

1 Scope of the Testing and Certification Regulations

The Testing and Certification Regulations shall apply to the granting of certificates, EC-type examination certificates and EC certificates of conformity by the DMT-Certification Body (hereafter referred to as 'certificate' and 'certification body') going along with the evaluation (hereafter referred to as "testing") required by DIN EN ISO/IEC 17065 for products, processes and management systems (hereafter referred to as "objects").

2 Testing and Certification Procedure

2.1 Applicants shall request certification from the certification body in writing (generally including testing). For the initial certification order, the certification body and the applicant shall conclude a contract.

2.2 The object to be certified, including required documentation (possible languages: German, English, others permitted with agreement), shall be submitted by no later than the beginning of testing by the certification body.

2.3 Testing and certification requests will be processed in the order of the required documents and, if necessary, the test samples are received.

2.4 The certification body shall select the testing site. Tests will be conducted by the certification body itself or external assessment bodies appointed by the certification body or — if the type of object requires or allows — at the applicant's site. This shall occur in coordination with the applicant.

2.5 The certification body or conformity assessment body must be granted access to information and relevant locations at all times. In case of the certification of newly developed hardware, the certification body or conformity assessment body shall conduct an initial inspection of the production site at the applicant's expense and write a report.

2.6 After completing the testing and certification process, the applicant shall receive a written evaluation report and, in case of a flawless evaluation, a certificate and, if necessary, permission to carry / install and use a conformity mark.

2.7 The applicant must pay a fee for every certification procedure.

2.8 After receiving a certificate, submitted test samples will, as far as their type permits, be taken into safekeeping by the certification body or returned to the applicant signed for safekeeping. In case test samples cannot be stored, sufficient documentation must be created.

The retention of test samples whose tests did not meet the requirements for a certificate shall be determined by an individual agreement with the applicant. The certification body shall not be liable for damages to test samples resulting from testing or from burglaries, theft, fire, water or any other external damage the certification body is not to be held accountable for. The certification body must only exercise the care it would apply in similar matters (Section 690 of the German Civil Code (Bürgerliches Gesetzbuch)).

2.9 Should the awarding of a certificate be rejected, the certification body shall not be held liable for disadvantages suffered by the applicant due to the rejection.

3 Certificates

3.1 The permission to use a certificate shall only be granted to the company and the objects listed in the valid certificate or the referenced test report.

The owner of the certificate must report any intended moving of production sites or transfer of the company to another company or owner to the certification body in time.

A certificate may only be transferred to third parties by the certification body.

3.2 When transferring a certificate to the legal successor of the certificate owner or when transferring it for other reasons, in case of continued production, the certificate owner must attach a control mark specified by the certification body to the objects on request by the certification body to allow the certification body to distinguish between objects produced at different times.

3.3 A certificate shall only be valid for complete objects (referring to tested samples).

3.4 The certificate owner must pay an annual fee for each certificate determined by the certification body.

3.5 The certificate owner must constantly monitor the correspondence of certified objects produced to the test samples and, if necessary, conduct any additional tests requested by the certification body.

4 Conformity Marks

4.1 The type of labeling of the certified objects with conformity marks and identification numbers as well as any other use of the conformity mark must be submitted to and approved by the certification body before being distributed / used.

4.2 Use of conformity marks for comparable or altered objects is not permitted.

4.3 When altered for advertising purposes, conformity marks must be designed so that no false impressions about the qualitative certification performed by the DMT-Certification Body are created regarding the advertised object.

This includes clearly distinguishable statements for advertisements referring to the certification conducted by DMT in contrast to other statements.

4.4 The applicant shall receive the non-transferrable, nonexclusive right from DMT to use the conformity marks according to these regulations for the duration of the certificate. The supplier may not offer sublicenses.

DMT shall not guarantee that conformity marks can be used without limitation when in competition. Should the supplier use the conformity mark in advertisements, only the applicant must ensure that use of the conformity marks follows the legal regulations regarding competition.

4.5 According to the Marine Equipment Directive (Schiffsausrüstungsrichtlinie) (wheel mark), conformity marks may only be attached in the respective module combination if all certificates have been fully presented. Behind the conformity mark, the identification number 2509 must be affixed.

The criteria on the conformity marks stated in the Marine Equipment Directive shall also apply to the identification number.

5 Changes

5.1 Changes to

- the legal or organizational form, economic or ownership situation of the certificate owner,
- the organization and management, (e.g., key personnel in executive positions, decision-making or qualified personnel)
- the contact address and locations
- the applicability of the certificate
- objects and relevant processes towards the certified implementation

must be immediately reported to the certification body. Deviations require special agreements.

