentation and supporting evidence (referred to in point I.3 of Annex II of Directive 2014/90/EU) and evaluating sample units representative of the anticipated production, at least one of the relevant parts of the product (combination of production type and design type).

Paragraphs 3.2.3 through 3.2.7 of this procedure apply to both modes of EC type testing.

3.2.1 EC type examination - production type

3.2.1.1 This type of test is used if a product with recognition has been modified or the parts/materials from which it was manufactured have been changed.

3.2.1.2 The expert evaluates the product design by checking whether it is made in accordance with the technical documentation, whether it has a unique identification and whether it is properly prepared for testing. If doubts arise, it is imperative to clarify them with the Principal before proceeding with testing.

3.2.1.3 After the evaluation of the design, type tests are carried out according to the program approved by the expert by:

- PRS Testing Laboratory, and/or
- laboratories accredited by PCA for compliance with the requirements of PN-EN ISO/IEC 17025, or/and
- external laboratories (meeting the requirements of PN-EN ISO/IEC 17025) which PRS has recognized/agreed to cooperate with, and/or
- the manufacturer's laboratory/testing station, if specialized tests cannot be carried out in PRS laboratory and laboratories cooperating with PRS, if accepted by PRS in the given scope.

When conducting tests, it is necessary to prevent damage or deterioration of the objects subjected to these tests.

3.2.1.4 In the case of outsourcing samples, the expert prepares an order for the CW Manager, and after approval of the order for external testing, it is approved and signed by the DC Director.

3.2.1.5 In the case of third-party laboratories and manufacturers' laboratories, the expert supervises the tests, a detailed report of which is made by the laboratory / test station performing the tests.

3.2.1.6 From the supervision of type tests, the expert prepares an Survey Report (Form. 9/PCW-01), in which he states whether the product meets the requirements of the applicable IMO documents and standards, and makes an application, with justification, for the issuance of an EC Type Examination Certificate (Module B) (Form. 7/PCW-01/MED). In the application, he shall give the name and address of the principal and manufacturer, as well as data enabling unambiguous identification of the product in question. The expert shall attach a test report to the report.

3.2.1.7 As an alternative to the provisions of 3.2.1.2 through 3.2.1.5, the results of tests performed prior to receipt of the order may be accepted, provided that they were carried out in a laboratory accredited and/or recognized by PRS and/or another notified body.

3.2.2 EC type testing - a combination of production type and design type.

3.2.2.1 This type of testing is used to assess the conformity of newly certified products.

3.2.2.2 The expert considers and approves the technical documentation, as specified in paragraph I.3 of Annex II of Directive 2014/90/EU, in accordance with *Instruction ICW-02,* and the product test program for compliance with the requirements of applicable IMO documents and standards specified in the MED Directive. As part of the approval, it also checks calculations and transferred data.

3.2.2.3 In next step the expert evaluates the product design by checking whether it is made in accordance with the technical documentation, whether it has a unique identification and whether it is properly prepared for testing. If doubts arise, it is imperative to clarify them with the Principal before proceeding with testing.

3.2.2.4 After approval of the documentation and evaluation of the design, type tests are carried out according to the approved program by:

- PRS Testing Laboratory, and/or

- laboratories accredited by PCA for compliance with the requirements of PN-EN ISO/IEC 17025, or/and
- external laboratories (meeting the requirements of PN-EN ISO/IEC 17025) which PRS has recognized/agreed to cooperate with, and/or
- the manufacturer's laboratory/testing station, if specialized tests cannot be carried out in PRS laboratory and laboratories cooperating with PRS, if accepted by PRS in the given scope.

When conducting tests, it is necessary to prevent damage or deterioration of the objects subjected to these tests.

3.2.2.5 In the case of outsourcing samples, the expert prepares an order for the CW Manager, and after approval of the order for external testing, it is approved and signed by the DC Director.

3.2.2.6 In the case of third-party laboratories and manufacturers' laboratories, the expert supervises the tests, a detailed report of which is made by the laboratory / test station performing the tests.

3.2.2.7 From the supervision of type tests, the expert prepares an Survey Report (Form. 9/PCW-01), in which he states whether the product meets the requirements of the applicable IMO documents and standards, and makes an application, with justification, for the issuance of an EC Type Examination Certificate (Module B) (Form. 7/PCW-01/MED). In the application, he shall give the name and address of the principal and manufacturer, as well as data that allow for clear identification of the product in question. The expert attaches the approved technical documentation and test report to the report.

3.2.2.8 As an alternative to the provisions of 3.2.2.3 through 3.2.2.6, the results of tests conducted prior to receipt of the order may be accepted, provided that they were carried out in a laboratory accredited and/or recognized by PRS and/or another notified body.

3.2.3 The expert/auditor sets up the form *Evaluation of the Certification Process/Evaluation of Conformity of the Product (*Form. 4/PCW-01) and makes appropriate entries in it. The expert's report and the process evaluation are accepted by the CW Manager, who makes the decision to issue or refuse to issue the *EC Type Examination Certificate* (Form. 7/PCW-01/MED). If the CW Manager is not competent in a given process, or if the CW Manager has performed an evaluation in a given process, the decision to issue or not to issue a document of compliance with the Directive is carried out by a designated expert with the appropriate competence (see Attachment 2/PCW-01). The expert prepares the *EC Type Examination Certificate* (Form. 7/PCW-01/MED), or a letter informing the manufacturer or its authorized representative of the refusal to issue the certificate, including the reasons for the refusal.

3.2.4 *The EC Type Examination Certificate* is signed by the DC Director, after prior approval by the CW Manager (confirmed by his signature on a copy of the certificate).

3.2.5 In the case of refusal to issue an *EC Type Examination Certificate,* a letter informing of this is signed by the CW Manager.

3.2.6 If the recognized type, due to changes made by the manufacturer, no longer complies with the requirements relating to it, the DC must assess whether a new conformity assessment is required.

