

Testing and Certification Regulations of TÜV NORD CERT GmbH for the field of activity of Product Testing and Certification

1 Scope and Definition

The Testing and Certification Regulations apply for the performance of tests and for the granting of TÜV certificates for products by the certification bodies and testing laboratories of TÜV NORD CERT within the following fields of activity:

Safety of technical systems, explosion protection and monitoring equipment, as well as medical devices.

Tests, examinations and inspections are taken to mean activities such as the performance of tests specified, for example, in technical rules and regulations, expert appraisals and tests in order to verify a specific product feature and also the assessment of quality assurance systems.

TÜV certificates include, for example, EC type approval certificates, EC certificates for medical devices, GS mark permission certificates, type approval certificates, IEC Ex certificates of conformity, Safety Approved certificates etc.

In this case, the evaluation basis is formed by the DIN EN ISO standards applied for and/or the respective directives of the European Union in their respective latest version, and those of the national legislation on which the accreditation / designation of the certification body / Notified Body is based.

2 Testing and Certification Procedures

2.1 The client instructs the certification body or testing laboratory to test and/or certify. When a certification order is placed for the first time, the certification body or testing organisation and the client conclude a contract.

2.2 The type specimen (test specimen) to be tested must be forwarded to the certification body or testing laboratory as far as possible together with the order and the necessary documentation. If a number of test specimens are required, the client will be notified of the required quantity.

2.3 The client shall ensure carriage-free delivery of the test specimens free of charge in the required packaging appropriate to the relevant test specimen.

The packaging must, if necessary, also be suitable for return purposes. The cost of return to the client shall also be borne by the client.

2.4 The testing and certification orders are handled in the order in which the necessary documents and test specimens are received.

2.5 The place of the test is agreed with the client. The tests are performed in the testing laboratory or at a suitable external test site or – if the nature of the product makes it necessary or possible – at the client's premises.

The testing laboratories shall only engage subcontractors following consultation with the client.

2.6 After the conclusion of the testing and certification procedure, the client receives a written test report and, provided the result of the test reveals no nonconformities, a TÜV certificate if this has been requested.

2.7 For every test and certification the client shall pay a fee in accordance with the schedule of fees (Entgeltordnung) of TÜV NORD CERT, provided nothing different has been agreed, for example in an offer.

2.8 Following completion of the order, the test specimens submitted are kept by the certification body or the testing laboratory where the nature of the specimens permits, or are handed over to the client for retention and storage.

The certification body or testing laboratory shall not be liable for any damage to test specimens and documents submitted which is caused by the test or by burglary, theft, fire or water. TÜV NORD CERT shall exercise the care which it would normally exercise when acting on its own behalf (Art. 690 BGB – Germany Civil Code).

2.9 If issuance of the certificate is refused, the certification body shall not be liable for any disadvantages which the client experiences as a result of such refusal.

2.10 When a certificate is to be issued with award of a mark, the certification body shall conduct an initial inspection of the production shop at the client's expense. A report shall be drawn up regarding this inspection and the intervals for regular inspection shall be laid down. This does not include tests according to Module F of Directive 93/42/EEC and/or the IEC Ex Scheme.

2.11 If the accreditation of the testing laboratory or the certification body ends or is terminated, the client shall be notified accordingly; from this point on the client may no longer advertise by referring to this accreditation.

3 TÜV Certificates

3.1 Issuance of the certificate and use of a mark.

3.1.1 Permission to use a mark only applies for that company and those operating facilities and for those products mentioned in the certificate. The holder of the certificate shall notify the Certification body in good time of any intention to relocate an operating facility or to transfer the company to another company or another company owner. The certificate may only be transferred to third parties by the certification body.

3.1.2 Payment of annual fees for certificates in accordance with the schedule of fees (Entgeltordnung) of TÜV NORD CERT may be agreed.

3.1.3 The mark awarded may only be modified in size without changing its geometrical proportions. Reproduction of marks with a height of less than 5 mm and with colour deviations shall be subject to separate agreement.

Affixing of the mark to the products certified shall be reported to the certification body before the products are put into circulation.

3.1.4 The holder of the certificate is obliged to manufacture the products bearing the mark in continuous compliance with the inspections laid down in the test regulations or with the controls required by the certification body.

3.1.5 The certification body must be notified immediately of any modifications to the products as against the certified version. The certification body may make maintenance of the certificate conditional on the presentation of evidence by the manufacturer that the underlying rules are complied with, or on a supplementary test.

3.1.6 If major nonconformities are found in a product submitted during the inspection or test, and if the client has already delivered products which correspond to the test specimen, the certificate may only be issued for the newly submitted and modified test specimen if the manufacturer changes the designation of the type to distinguish it from the products already delivered.

3.1.7 The certification is only valid for the complete product. The certification body may, however, permit the holder of the certificate in special cases to dismantle the products for despatch to the extent which is normal for installation of the product in a plant.

In addition, permission may be given to dismantle the product further into its individual parts if the holder names the subsequent assembly shop, which must then be subjected to inspection by the certification body in the same way as the initial production shop.

