Assessment and examination
of marine equipment in
accordance with directive
2014/90/EU
MED
Foreword

A manufacturer can apply the wheel-mark on Marine Equipment after performing necessary activities as described in Directive 2014/90/EU.


Directive 2014/90/EU is implemented in Swedish law by TSFS 2016:81

All evaluation and testing is carried out based on indicated standards/normative documents. The activities for certification are in line with ISO/IEC 17065.

The rules can be revised as necessary to suit new and revised harmonised standards/normative documents. Revision may also be necessary if the Directive changes or as a consequence of experience gained from the application of the system, within the framework of the Directive.

This version of the rules replaces the previous version dated 2020-12-02.

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RISE Research Institutes of Sweden AB
Certification - Notified body no. 0402

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1 Scope

These rules cover procedures for assessment of marine equipment in accordance with Directive 2014/90 EU (MED) with the aim of issuing documents for the wheel-mark. The services which RISE can offer are set out below.

Module B  EC type examination
Module D  Conformity to type based on quality assurance of the production process
Module E  Conformity to type based on product quality assurance of products
Module F  Conformity to type based on product verification

The prerequisites for the respective modules are described in the following document in sections 2-5. Within certain frameworks the manufacturer chooses which modules it wants to use and, in the same manner, the manufacturer chooses which notified body/bodies should perform which task.
2 EC type examination (Module B)

2.1 General
This section describes the EC type examination (certification) of marine equipment, which is based on Directive 2014/90/EU, annex II, module B, and involves examining that the product meets the applicable requirements of the Directive. The EC type examination can be performed in one of the following ways:

- Inspection (testing) of one or more samples that are representative of the production
- Assessment of the technical design by means of review of the technical documentation as well as inspection (testing) of one or more critical parts of a sample. The sample shall be representative of the production

RISE assesses which manner is appropriate for the current product. See also below evaluation section 2.3.3. Other conditions are listed in section 5.

2.2 Required characteristics
Equipment that is manufactured in accordance with, and complies with the requirements in, the standards that have been indicated for the purpose are considered to comply with the requirements of the Directive. See the Directive's list.

2.3 The assessment process

2.3.1 Applications
Applications for EC type examinations (certification) shall be in writing and must be accompanied by:

- The manufacturer’s name and address and, if the application is lodged by an authorised representative, his name and address as well.
- A written declaration that the application has not been submitted to another notified body
- Technical data (see below).
  - When applicable, the equipment that is representative of the type shall be placed at RISE disposal for review.
  - Documents that illustrate that the technical design is appropriate. The documents shall include or refer to the standards that are used.
  - A declaration that the equipment is representative for the planned production.

A special application form is available on RISE website.

2.3.1.1 Technical data
Technical data shall describe, among other things, the design, manufacture and working method of the equipment. This means that the appropriate sections shall contain:

- a general description of the marine equipment
- design and manufacturing drawings and charts of components, sub-assemblies, circuits, etc.
- descriptions and explanations necessary for understanding the above
- a list of the requirements and testing standards that are applied, as well as descriptions of the solutions chosen in order to comply with the requirements in these
• results of calculations and inspections
• test reports*.

* Test reports may not be older than five years at the time of application.

All documents including drawings, product descriptions, assembly instructions, user manuals etc. should be given a name or number and date as well as date of last revision.

2.3.2 Review of application
When reviewing the application, RISE checks that the application is complete and that the application can be handled within RISE notification. The review may mean that RISE cannot accept the assignment, which is then communicated to the manufacturer with an explanation.

If the application is accepted, the manufacturer is notified by means of a confirmation. An evaluation plan is prepared if this does not already exist. The standard applied constitutes as a rule the evaluation plan. If a subcontractor must be engaged, this is communicated to the manufacturer. The manufacturer is entitled to object to the selected subcontractor.

If this is not done with the application, the manufacturer is asked to send test samples to the extent that the evaluation plan requires.

2.3.3 Evaluation
During the evaluation process, the product is checked to ensure it has been manufactured in accordance with the technical data, and that it meets the requirements that the standard or specification requires. The evaluation process includes tests and inspections that are carried out to the extent specified by the requirements specification and/or evaluation plan. In some cases, previous test results can be used for the evaluation. The requirements for these tests include that they shall have been carried out by an accredited independent testing laboratory. The evaluation also includes a review of marking and information to the user etc. In cases where the product and/or documentation shows deficiencies, i.e. does not meet the requirements, the evaluation may be cancelled.

Results of the evaluation are summarised in an assessment report, which is presented to the manufacturer. The report is confidential and may not, in full or part, be disseminated without the manufacturer’s consent.