3.2.7 When the international requirements are changed, the conformity assessment of the product should be carried out again

3.3 Conformity assessment according to module D (production quality assurance)

3.3.1 The auditor evaluates the documentation of the production quality assurance system for compliance with the requirements for Module D specified in paragraph II.3.2 of Annex II to Directive 2014/90/EU, for the production of the products subject to certification.

All considerations, requirements and regulations taken into account by the manufacturer must be collected in a systematic and orderly manner in the form of written operating policies, procedures and instructions. Approved documentation must include forms for recording inspection and test results.

3.3.2 From the evaluation of the documents, the auditor prepares the *Report from assessment of production quality assurance systems documents* (Form. 1/PCW-01/MED), which he sends to the manufacturer.

3.3.3 In case of a positive result of the documentation evaluation, together with the *Report from assessment of production quality assurance systems documents,* the auditor sends the *Audit Plan* (Form. 2/PCW-01/MED) in which he determines the objectives, scope and criteria of the audit. The duration of the audit is determined based on *Annex 5/PCW-01/MED*. If the auditor does not have experience in evaluating the technology of a product, an expert also participates in the audit. Sending the audit plan, which includes the names of the auditors, is treated as notification to the ordering party of the composition of the audit team.

NOTE:

It is not planned to develop an audit program, since the scopes of certification, surveillance and renewal audits differ slightly because they relate only to the production quality system, the requirements for which are specified in detail in the MED Directive. The selection of requirements to be audited, depending on the type of audit, results from Note No. 1 of the Audit Questionnaire (Form. 3/PCW-01/MED-D).

3.3.4 In the event of an emergency situation, the Auditor, in consultation with the CW Manager, may take steps to use Information and Communication Technology (ICT - eng. Information and Communication Technology) to conduct an Audit at the Organization.

3.3.5 The auditor of the CW Bureau may conduct an audit by means of information and communication technology ("ICT") only with the use and application of documents such as:
- IAF MD4: 2023 - IAF mandatory document on the use of information and communication technology ("ICT") for audits/assessments,
- IAF ID12: 2023 - Principles of remote evaluation

3.3.6 The Lead Auditor should send a questionnaire (PCW-01_COVID-19) to the organization for completion and return to the Lead Auditor before deciding to conduct an audit using information and communication technology ("ICT").

3.3.7 The lead auditor, on the basis of the received Questionnaire and information obtained from the organization, conducts a risk analysis as to whether there are any obstacles to conducting the audit in accordance with the appointment of the audit team. This analysis should be documented on the form PCW-01/COVID-19 Risk Analysis.

3.3.8 As a result of the risk analysis, the lead auditor recommends the following decisions:
- Planning a completely remote audit,
- Increase in remote audit time - provide the proposed number of remote audit hours,
- Performing the audit in accordance with the appointment - without deviating from the standard procedure,
- postponement of the audit until the threat has ceased (in agreement with the Organization).

The risk analysis shall be sent immediately to the CW Office, which shall amend the appointment of the audit team if necessary. The CW Office shall immediately send the revised appointment to all members of the audit team and inform the Organization of the decisions made.

3.3.9 In the event of a change in the method of audit execution resulting from the risk analysis performed, the Lead Auditor shall amend the audit plan accordingly.

3.3.10 Certification audit

The purpose of the audit is to evaluate the implementation, including effectiveness, of the customer's production quality assurance system. It should be conducted at the customer's location where production of the certified product takes place. It should include at least:

- Information and evidence of compliance with all requirements of Directive 2014/90/EU for Module D,
- quality objectives and organizational structure, responsibilities and authority of management in the field of product quality,
- production process, quality control and quality assurance techniques, as well as the processes and systematic measures that will be used,
- checking activities and tests that are carried out before, during and after production, and the frequency with which they will be carried out,
- Quality assurance documentation such as inspection reports, test data and calibration data, and qualification reports of production workers, etc..,
- the means of monitoring the process of achieving the desired quality of the product and the effective operation of the quality control system.

NOTE:

Due to the much smaller scope of the audit of the quality of production of certified products, described in detail in Module D of the MED Directive, than, for example, the scope of the audit of the entire ISO 9001 standard, it is not envisaged to conduct the audit of the initial certification in two stages. The customer's system is initially evaluated at the auditor's premises on the basis of the documentation provided, and any doubts are clarified with the customer by correspondence.

3.3.11 Immediately prior to the audit, the auditor/expert team reviews the evaluated technical documentation of the product to verify the manufacturer's ability to indicate the applicable requirements of international instruments and to perform the necessary tests to ensure compliance of the product with these requirements.

3.3.12 The auditor then conducts an audit of the production quality assurance system according to the agreed *Audit Plan*.

3.3.13 Opening meeting

The auditor meets with the management and designated personnel of the organization in an opening meeting aimed at:

- Introduction of the participants, including the presentation of their roles,
- Confirmation of the audit plan (type, scope of audit, objectives and criteria),
- confirmation of the scope of certification,
- Confirm proper work safety, emergency and security procedures for the audit team,
- reporting method, including grading of audit findings,
- information about the conditions under which the audit may be interrupted,
- Confirm confidentiality issues, including those related to the protection of the organization's personal data,
- Confirmation of the status of findings from the previous audit, if applicable,
- The methods and procedures used to conduct the audit based on sampling,
- Agreeing on other matters conditioning the smooth conduct of the audit,
- Agreeing on a date for the closing meeting.

3.3.14 Communicating during the audit

If the available audit evidence indicates that the audit objectives cannot be achieved or indicates the existence of an immediate and significant risk (e.g., safety), the auditor should present it to the client and, if possible, to the certification body for appropriate action. These actions may include reconfirming or revising the audit plan, changing the objectives or scope of the audit, or terminating the audit. The auditor should present the results of the action taken to the certification body.

The auditor, together with the client, should review any needed change in the scope of the audit that may arise as a result of on-site audit activities, and submit these changes to the certification body.

