

# Testing and Certification Regulations for Pressure Equipment Modules D, D1, E, E1, H, H1 and 2 QA-Assessment of Material Manufacturers

## 1 Scope

The Testing and Certification Regulations apply for the conduct of audits and the issue of certificates (hereinafter called "Certificates") for products by the TÜV CERT Certification Body (hereinafter called "Certification Body") and for the use of the Identification Number of the Notified Body

according to the Directive for  
Pressure equipment 97/23/EC,  
Transportable Pressure Equipment 1999/36/EC

in the modules D, D1, E, E1, H, H1 and 2 as well as analogous for the QA-assessment of Material Manufacturers.

The Testing and Certification Regulations apply in particular with regard to:

- Preparation of the Certification Audit: (Phase 1)
- Review and Assessment of QA Documents: (Phase 2)
- Certification Audit and Issue of Certificate: (Phase 3)
- Surveillance: (Phase 4)

## 2 Testing and Certification Procedure

2.1 The Client applies to the Certification Body for the testing, certification and use of the Notified Body's identification number. The first time a certification order is placed the Certification Body and the Client conclude a module-related contract (Contract on the Testing, Certification and Use of the Identification Number).

2.2 When the testing and certification procedure has been completed, the Client will receive a written test report and, if the result is positive, he will also receive a Certificate.

2.3 If it is not possible to issue a Certificate because the test result is negative, neither the Testing nor the Certification Body shall be liable for any disadvantages the Client may experience because of this.

2.4 Procedure for and Handling of Certifications

2.4.1 Phase 1: Preparation for the Certification Audit

In Phase 1 the Client receives a questionnaire to prepare for an audit.

The questionnaire, completed and signed, is returned to the Certification Body. It is used to conduct a preliminary assessment of whether the Client's QA system satisfies the basic requirements for a Certification Audit. At the same time the scope and verification level according to PED are laid down. The Client also names a contact person from the

company management who will be responsible for handling the certification procedure (Audit Representative).

The Client may receive a report on the preliminary assessment.

As an option, more extensive preliminary assessments may be agreed by the Certification Body. These may include, for example:

- preliminary assessment of the QA systems on the basis of documents submitted
- pre-audit

These preliminary assessment have proven valuable and are normally ordered. They are not a condition for implementation of the certification procedure, however.

#### 2.4.2 Phase 2: Review and Assessment of the Quality Assurance Documents

In Phase 2 the Client's valid QA documents (QA manual and possible other applicable documents, such as written procedures, working instructions and inspection and test instructions) are examined to establish whether the PED requirements are met.

The Client receives a report on the assessment of the QA documents.

If the QA documents do not meet the requirements, and additional meeting may be agreed at the Client's request to discuss how to proceed or a pre-audit may be agreed.

#### 2.4.3 Phase 3: Certification Audit and Issue of Certificate

The Client receives the audit schedule, which has been agreed with him beforehand.

The company demonstrates in the audit the practical application of its documented procedures.

In the course of the audit the effectiveness of the QA system introduced is checked and assessed.

After the audit has been completed, the Client is informed of the result of the appraisal in a final meeting. Any nonconformities are explained with reference to the nonconformities reports available and countersigned by the company's Audit Representative.

Finally the Client receives an audit report and the certificate from the Certification Body, provided no critical nonconformities have been found.

If required, a follow-up audit is conducted.

The Certificate is valid for 3 years and will be extended provided that surveillance show that the Client maintains and applies his QA system. Where there are special reasons, e.g. planned update of the QA system, an audit may be necessary at short notice.

#### 2.4.4 Phase 4: Surveillance

The surveillance is intended to ensure that the Client fulfils his obligations arising from the approved QA system in a proper fashion.

##### 2.4.4.1 Audits

The Certification Body conducts regular audits to ensure that the Client maintains and applies the QA system. The frequency of the audits is laid down in article 10 (1) 1.5 and annex III. Surveillance audits ensure that a complete new assessment is conducted every three years.

#### 2.4.4.2 Unannounced Visits

In addition the Notified Body may conduct unannounced visits to the Client.