If the results of the evaluation show that the product and documentation meet the requirements of the specification, the process proceeds to review and then decision.

2.3.4 Review and decision
The evaluation work is reviewed, and following successful results, the process proceeds to the decision phase. When a decision on certification has been taken, an EC type examination certificate is issued to the manufacturer. This can be used by the manufacturer as a part of the documentation required for issuing a declaration of conformity and to wheel-mark the product.
2.4 EC type examination certificate

2.4.1 Validity
EC type examination certificates for marine equipment are normally issued with a validity period of five years from the date of issue. The validity period may then be extended for five years at a time. In the event of revision of a certificate, the original validity period is retained.

2.4.2 Extension of validity period for the issued certificate.
Applications for extension shall be made in writing, at least 6 months before the end of the validity period. For the application, an assessment is made of the measures required for the extension. If no changes are made to the regulations, specifications, etc. the certificate can be extended without any further action. Of course, this presumes that the product is unchanged relative to the original certification or the latest revision. The applicant must certify that no changes have been made. A current set of the technical documentation shall be attached (see 2.3.1.1). Note, that test reports used as basis for the initial evaluation, may not be older than 15 years at the time of application of the extension of validity. RISE can also demand for results from assessments of the quality system according to module D/E or product verifications according to module F.

If changes are planned for the product, the application shall be supplemented with details about this. This may result in the need to conduct additional assessments and/or tests. In this case, the manufacturer must be informed thereof and will then also receive a price quotation for this.

2.5 Changes to certified products
Note that no changes may be made to the certified product, without this being assessed and approved by RISE. For this reason, the manufacturer must notify RISE of any planned changes to the certified product. Along with this notification, a description of the changes as well as supplementary information to the technical data must be attached. RISE will then assess what measures need to be taken in order for the certificate to remain in force after such changes have been made. The assessment may result in the need to conduct additional tests. In this case, the manufacturer is notified thereof and will then also be given a price quotation for this. If the result of the change means that the certificate is still valid, the certificate is revised with the new data.

2.6 Market access and marking
Introducing a product to the market requires that in a supplement to a valid EC type examination certificate, the manufacturer must also allow a notified body to perform any of the confirmation procedures stated in point 1.3. The manufacturer chooses the appropriate confirmation procedures to be used and the notified body that will perform each task. The procedures that are applicable are set out in the equipment list associated with the Directive. The wheel-mark must be supplemented with the identification number of the notified body that performs this task. See more on this in section 5. See section 3 and onwards for the different procedures.
3 Conformity to type based on quality assurance of the production process/products (Module D/E)

3.1 General
Directive 2014/90/EU states a number of options from which manufacturers can choose for examination of type approved/certified equipment with the aim of approving them for the market. One option is the quality assurance of the production, for which the manufacturer is responsible, and which is followed up through monitoring, for which RISE is responsible. This is based on the Directive, 2014/90/EU, annex II Module D. Following inspection, a report is issued with an assessment and proposed decision. Using this as a basis, a decision is taken to issue a certificate. Other conditions are listed in section 5. For Module D, the manufacturer must have one or more valid EC type examination certificates for the equipment that will be included.

For Module E, the same conditions apply in principle as for module D, with the exception that it is assumed in this case that there is a relevant final examination of the equipment. This means that in the examination, less importance is given to the steps that precede the final inspection.

3.2 Applications
The application for examination (certification) of the quality system shall be in writing and be accompanied by:
• The manufacturer's name and address, and if the application is lodged by an authorised representative, his/her name and address as well.
• A written declaration that the application has not been submitted to another notified body
• All information of significance for the concerned category of equipment
• Quality manual or equivalent documentation for the quality system
• The technical documentation for the type/types and a copy of the EC type examination certificate or certificates.

The application must also state if the quality system covers all or parts of the company, or all or parts of the production.

The manufacturer shall undertake to:
• Maintain the approved quality system to ensure its continuing suitability and effectiveness.
• Inform RISE about all changes that are planned in the quality system.

3.3 Quality system requirements
The requirements on the quality system are stipulated in the Directive's annex II Module D and E respectively. The quality system shall ensure that the equipment complies with the type approval and meets applicable requirements in the Directive. The system shall be documented in accordance with point 3.4 below.