3.3.15 Observers and guides

The presence and justification for the attendance of observers during audit activities should be agreed by the certification body with the client before the audit is conducted. Each auditor should be accompanied by a guide, unless otherwise agreed between the lead auditor and the client. Guides are assigned to the audit team to facilitate the audit. The audit team should ensure that observers do not influence or interfere with the conduct or outcome of the audit.

3.3.16 Collecting and verifying information

During the audit, information related to the objectives, scope and criteria of the audit should be collected through appropriate sampling and verified to provide audit evidence.

Information collection methods should include, but not be limited to:
- conversations,
- Observation of processes and activities,
- review of documentation and records,
- research.

3.3.17 The auditor also checks whether:
- the manufacturer has affixed the mark of the steering wheel and the identification number of PRS as a notified body, together with the four-digit year of manufacture, to each unit of the product that conforms to the product type described in the EC Type Examination Certificate,
- the manufacturer has drawn up a written declaration of conformity for the type of product and whether it is kept at the disposal of national authorities. The retention period should be specified in the documentation of the production quality assurance system and should be at least 10 years after the steering wheel mark was applied to the last manufactured product, and in any case, not less than the expected service life of the marine equipment in question,
- the production quality assurance system documentation specifies that the EC type-examination certificate and the approved technical documentation are to be kept for at least 10 years after the steering wheel mark is applied to the last manufactured product, and, regardless of the situation, not less than the expected service life of the marine equipment in question.

3.3.18 Audit records are made on the *Questionnaire for certification/intermediate/renewal audit of the production quality assurance system (Module D)* (Form. 3/PCW-01/MED-D).

NOTE:

Appearing in the audit forms and the Audit Plan, the audit number is in the form: CW/MED/xxx/Czz/yyyy, where:

xxx - the anticipated or assigned number of the EC Production Quality Assurance Certificate (Module D),

C - certification audit, interchangeable with P (intermediate audit), S (special audit), O (renewal audit),
zz - the number of the next audit in a given company,
yyyy - the year of the audit.

3.3.19 Observations and nonconformities found during the audit are recorded on the *Findings from audit* (Form. 4/PCW-01/MED) and presented to the auditee at the closing meeting. Observations show areas for improvement, but should not be recommendations proposing or suggesting specific solutions to take preventive or other improvement actions. Nonconformities obligate corrective and/or corrective actions.

3.3.20 Closing meeting

A formal closing meeting should be conducted with the client's management and, if appropriate, with those responsible for the audited functions or processes. The purpose of the closing meeting is to present the audit findings including a recommendation for certification. Nonconformities should be presented in such a way that they are understood, and a time frame for addressing them should be agreed upon.

The closing meeting should also include the following:

- Instructing the customer that the audit evidence was collected on the basis of sample information,
- information on the certification body's process for dealing with nonconformities, including any consequences with respect to the customer's certification status,
- Information on the timeframe for the customer to submit a corrective action plan and corrective actions for any nonconformities found during the audit,
- Information on the processes for handling complaints and appeals.

3.3.21 Within 7 days from the end of the audit, the auditor prepares a Report from audit production/product quality assurance system (Form. 5/PCW-01/MED) in which he requests the issuance of a certificate for the module, the issuance of a certificate for Module D after the implementation of corrective actions/no certificate.

3.3.22 The organization submits to the Products and Persons Certification Bureau information confirming the implementation of corrective and corrective actions for non-conformities, the implementation of which, is a prerequisite for the issuance of a certificate. Evaluation of the effectiveness of the implementation of corrective actions is carried out during a surveillance audit.

3.3.23 The audit documentation is evaluated by the CW Manager, who makes the decision to issue, or refuse to issue, the *EC Production Quality Assurance Certificate (Module D)* (Form. 8/PCW-01/MED).

3.3.24 If the CW Manager is not competent in a particular process, or if the CW Manager has performed an assessment in a particular process, the decision on whether or not to issue a document of compliance with the directive is carried out by a competent designated auditor, (see Attachment 2/PCW-01).

3.3.25 *The EC Production Quality Assurance Certificate (Module D)* is signed by the DC Director, after prior approval by the CW Manager (confirmed by his signature on a copy of the certificate).

3.3.26 In the case of refusal to issue an *EC Production Quality Assurance Certificate (Module D),* a letter informing of the refusal, including the reasons, is signed by the DC Director.

3.3.27 The documents referred to in 3.3.11 and 3.3.12 sent to the manufacturer shall be accompanied by an *Audit Report.*

3.3.28 Supervision of the production quality assurance system is carried out through surveillance audits.

Surveillance audits are conducted once a year.

Audits for renewal of the *EC Production Quality Assurance Certificate* shall be carried out not earlier than 60 days and not later than on the day of expiration of the certificate, after receipt of the request for certification. In justified cases, due to appropriately documented special circumstances, renewal audits can be conducted after the day of expiration of certificate, however not later than 6 months after this date.

NOTE:

Surveillance and renewal audits are conducted in a manner analogous to that described in 3.3.3-3.3.13, taking into account the specifics of these audits.

3.3.29 Independently of the supervision of the production quality assurance system referred to in 3.3.14**,** unannounced visits may be made to the manufacturer to verify that the system is functioning properly and, if necessary, to conduct trials. The auditor conducting the visit shall prepare a report on the visit, accompanied by a report on trials, if conducted. The visit report, with the test report attached, after approval by the CW Manager, is submitted to the manufacturer.

3.3.30 If, during the supervision of the system, the auditor finds that the product no longer meets the requirements, the CW Manager shall require the manufacturer to take appropriate corrective measures and suspend or revoke the issued certificate for Module D, if necessary.

3.3.31 If corrective measures are not taken, or if these measures do not have the required effect, the CW Manager shall restrict, suspend or revoke all certificates for Module B and D, as appropriate.