3.2 Expiry or declaration of the invalidity of a certificate

3.2.1 A certificate expires or is invalidated if among others

- the General Agreement on Certification of Products and Award of Mark ends,
- the holder of the certificate renounces use of the certificate,
- the holder of the certificate does not accept in a binding fashion changes to the terms and conditions of business, the testing and certification regulations or the schedule of fees of TÜV NORD CERT after the end of the transitional period laid down in section 8,
- the holder of the certificate is declared bankrupt or an application for bankruptcy proceedings against him is rejected due to lack of assets,
- the rules or regulations governing the certificate have been changed and, where relevant, transitional periods have expired. The validity of the certificate is extended if it is demonstrated in a follow-up check conducted at the expense of the holder of the certificate within a specified period that the products certified are also in compliance with the new rules.

3.2.2 A certificate can also be declared invalid or terminated by the certification body if among others

- faults not evident or not ascertained during the test are subsequently found in the products,
- the examination of the products bearing a mark reveals faults,
- products bearing a mark do not conform to the test specimens certified,
- it is not demonstrated that fabrication inspections are conducted in a proper fashion in the operating facility of the certificate holder or at another test facility within a period of 4 weeks, despite a written request by the certification body (see section 3.1.4),
- the holder of the certificate refuses to allow inspection of the production and testing facilities or the storage facility by the delegated representative of the certification body

or does not allow products to be taken by the certification body for examination purposes,

- major deficiencies are found in the quality assurance system during the regular inspection according to section 4.1,
- the fees are not paid within the period specified after a reminder has been issued. If the fees do not relate to a particular certificate, the certification body shall decide which certificate is to be affected by the measures taken,
- misleading or otherwise inadmissible advertising is undertaken using the mark,
- in view of facts not clearly evident at the time of the test, continued use of the mark is not acceptable with respect to the signal it gives to the market.

The certification body is entitled to suspend or terminate a certificate, and hereby the entitlement to use the test mark, if the certification body subsequently becomes aware of new information pertaining to the assessment of the certification procedure or its result.

- 3.2.3 The declaration of invalidity may be published.
- 3.2.4 If the validity of the certificate expires or the certificate is declared invalid, the holder of the certificate shall lose the right to continue to affix the mark to the products mentioned in the certificate.
- 3.2.5 After a certificate has expired or been declared invalid, the certificate must be returned to the certification body, even if permission to market the remaining stocks with the mark still applies.
- 3.3 Marketing of products bearing the mark after the validity of the certificate has expired (permission to market).
- 3.3.1 After the validity of a certificate has expired, the stock of ready-to-use end products may still be marketed, but only for a maximum period of 12 months. Permission may be given to assemble the prefabricated parts already available at the time the certificate expires, and which were intended to make the end product in its originally certified design, for a number of units of the end product to be specified by the client, but only for a maximum period of 6 months from the date on which the validity of the certificate expires.
- 3.3.2 Stocks of finished products bearing a mark must be notified without delay to the certification body on demand, presenting an affidavit which can be used in a court of law.
- 3.3.3 The terms and conditions of business, the testing and certification regulations and the schedule of fees of TÜV NORD CERT shall continue to apply for the duration of the marketing permit.
- 3.3.4 If a marketing permit is not issued or is withdrawn, the holder of the certificate is obliged to remove the mark from all products of the type in question to which he has access or to destroy the products and to provide facilities for the certification body to conduct a corresponding follow-up check.

In special cases the certification body may demand a recall.

- 3.4 The validity of the certificates and, hence, the right to use the mark is limited to a maximum of five years und stated on the certificates. In case of changes to the certification programme, e.g. caused by legal proceedings against standards, introducing/changing testing principles of GS-proceedings etc. resulting in an early withdrawal of certificates, the certification body will inform all customers affected in writing. Not included in this duty to supply information are changes in the testing principles affecting the recertification. In such circumstances like e.g. changes in the standards it is the duty of the holder of the certificate to retrieve sufficient information from the publishers of the standard or other sources.

4 Regular inspection of the QA measures, in particular during production and quality testing, as well as surveillance of the market.

- 4.1 In order to ensure consistent product quality the certification body shall, upon the award of a quality mark, conduct regular inspections of the production and testing facilities and equipment and of the QA system at the expense of the holder of the certificate. It is possible to link these inspections contractually with regular inspection of the quality assurance system within the framework of TÜV CERT certification for quality assurance systems according to ISO 9001. Such an arrangement is subject to a specific agreement.
- 4.2 In addition, the certification body may, at any time and without prior notice, inspect the production shops and operating facilities mentioned in the certificate and the storage facilities (in the case of foreign holders of the

certificate also the storage facilities of the authorised representatives and branches, in the case of importers also their storage facilities), and may remove products for which a certificate has been issued for purposes of examination. The products shall be provided free of charge.