The quality assurance system of the production can be based on a quality system according to EN-ISO 9001, including examination that the measuring instruments meet the requirements of the Directive.
3.4 Documentation requirements
The documentation shall describe,
for module D:
• quality objectives and the organisational structure, management responsibilities and authority with regard to product quality
• manufacturing processes, methods and techniques for quality control and quality assurance as well as the systematic measures that will be taken
• the inspections and tests that will be carried out before, during and after manufacture, including frequency
• quality documents, for example, audit reports, test results, calibration results, documentation of the expertise of staff, etc.
• the methods for monitoring that the set quality objectives are achieved and that the quality system works effectively

for module E:
• quality objectives and the organisational structure, management responsibilities and authority with regard to product quality,
• the inspections and tests that will be carried out after manufacture,
• quality documents, for example, audit reports, test results, calibration results, documentation of the expertise of staff, etc.
• the methods for monitoring that the quality system works effectively

All relevant information such as quality documents and design documents shall be kept available for RISE.

3.5 Review and assessment of the quality system

3.5.1 General
During the assessment (audit), auditors and technical experts who are employed or contracted by RISE are used. At least one of the members in the audit team has experience of the product area. Auditors or technical experts may not participate in an audit if impartiality can be questioned. Companies undergoing an audit can veto an auditor without needing to state the reason why. The assessment (audit) shall be carried out where the manufacturing and/or final inspection takes place. Agreements on dates and times for assessments are normally made between the lead auditor in question and the manufacturer. The requested documentation shall be sent to the auditor in question.

3.5.2 Initial audit stage 1
The initial audit stage 1 is carried out in order to plan the initial audit stage 2 and to ensure that the management system is auditable. Review of documentation and examination of product certificates, type approvals and similar which are covered by the management system are also conducted. Following the initial audit stage 1, the total scope of the initial audit is determined. If it differs from what was stated in the original tender, a new tender is submitted. In some cases audit stage 1 has to be performed at the manufacturer premises.

3.5.3 Initial audit stage 2
Initial audit stage 2 is conducted to assess the conformity of the management system with all requirement elements in the directive. All departments, units, functions or similar that are covered by the audit shall be reviewed.
3.5.4 Report
An audit report containing the results, recommendation on approval and the scope of the audit is compiled for the audit. The result contains information on any deviations against requirements which emerged during the audit. Deviations are classified as major deviations, minor deviations or notes. Major deviations are serious and mean that corrective measures should be performed immediately, and should be audited through another visit by the auditors or through a document review (post audit). In the event of a risk of products which do not fulfil essential requirements reaching the market, a major deviation is always issued. Minor deviations also need to be rectified. A note is an observation which may be useful to consider, but there is no requirement for any measure.
The company should report corrective measures for deviations (major and minor) within the period stipulated in the report. The auditor checks and approves the corrective measures and sends an acceptance of measures statement to the manufacturer.

3.5.5 Post audit
In the event of major deviations from the requirements set out in the directive, a complementary post audit is required. This can be performed as a document review or audit on site at the company and is charged in accordance with the applicable price list.

3.5.6 Re-audit
If initial audit Stage 2 results in a large number of major deviations, an entirely new audit (stage 2) may be required.

3.6 Certificate
When corrective measures of all non-conformities, if any, are finished, reported and accepted, RISE can take a decision on approval of the quality system. As a receipt, an assessment decision (certificate) will be issued. The certificate allows the manufacturer to use RISE identification number, see section 7. The validity period of this certificate is 5 years, provided that all conditions are fulfilled.

3.7 Marking
See section 5.

3.8 Surveillance of quality system
RISE will conduct audits at regular intervals, normally once a year, and submit audit reports as described under 3.5.3 above. RISE may visit the manufacturer without notice and/or conduct/allow the conduct of testing. RISE reports results in the audit report and/or testing report.
If major deviations are found, corrective measures should be performed immediately, and should be audited through another visit by the auditors or through a document review (post audit). In the event of a risk of products which do not fulfil essential requirements reaching the market, a major deviation is always issued. Minor deviations also need to be rectified, but the manufacturer will have 6-8 weeks respite to report this. A note is an observation which may be useful to consider,

3.9 Renewal of certificate
The certificate can be renewed every fifth year. One of the conditions for renewal is that surveillance audits has been performed as scheduled and with approved result.
4 Conformity to type based on product examination (Module F)

4.1 General
The procedure entails that the manufacturer takes all necessary measures for ensuring that manufactured equipment conforms to the requirements and that RISE establishes that manufactured equipment conforms to what is stated in EC type examination certificate. For Module F, the manufacturer must have one or more valid EC type examination certificates for the equipment that will be included.

4.2 Applications
The manufacturer applies for assessment of its equipment
A list of the products that will be covered by the review, the quantity involved and, when applicable, the EC type examination certificates that exist.