3.3.32 If the manufacturer holds a quality management system certificate for compliance with ISO 9001, issued by the PRS Certification Bureau, the certification process for compliance with Module D, specified in sections 3.3.1 to 3.3.15, may be simplified, with the subject of the certification audit being at least the production process of the products subject to conformity assessment, as well as inspections and tests before, during and after their production, in addition to the verifications specified in the *Production Quality Assurance System Audit Questionnaire (Module D)* (Form. 3/PCW-01/MED-D), under the heading "Verification of the recognized product".

3.3.33 If the manufacturer has a quality management system certificate for compliance with ISO 9001, issued by another accredited certification body, the possible possibility of simplifying the conformity assessment process for compliance with Module D is subject to separate consideration and decision of the CW Manager in each case.

3.4 Conformity assessment according to module E (product quality assurance)

3.4.1 The auditor evaluates the documentation of the product quality assurance system for compliance with the requirements for Module E specified in paragraph III.3.2 of Annex II to Directive 2014/90/EU, for the final inspection of the products subject to certification.

All considerations, requirements and regulations taken into account by the manufacturer must be collected in a systematic and orderly manner in the form of written operating policies, procedures and instructions. Approved documentation must include forms for recording inspection and test results.

3.4.2 From the evaluation of the documents, the auditor prepares a *Report from assessment of production quality assurance systems documents* (Form. 1/PCW-01/MED), which is sent to the manufacturer.

3.4.3 In case of a positive result of the documentation evaluation, together with the *Report from assessment of production quality assurance systems documents,* the auditor sends the *Audit Plan* (Form. 2/PCW-01/MED) in which he determines the objectives, scope and criteria of the audit. The duration of the audit is determined based on *Annex 5/PCW-01/MED*. If the auditor does not have

experience in evaluating the technology of a product, an expert also participates in the audit. Sending the audit plan, which includes the names of the auditors, is treated as notification to the ordering party of the composition of the audit team.

NOTE:

It is not planned to develop an audit program, since the scopes of certification, surveillance and renewal audits differ slightly because they relate only to the product quality assurance system, the requirements for which are specified in detail in Module E of the MED Directive. The selection of requirements to be audited, depending on the type of audit, results from Note No. 1 of the Audit Questionnaire (Form. 3/PCW-01/MED-E).

3.4.4 Certification audit

The purpose of the audit is to evaluate the implementation, including effectiveness, of the product quality assurance system. It should be conducted at the customer's location where production of the certified product takes place. It should include at least:

3 Information and evidence of compliance with all the requirements of Directive 2014/90/EU for Module E,
4 quality objectives and organizational structure, responsibilities and authority of management in the field of product quality,
5 checking activities and tests that are carried out before, during and after the production of the product and the frequency with which they will be carried out,
6 product quality assurance records, such as inspection reports, test data and instrument calibration data, and reports on the qualification of relevant personnel,
7 Product quality assurance system monitoring measures.

NOTE:

Due to the much smaller scope of the audit of the quality assurance system of certified products, described in detail in Module E of the MED Directive, than, for example, the scope of the audit of the entire ISO 9001 standard, it is not envisaged to conduct the audit of the initial certification in two stages. The customer's system is initially evaluated at the auditor's premises on the basis of the documentation provided, and any doubts are clarified with the customer by correspondence.

3.4.5 The auditor then conducts an audit of the product quality assurance system according to the agreed plan. The course of the audit is described in sections 3.3.6.1 to 3.3.6.8.

3.4.6 Audit records are made in the *Product Quality Assurance System Audit Questionnaire* (Form. 3/PCW-01/MED-E) .

NOTE:

Appearing in the audit forms and the Audit Plan, the audit number is in the form: CW/MED/xxx/Czz/yyyy, where:

xxx - the anticipated or assigned number of the EC Product Quality Assurance Certificate (Module E),
C - certification audit, interchangeable with P (intermediate audit), S (special audit), O (renewal audit),
zz - the number of the next audit in a given company,
yyyy - the year of the audit.

3.4.7 Observations and nonconformities found during the audit are recorded in the *Findings from audit* (Form. 4/PCW-01/MED) and presented to the auditee at the closing meeting.

3.4.8 Within 7 days from the end of the audit, the auditor prepares a Report from audit *Production/Product Quality Assurance System* (Form. 5/PCW-01/MED) in which the auditor requests

the issuance of a certificate for Module E after the implementation of corrective actions/non-certification.

3.4.9 The organization submits to the Products and Persons Certification Bureau information confirming the implementation of corrective and corrective actions for nonconformities, the implementation of which, is a prerequisite for the issuance of a certificate. Evaluation of the effectiveness of the implementation of corrective actions is carried out during a surveillance audit.

3.4.10 The audit documentation is evaluated by the CW Manager, who makes the decision to issue, or refuse to issue, the *EC Product Quality Assurance Certificate (Module E)* (Form. 8/PCW-01/MED). If the CW Manager is not competent in a particular process, or if the CW Manager has performed an assessment in a particular process, the decision to issue or not to issue a document of compliance with the directive is carried out by a designated expert with the appropriate competence (see Attachment 2/PCW-01).

3.4.11 *The EC Product Quality Assurance Certificate (Module E)* is signed by the DC Director, after prior approval by the CW Manager (confirmed by his signature on a copy of the certificate).

3.4.12 In the case of refusal to issue an *EC Product Quality Assurance Certificate (Module E),* a letter informing of the refusal, including the reasons, is signed by the DC Director.

3.4.13 The documents referred to in 3.4.13 and 3.4.14 sent to the manufacturer shall be accompanied by the *Production/Product Quality Assurance System Audit Report.*

3.4.14 Supervision of the product quality assurance system is carried out through surveillance audits.
Surveillance audits are conducted once a year.
Audits for renewal of the *EC Product Quality Assurance Certificate (Module E)* shall be conducted no earlier than 60 days and no later than 60 days before the expiration of the certificate.