- 4.3 The holder of the certificate will receive a written report on the result of the examination.
- 4.4 If any defects are found in the course of the examination, the holder of the certificate shall bear the costs thereby incurred.
- 4.5 The holder of the certificate is obliged to maintain records of all complaints addressed to it with respect to the conformity of a product with the requirements of the standard concerned and make these accessible to the certification body at all times upon request. In the case of serious complaints, the certification body is to be notified immediately in writing. Furthermore, the holder of the certificate is obliged to take reasonable and appropriate measures if the complaints are based on actual defects, which negatively affect fulfilment of the certification requirements. These measures are to be documented accordingly and reported to the certification body.
- 4.6 The holder of the certificate is obliged to notify the Certification Body of any damage resulting from the products or any damages paid.
- 4.7 The testing laboratory shall, upon the request of the accreditation body and at the expense of the client, provide test specimens for a follow-up check.

5 Legal Requirements from §§ 16, 17 ProdSG

- 5.1 If necessary, a certificate may be suspended or withdrawn by the Certification Body if it is established within the conformity surveillance process that the QS system no longer fulfils the requirements. In such case, the Certification Body shall require the Client to take reasonable corrective measures. If no corrective measures are taken or such measures are not sufficient to ensure that the requirements are fulfilled, the Certification Body shall limit all affected certificates, suspend them or withdraw them. The certificate shall be withdrawn if the relevant audit report is no longer suitable according to item 2.6 to justify the Product certification.
- 5.2 The Certification Body reserves the right to announce the declaration of invalidity, limitation, suspension or withdrawal of certificates within the framework of its statutory obligations. The Certification Body is permitted to forward information, documentation, etc., which has been disclosed due to legal or administrative notification obligations, in connection with inspection and/or certification, and also upon request by the issuing body. The client and/or certificate holder recognises the obligation of the Certification Body, whereby it must notify the issuing body of
- Every refusal, restriction, suspension or withdrawal of a certificate, as well as
 - Every request for information regarding conformity assessment activities, which it has received from the market surveillance authorities.

The Certification Body shall send relevant information regarding the negative and also, upon request, regarding the positive results of conformity assessments to the other Certification bodies, which are Certification under the respective harmonisation regulations of the European Union, pursue similar activities and cover products of the same type. Moreover, the Certification Body shall report any improper use of certificates of which it becomes aware in particular to the responsible licensing authority of the Certification Body. This shall not be subject to any specific consent from the Client or certificate holder. The Client or certificate holder is obliged to inform the Certification Body immediately regarding any improper use of certificates issued by the Certification Body, as soon as the Client becomes aware of this.

6 Arrangements regarding occupational health and safety

- 6.1 Arrangements to be undertaken by the client
- Before performance of the contractual services, the client shall provide information regarding risks, hazards and stress which could originate from the working environment in the client's factory or at the client's premises. This information shall include information regarding hazardous substances in test pieces. The client shall provide information concerning whether and if appropriate, to what extent, risk and hazard assessments are required for the activities that have been ordered.
 - The client shall have sufficient arrangements in place for first aid, alarm and rescue, and shall name contacts and

responsibilities in this regard.

- The client shall ensure that employees of TÜV NORD CERT only perform work when accompanied by an employee of the client.
- The client shall provide the employees of the certification body with instruction on the basis of risk and hazard assessment(s) and work and operating instructions. The instruction shall include communication of emergency telephone numbers and collection points in case of danger, and also a description of the functioning and safety of any equipment to be used under such circumstances.
- The client shall supply any necessary personal protective equipment which may be necessary and which is not provided by the certification body (helmet, safety boots or shoes, ear and eye protection – e.g. ear defenders, safety spectacles/goggles) free of charge.

6.2 Certification body

- The employee of the certification body may only undertake work if the circumstances and the working environment are safe. The employee is entitled to refuse to perform the work in the presence of unacceptable hazards / risks / stresses.

7 Publication of test reports and TÜV certificates

The holder of certificates or test reports may only transfer them on to third parties in their full wording, indicating the date of issue. Any publication or duplication is subject to prior permission from the issuing body.

8 Consumer information

The certification body reserves the right to publish a list of the certified products as consumer information.

9 Breach of the Testing and Certification Regulations

If it is found that the client has wilfully breached the present Testing and Certification Regulations, and in particular if such breach involves the illegal use of a mark, the certification body shall be entitled to demand a contractual penalty of up to € 10,000 for each case of breach.

Illegal use of a mark shall be deemed to have occurred if products bearing a mark are offered or put into circulation before a certificate has been issued, or if inadmissible advertising is conducted.

10 Complaints

Appeals against testing and certification decisions and complaints regarding the execution of procedures are possible. Appeals regarding European or international procedures e. g. notified bodies groups, IECEE or IECEx have to be addressed to the board of appeal responsible for the procedure in question.

11 Entry into force and amendment of the Testing and Certification Regulations

- 11.1 This Inspection and Certification Ordinance shall become effective on 1 June 2014.
- 11.2 If new Testing and Certification Regulations are drawn up, the present Regulations shall cease to be valid after a transitional period of 6 months.
- 11.3 The attention of the client or holder of a certificate shall be drawn in particular to the entry into force of any new Testing and Certification Regulations and/or the invalidation of the existing Testing and Certification Regulations.

12 Access for accreditation personnel and official approval bodies

On placement of the order, the client agrees to grant employees of the accrediting body of TÜV NORD CERT and of official approval bodies responsible for the area in question access to his premises within the certification body's surveillance framework.