Changes may influence the granting or receipt of a certificate.

Changes may depend on the producer providing proof of adherence to the rules of technology or on an additional test.

5.2 If significant defects or non-conformities are discovered during testing or auditing of a submitted object and if the applicant already supplied the objects corresponding to the test samples, a certificate for the newly submitted and changed test samples may only be granted if the producer changes the description of the type of the objects already supplied. This requires the description and timely implementation (within no longer than six months) of specific corrective measures.

6 Expiry or Annulment of a Certificate

6.1 A certificate shall be annulled when

- the contract relating to the certification of objects ends,
- the certificate owner rejects the certificate,
- the certificate owner does not recognize changes to the General Terms or the Testing and Certification Regulations of the certification body as binding,
- the owner of the certificate becomes insolvent or an application for insolvency proceedings against him is rejected for lack of assets,
- the date stated on the certificate is exceeded. This depends on the validity / changes to the underlying rules of technology. The validity of a certificate shall be extended if a review conducted at the expense of the owner of the certificate within an imposed deadline proves that the certified objects still follow the rules of technology. A period of up to six months without a valid certificate is permissible for assuming that an object has been certified during this extension.

3.2.2 A certificate may also be annulled or cancelled by the certification body if

- defects that were not detectable or discovered during testing appear (these must be reported to the certification body immediately),
- reviews of objects that received conformity marks reveal defects,
- objects with conformity marks do not correspond to their test samples,
- no orderly review required by the certification body is provided by the owner of the certificate within 4 weeks, despite receiving a written notice (see Section 3.5),
- the owner of the certificate refuses inspection of production and testing facilities or the warehouse by the certification body representative or resists the taking of objects for review,
- intended surveillance cannot be properly performed for reasons for which the applicant is responsible,
- defects, deviations (among others, of quality assurance) or non-conformities are discovered during regular surveillance in accordance with Section 7 (follow-up service),
- fees are not paid before their deadline, despite notices. Should these fees not be related to a specific certificate, the certification body shall decide for which certificate measures shall be taken,
- misleading or otherwise unpermitted advertisement is made using merely possibly awarded conformity marks,
- due to circumstances that were not clear at the time of the evaluation, continued use of conformity marks and / or certificates proves unjustifiable on the market because of their significance,
- the condition of objects no longer meets the certification requirements,
- conformity marks are used in any way contrary to these regulations,
- competition law or industrial property protection disputes of any kind occur about the conformity marks.

6.2 Annulments shall be reported to the respective authorities (if present).

6.3 The owner of a certificate shall lose the right to label the objects listed in the certificate if the validity of the certificate expires or is annulled.

6.4 After an annulment, the certificate must be returned to the certification body.

7 Regular Surveillance

7.1 After every successful certification, the certification body may keep the contractual use of the certificate and of the conformity marks and the consistent quality of the certified objects under surveillance.

7.2 The certification body may demand information on the certified objects and their production, changes, complaints, reports on employee qualifications, etc., for the surveillance. For developed hardware, production sites will be inspected. For management systems, audits will be performed.

7.3 The surveillance will be performed with regular frequency determined by the certification body, but annually at the earliest. Deviations require special agreements. In justified cases, inspections may be conducted at irregular intervals for special occasions.

7.4 Should the surveillance reveal that requirements for conformity to the certificate are no longer fully met, the producer will be asked to take necessary corrective measures. If necessary, the certificate will be suspended or revoked. Should no corrective measures be taken or should they prove ineffective, the awarded certificate shall be limited, suspended or annulled.

7.5 The owner of the certificate must document complaints received by him about certified objects as well as resulting measures. This documentation must be saved by the owner and provided to the certification body on request.

8 Publication of Test Reports and Certificates

8.1 The owner of a certificate may only provide test reports and certificates to others that contain their full text and issuance date.

8.2 If necessary, relevant information shall be submitted to the respective authorities (if present).

9 Consumer Information

The certification body reserves the right to publish a list of certified objects for consumer information.

10 Violations of the Testing and Certification Regulations

Should culpable violations of the Testing and Certification Regulations be discovered, especially unlawful use of the agreed conformity marks, the certification body may charge a contractual penalty of up to €5,000.00 for each violation.

Unlawful use of conformity marks occurs also if objects labeled with conformity marks are offered or distributed before a certificate is awarded or if impermissible advertisements are made.

11 Effectiveness of and Changes to the Testing and Certification Regulations

These Testing and Certification Regulations shall enter into effect on 01 November 2021.

Applicants and certificate owners must note the effectiveness of the new and the annulment of the existing Testing and Certification Regulations.

2021-07-09

Rev1.0

MED-VA7en