NOTE:

Surveillance and renewal audits are conducted in a manner analogous to that described in 3.4.3-3.4, taking into account the specifics of these audits.

3.4.15 Independently of the supervision of the product quality assurance system referred to in 3.4.14, unannounced visits may be made to the manufacturer to verify that the system is functioning properly and, if necessary, to conduct tests. The auditor conducting the visit shall prepare a report on the visit, accompanied by a report on trials, if conducted. The visit report, with the test report attached, after approval by the CW Manager, is submitted to the manufacturer.

3.4.16 If the manufacturer holds a quality management system certificate for compliance with ISO 9001, issued by the PRS Certification Bureau, the certification process for compliance with Module E, as specified in 3.4.1 to 3.4.14, may be simplified, with the subject of the certification audit being at least the final inspections and tests of the products subject to certification, in addition to the checks specified in the audit questionnaire under the heading "Verification of the recognized product".

3.4.17 If the manufacturer has a quality management system certificate for compliance with ISO 9001, issued by another accredited certification body, the possible possibility of simplifying the conformity assessment process for compliance with Module E is subject to separate consideration and decision of the CW Manager in each case.

3.5 Conformity assessment according to module F (product verification)

3.5.1 The expert verifies that the products submitted for verification have *EC Type Examination Certificates* issued by PRS or another notified body.

3.5.2 If the products have an *EC Type Examination Certificate*, in order to confirm the compliance of the products
with the requirements of the applicable IMO documents and standards referred to in 3.2.1, the expert shall supervise the manufacturer's final tests of the products by one of the following methods:
- verification of each product, according to the principles set forth in 3.5.3,
- verification by statistical method, according to the principles set forth in 3.5.4.

It is up to the manufacturer to choose the method of product verification.

3.5.3 Verification of each product

3.5.3.1 The expert supervises the manufacturer's inspection and testing of the product according to the approved program, for each product separately.

3.5.3.2 On products that have passed inspections and tests with positive results, the expert verifies that the manufacturer has applied the PRS identification mark, as a notified body, and has placed the steering wheel mark on them.

3.5.4 Verification by statistical method

3.5.4.1 From the homogeneous batch of products presented for verification, the expert randomly selects a sample. The sample count is determined according to the relevant ISO 2859-2:2020 standard.

3.5.4.2 The expert then supervises the manufacturer's inspection and testing of the product according to the approved program, for each product in the sample, in order to decide whether to accept or reject the batch.

3.5.4.3 If the batch of products is accepted, the expert shall put the PRS identification mark, as a notified body, on each product from the batch, except for those products whose sample has not passed inspection and testing, and check whether the manufacturer has put the steering wheel mark on it.

3.5.4.4 If a batch of products is rejected, the expert shall report this fact in the report referred to in 3.5.6.

3.5.5 The expert verifies that the manufacturer has drawn up a written declaration of conformity for the batch of the product and that it is kept at the disposal of the national authorities. The retention period of the declaration should be specified in the system documentation and be at least 10 years after the steering wheel mark was applied to the last manufactured product, and in any case, not less than the expected service life of the marine equipment in question.

3.5.6 From the verification of the product, the expert prepares an *Survey Report* (Form. 9/PCW-01), in which he reports on the course and results of the *evaluation*, and makes an application, with justification, for an *EC Product Verification Certificate* (Form. 9/PCW-01/MED). He attaches technical documentation to the report, including documents containing the results of inspections and tests carried out by the manufacturer.

3.5.7 The expert's report is accepted by the CW Manager, who makes the decision to issue, or refuse to issue, an *EC Product Verification Certificate*. In the absence of the CW Manager's competence in a particular process, or in the case where the CW Manager has made an assessment in a particular process, the decision to issue or not to issue a document of compliance with the Directive is carried out by a designated expert with the appropriate competence (see Attachment 2/PCW-01). The expert prepares the *EC Product Verification Certificate* (Form. 9/PCW-01/MED) , or a letter informing the manufacturer or its authorized representative of the refusal to issue the certificate, including the reasons for the refusal.

3.5.8 *The EC Product Verification Certificate* is signed by the DC Director, after prior approval by the CW Manager (confirmed by his signature on a copy of the certificate).

3.5.9 In case of refusal to issue a certificate, a letter informing about it is signed by the DC Director.

3.5.10 If the statistical verification report contains information about the rejection of a batch of products, the CW Manager prepares a letter notifying the Maritime Offices in Gdynia and Szczecin of this fact in order to prevent the introduction of products from the batch into the market.

3.5.11 If the rejection of a batch of products is not the first such case, the CW Manager may request the suspension of the application of statistical verification. In this case, he shall prepare a letter notifying the manufacturer of this decision.

3.5.12 The letters referred to in 3.5.10 and 3.5.11 are signed by the CW Manager.

3.6 Conformity assessment according to module G (unit verification)

3.6.1 The expert considers and approves the technical documentation, as specified in paragraph V.2 of Annex II of Directive 2014/90/EU, in accordance with *Instruction ICW-02,* and the product test program for compliance with the requirements of applicable IMO documents and standards specified in the MED Directive. As part of the approval, it also checks calculations and transferred data.

3.6.2 The expert then evaluates the product design by checking whether it is made in accordance with the technical documentation, whether it has a unique identification and whether it is properly prepared for testing. If doubts arise, it is imperative to clarify them with the Principal before proceeding with testing.

3.6.3 After approval of the documentation and evaluation of the product, type tests are carried out according to the approved program by:

- PRS Testing Laboratory, and/or
- laboratories accredited by PCA for compliance with the requirements of PN-EN ISO/IEC 17025, or/and
- external laboratories (meeting the requirements of PN-EN ISO/IEC 17025) which PRS has recognized/entered into a cooperation agreement, or/and
- the manufacturer's laboratory/testing station, if specialized tests cannot be carried out in PRS laboratory and laboratories cooperating with PRS, if accepted by PRS in the given scope.

When conducting tests, it is necessary to prevent damage or deterioration of the objects subjected to these tests.