4.3 Inspection
RISE conducts, or has another conduct, inspections/testing in order to check conformity with type in accordance with the description in EC type examination certificates. Testing is conducted of each piece of equipment or of a number of products that have been selected according to a statistical selection procedure.

4.4 Certificate of Conformity
RISE issues a Certificate of Conformity based on the inspections conducted. The certificate shall contain a list of the equipment that has been approved.

4.4 Marking
See section 5.

4.5 Failed products
In the case of any failed shipment, RISE will take appropriate measures to prevent release to the market. In principle, this means that the products must be destroyed or reworked. A renewed inspection/review shall be conducted following any rework.
5 General conditions

5.1 Marking
The wheel-marking of marine equipment is carried out on the manufacturer's responsibility. In those cases where RISE has carried out the assessment procedures according to modules D-F, RISE ID number as notified body (0402) shall be placed adjoining the wheel-mark. Only the products that comply with the requirements in the Directive may be marked. Misuse of RISE ID number may lead to legal action.

5.2 Certificate
The validity of the certificate is based on continuous compliance with the conditions. Certificates are not transferable. Copies of certificates and associated documents may only be reproduced in their entirety, unless otherwise agreed with RISE

5.3 Responsibility
The certificate holder is responsible:
- to fulfil all requirements connected to the certification including notified changes in certification rules or conditions,
- to not provide any misleading information about the extent or conditions of the certification which can harm the confidence for the certification or RISE
- that products marked with the wheel-mark comply with the applicable requirements in the directive, with corresponding national provisions and the requirements specified in the certificate

RISE is responsible for:
- ensuring that all processing is carried out with the necessary care and in accordance with the procedures of RISE quality system
- the certification rules
- to inform about changes in the certification rules and conditions.

RISE has no responsibility for certified products.

5.4 Withdrawal of certificate
RISE, either definitely or permanently, can withdraw a certificate if:
- the product no longer meets the set requirements
- errors in the certificate come to light
- demands for continual examination are not met
- the internal examination shows serious shortcomings
- shortcomings in the internal examination are not remedied in the time prescribed
- there are failed results in examination testing in the regulatory examination
- the product is not suitable for its purpose or can cause injury or problems
- changes are made to legislation, regulations or similar.
- the competent authorities or coordinating body for a notified body recommends RISE to do so
- the holder has used the certificate or in connection with products that do not meet the requirements or are not covered by the certificate
- fees are not paid within the prescribed deadline, the certificate holder is subject to bankruptcy, has gone into liquidation or has transferred the business
- breach of the conditions for the certificate.

If a certificate is withdrawn, the holder shall cancel all reference to the certificate and RISE name and id.no. 0402 in his EC declaration of conformity and marking. The holder
may neither refer to the certificate or RISE in advertisements or other publications for the product in question.

5.5 Changes to products, quality systems, organisation
Changes to certified products, see 2.5.
Regarding quality systems according to modules D and E, changes to the quality system shall be notified to RISE. Even major organisational changes or other factors which may impact the certificate should be notified.

5.6 Information obligation, confidentiality and access
As a notified body, RISE is in some cases obliged to reveal information on certificates to other notified bodies and competent authorities. RISE informs Swedac about issued certificates as well as refusals, restrictions, suspensions and withdrawals of certificates.

RISE keeps a register of certificate holders, certificates, certified products and certified quality systems, manufacturing sites, validity period for certificates etc. This information may be published, for example, on RISE websites. RISE may provide copies of or publish the certificates.

Regarding certificates issued according to the Directive 2014/90/EU, these are published in the common database, MarED. RISE is also entitled to publicise decisions on the withdrawal of certificates and the misuse of certificates or marking. Other information is classified.

The manufacturer, or its representative, should ensure that RISE, the control body that RISE has approved, or observers (e.g. from the accreditation body) have access to premises and documents that are needed to perform the duties described in the sections 2-4.

5.7 Revised rules
RISE reserves the right to modify these rules in order to harmonise them with standards, changes to the Directive or rules for Notified Bodies, or as a result of experience of application of the system.

5.8 Fees
Fees are set according to agreement and shall be paid by the certificate holder. Costs for work resulting from deviations in the continuous examination should be paid by the certificate holder. The fees for another examination should only be paid by the certificate holder if the examination results show that the requirements of the certification regulations are not fulfilled.

Application and registration fees are normally not reimbursed when an assignment is cancelled or a certificate cannot be issued. In the case of assignments that are not estimated to be completed within a month of the acceptance date, RISE has the right to issue regular (monthly) invoices for costs to date.

5.9 Appeals
Appeals against RISE decisions should be made in writing. Decisions on measures necessary as a result of appeals are taken by the RISE Certification board.