3.6.4 In the case of outsourcing samples, the expert prepares an order for the CW Manager, and after approval of the order for external testing, it is approved and signed by the DC Director.

3.6.5 In the case of third-party laboratories and manufacturers' laboratories, the expert supervises inspections and product tests conducted according to the approved program, for each product separately, from which a detailed report is made by the laboratory/testing station performing the tests.

3.6.6 As an alternative to the provisions of 3.6.3 to 3.6.5, the results of tests carried out prior to receipt of the order may be accepted, provided that they were carried out in a laboratory accredited and/or recognized by PRS and/or under the supervision of another notified body.

3.6.7 On products that have passed inspections and tests successfully, the expert verifies that the manufacturer has affixed the PRS identification mark, as a notified body, and has placed the rudder wheel mark on them.

3.6.8 The expert verifies that the manufacturer has drawn up a written declaration of conformity for the type of product and that it is kept at the disposal of national authorities. The expert also checks whether the system's documentation specifies that the declaration of conformity, the EC type-examination certificate and the approved technical documentation are to be kept for at least 10 years after the rudder wheel mark was applied to the last manufactured product, and in any case not less than the expected service life of the marine equipment in question.

3.6.9 From the unit verification carried out, the expert prepares an *Evaluation Report* (Form. 9/PCW-01) in which he informs about the course and results of the *evaluation* and puts forward an application, with justification, for the issuance of an *EC Certificate of Conformity* (Form. 10/PCW-01/MED). In the application, he gives the name and address of the principal and the manufacturer, as well as data that enable unambiguous identification of the product(s). He attaches technical documentation to the report, including documents containing the results of inspections and tests.

3.6.10 The expert's report is accepted by the CW Manager, who decides whether or not to issue an EC Certificate of Conformity. In the absence of the CW Manager's competence in a particular process, or in the case where the CW Manager has made an assessment in a particular process, the decision to issue or not to issue a document of compliance with the directive is carried out by a designated expert with the appropriate competence (see Attachment 2/PCW-01). The expert prepares the *EC Certificate of Conformity* (Form.10/PCW-01/MED), or a letter informing the manufacturer or its authorized representative of the refusal to issue the certificate, including the reasons for the refusal.

3.6.11 *The EC Certificate of Conformity* is signed by the DC Director, after prior approval by the CW Manager (confirmed by his signature on a copy of the certificate).

3.6.12 In the case of refusal to issue an *EC Certificate of Conformity*, a letter stating this is signed by the DC Director.

3.7 U.S. Coast Guard Approval

3.7.1 In case the customer is interested in selling the products, covered by the assessment, on the market of the United States of America (USA), certificates of conformity should be issued on forms with *USCG* extension. The rules for issuing certificates have been developed on the basis of the "Agreement between the European Community and the United States of America concerning the mutual recognition of certificates of conformity for marine equipment" signed on February 27, 2004. Under the terms of this Agreement, products for which the certification process has been completed with the issuance of certificates of conformity with the MED Directive according to module: B+D, B+E, B+F or G may be sold in the US, without the need for additional assessment of compliance with the requirements of US regulations.

USCG recognition applies only to products covered by the February 27, 2004 Agreement, which are listed in *Exhibit 4/PCW-01/MED.*

3.7.2 Principles for the issuance of *EC Type Approval Certificates with U. S. Coast Guard* (Module B):

3.7.2.1 In case PRS expert, conducts only conformity assessment according to module B, issues *EC Type Examination Certificate (module B)* Form. 7/PCW-01/MED_USCG in accordance with the principles given in paragraph 3.2;

3.7.2.2 If, in addition to the conformity assessment of the product type, PRS expert conducts the assessment of the production quality assurance system, the assessment of the product quality assurance system or the verification of the product (Module D, E or F, the *EC Type Examination Certificate* shall be issued on Form. 7/PCW-01/MED.

***NOTE**:*

1. *USCG Approval categories are given in Appendix 4/PCW-01/MED - Approval Categories by U.S. Coast Guard.*
2. *The U.S. Coast Guard Approval number is assigned according to the following rules: USCG/EC recognition category No. of notified body, e.g.* ***164.106/EC1463***

3.7.3 Certificates of conformity according to modules D, E and F with the approval number of the U. S. Coast Guard should be issued to:

- Form. 8/PCW-01/MED_USCG for Module D or E,
- Form. 9/ PCW-01/MED _USCG for Module F.

NOTE:

1. *The USCG approval categories are given in Appendix 4/PCW-01/MED - Approval Categories by U.S. Coast Guard*
2. *The U.S. Coast Guard approval number is assigned according to the following rules:*
   - *where the PRS expert performs conformity assessment according to modules B+D, B+E or B+F:*
     USCG/EC approval category Notified body number/Module certificate number B
     np. ***164.106/EC1463/CW/MED/1/11/2019***

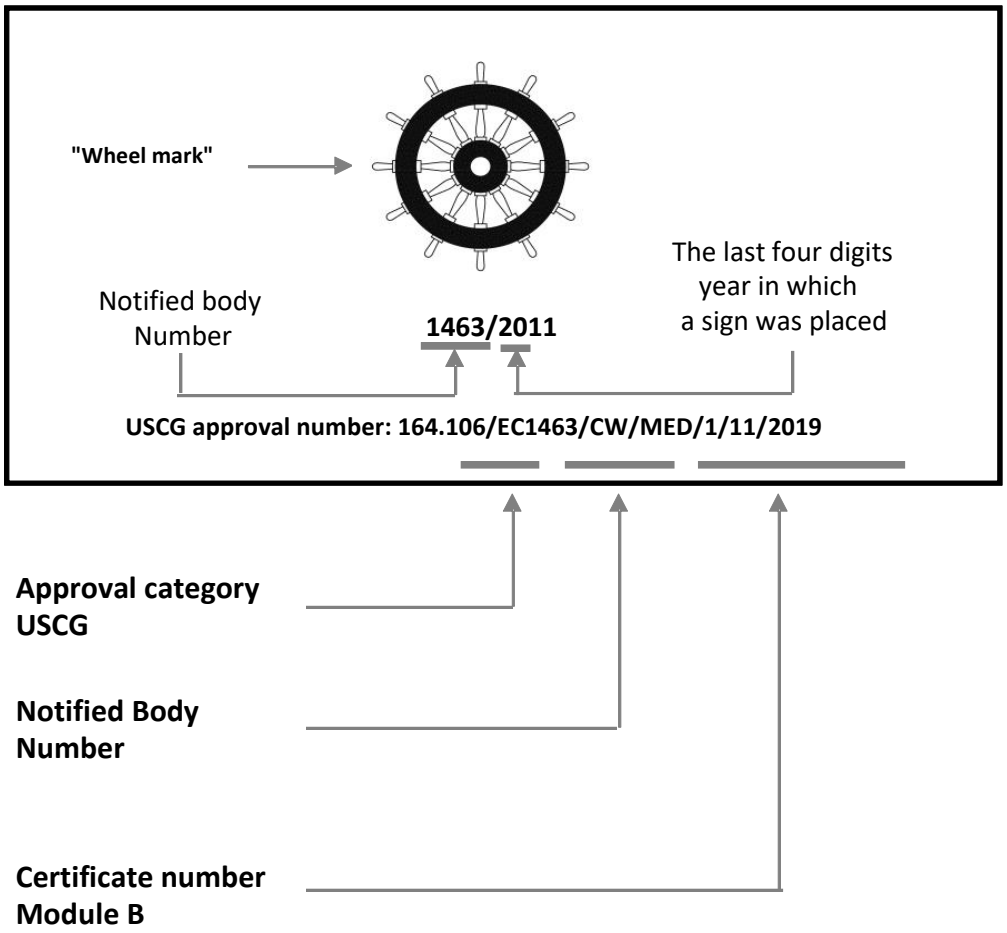

Fig.1 *Example of the mark of conformity on the product in the case of conformity assessment according to modules B+D, B+E or B+F.*

– *in case PRS expert performs conformity assessment according to Module D, E or F only: USCG/EC Recognition Category No. of Notified Body issuing Module B certificate/Module B/EC certificate No. of Notified Body issuing Module D, E or F certificate.*
e.g. ***164.106/EC0038/MED 040123/EC1463***

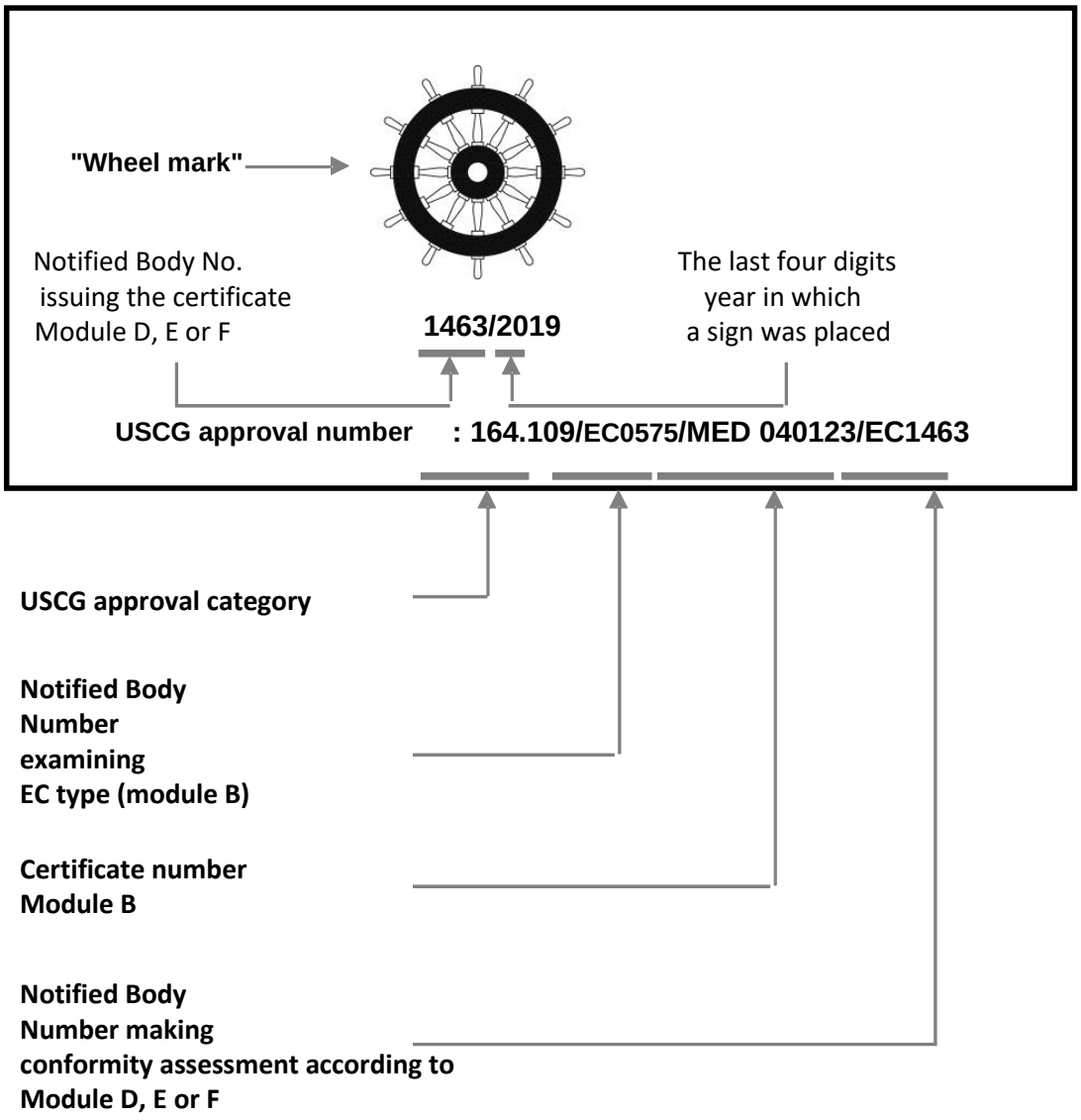

Fig.*2* *Example of the mark of conformity on the product in the case of conformity assessment according to modules D, E or F.*

3.7.4 Certificates of conformity according to Module G with the approval number of the U. S. Coast Guard should be issued to Form. 10/PCW-01/MED _USCG.

NOTES:

(1) USCG Approval categories are given in Annex 4/PCW-01/MED - Approval Categories by U.S. Coast Guard.

(2) U.S. Coast Guard approval number is assigned according to the following rules: USCG/EC approval category Notified body number/module certificate number G for ex. ***164.106/EC1463/CW/MED/1/11/2019.***

3.8 Final provisions

3.8.1 The maximum validity period of certificates for Module B is 5 years.

3.8.2 The maximum validity period of certificates for D and E modules is 5 years.
If the manufacturer has a quality management system certificate for compliance with ISO 9001, issued by the PRS Certification Bureau, the validity period of certificates for modules D and E may be limited to 3 years to coincide with the validity period of the quality management system certificate.

3.8.3 For certificates for modules F and G, the validity period is not limited.

3.8.4 Certificates issued as a result of successful completion of the certification process are assigned numbers according to the following rules:
Organizational unit symbol/MED/ Sequence number in a given month for Directive 2014/90/EU /Month/Year of issue (for example, CW/MED/1/11/2019).

3.8.5 Not later than 5 days after the issuance of the certificate (7/PCW-01/MED, 8/PCW-01/MED, 9/PCW-01/MED, 10/PCW-01/MED), the expert/auditor completes the List of Certificates of Marine Equipment according to the MED Directive (in Polish and in English) and saves it on the web resource in the directory ``Lists of Certificates issued for the following Directives. A copy of the certificate is placed in the folder "List of certificates ...". The expert updates the list in the folder. Once a month, the CW Manager or his/her designee shall post the updated list of certificates, marked with the date of editing, on the PRS website.

3.8.6 No later than 30 days after the completion of the conformity assessment process, the CW Manager or his designee shall complete the European Maritime Safety Agency database form (EMSA MED database). This form shall also be completed in the event of a negative result and in the event of cancellation of the certificate.

3.8.7 The completed form, the CW Manager or his designee submits to the database (EMSA MED database) maintained by the European Maritime Safety Agency available at https://portal.med.emsa.europa.eu/.

3.8.8 In the event of refusal to issue, limitation of scope, cancellation or suspension of the certificate, the relevant provisions of the General Rules of the Product Certification System - PVC-01 shall apply, whereby for Directive 2014/90/EU, the "relevant supervisory authorities" to which information is provided shall be understood as:

- supervisory authority or maritime administration of the European Union member state from where the complaint was received,
- Department of Maritime Affairs at the Ministry of Infrastructure,
- Department of International Cooperation at the Ministry of Infrastructure,
- President of the Office of Competition and Consumer Protection,
- Director of the Maritime Office in Gdynia,
- Director of the Maritime Office in Szczecin,
- EMSA MED database with which all notified bodies cooperate.

4. RELATED DOCUMENTS

Instruction ICW-02 - Instruction for consideration and approval of technical documentation.

5. FORMS

Form No.	Form name
Form. 1/PCW-01/MED	Report from assessment of production/product quality assurance systems documents
Form. 2/PCW-01/MED-D	Audit plan (module D)
Form. 2/PCW-01/MED-E	Audit plan (module E)
Form. 3/PCW-01/MED-D	Production quality assurance system audit questionnaire (module D)
Form. 3/PCW-01/MED-E	Production quality assurance system audit questionnaire (module E)
Form. 4/PCW-01/MED	Findings from audit
Form. 5/PCW-01/MED	Production/product quality assurance system audit report
Form. 7/PCW-01/MED	EC type examination certificate (Module B)
Form. 7/PCW-01/MED_USCG	EC type examination certificate (Module B) with USCG recognition number
Form. 8/PCW-01/MED	EC production/product quality assurance certificate (Module D/E)
Form. 8/PCW-01/MED_USCG	EC production/product quality assurance certificate (Module D/E) with USCG recognition number
Form. 9/PCW-01/MED	EC product verification certificate (Module F)
Form. 9/PCW-01/MED_USCG	EC product verification certificate (Module F) with USCG recognition number
Form. 10/PCW-01/MED	EC certificate of conformity (Module G)
Form. 10/PCW-01/MED_USCG	EC certificate of conformity (Module G) with USCG recognition number
Form. 12/PCW-01/MED	Annex to EC Production/Product Quality Assurance Certificate (Module D/E)
Form. 12/PCW-01/MED_USCG	Annex to EC Production/Product Quality Assurance Certificate (Module D/E) with USCG recognition number.
Form.13/PCW-01/MED	Appointment of a team of auditors

All records and documents related to the certified product are kept for 10 years after the last product was manufactured.

6. ANNOUNCEMENTS

Annexes introduced by the program:

- Annex 1/PCW-01/MED - List of personnel authorized to take actions in certification processes,

- Annex 2/PCW-01/MED - Equipment for which specific testing standards already exist in international acts (Commission Implementing Regulation (EU) 2024/1975 of 19/07/2024),
- Annex 3/PCW-01/MED - MarED Recommendations, Approved Recommendations,
- Annex 4/PCW-01/MED - Recognition categories according to the U.S. Coast Guard,
- Annex 5/PCW-01/MED - Determination of audit time.
- *Annex 6/PCW-01/MED - List of activities carried out within the flexible scope of accreditation No. AC 114*