##### 2.4.4.2.1 Regular Inspection of Production (applies only for module H1)

To ensure constant product quality, the Certification Body conducts regular inspections of the production and testing facilities in the form of unannounced visits, the costs of which are to be borne by the Certificate holder (including inspection of pressure equipment).

In addition the Certification Body may at any time and without prior notice inspect the production facilities and stores indicated in the certificate (in the case of foreign Certificate holders also the stores of the authorized agents and branches and in the case of importers also their stores) and remove free of charge products for which a Certificate has been issued to conduct checks on them.

### 3 TÜV CERT Certificate

#### 3.1 Issue of the Certificate and use of the Notified Body's identification number

##### 3.1.1 Entitlement to use the Notified Body's identification number only applies for that company and those production facilities and for those products indicated in the Certificate. Where it is intended to relocate a production facility or to transfer the company to another company or another owner the client shall notify the Certification Body in good time.

The Certificate can only be transferred by the Certification Body to third parties.

##### 3.1.2 The following only applies for module H1:

- If module H1 is applied, a design inspection of each item of pressure equipment must be conducted by the Notified Body. If any changes are made to the design documents and these changes may affect the safety of the pressure equipment, a new design examinations must be conducted with respect to the change.

Pressure equipment may only be brought into circulation by the manufacturer once the design examination has been concluded and the result is positive.

- The Client is obliged continuously to monitor products bearing the mark to ensure conformity with the design and to perform the control tests required in a proper fashion.

##### 3.1.3 If the Certificate is transferred to legal successors of the holder or for other special reasons, an additional mark shall be affixed by the holder of the Certificate, in consultation with the Certification Body, next to the identifying mark during the continued manufacture of the products.

##### 3.1.4 The Client is obliged to notify the Certification Body of any damage to products which are within the scope of the certification.

#### 3.2 Expiration of validity or declaration of invalidity

### 3.2.1 The validity of the Certificate expires if

- the contract governing the testing, certification and use of the identification number is terminated,
- the Client dispenses with the Certificate or ceases manufacture of the product certified,
- the Client does not recognise changes to the Terms and Conditions or to the Testing and Certification Regulations as binding on him at the appropriate time,
- the Client becomes insolvent or an application made for insolvency proceedings with respect to him is rejected because of lack of assets,
- the test specifications on which the Certificate is based have been changed. The validity of the Certificate will be extended if it is demonstrated by means of a retest conducted within a set period at the expense of the Certificate holder that the products certified also comply with the new test specifications.
- after a period of 3 years if the validity is not extended by the Certification Body.

### 3.2.2 A Certificate may also be declared invalid or terminated by the Certification Body if

- the surveillance reveals that major conditions which applied at the time the Certificate was issued are no longer met,
- surveillance is not possible, or not within the specified period, for reasons attributable to the Client,
- faults which were not evident or not detected at the test are discovered in the products subsequently,
- misleading or otherwise inadmissible advertising is issued using the mark,
- continued use of the mark is not acceptable for reasons no evident at the time of the test,
- a check of the products bearing the mark reveals faults,
- no evidence is produced of the proper conduct of control tests in the production facility of the Certificate holder or in another testing facility within 4 weeks of the issue of a written request for such by the Certification Body,
- the Client refuses to allow inspection of the manufacturing and testing facilities or the store by the Certification Body's authorized representative or refuses to allow products to be taken for the purpose of inspection by the Certification Body,
- the fees are not paid by the deadline set after a reminder has been issued; if the fees do not relate to a certain Certificate, the Certification Body shall decide to which Certificate the action to be taken applies.
- The following only applies for Module H1:  
products bearing a mark do not conform to the certified design,
- The following only applies for Module H1:  
in the regular inspection according to section 2 faults are found.



- 3.2.3 The declaration of invalidity may be published. The Certification Body forwards to the competent authority useful information regarding the quality assurance system approvals it has withdrawn or refused.
- 3.2.4 If the Certificate expires or has been declared invalid, the Client shall lose entitlement to continue to affix the intended marks to the products mentioned in the Certificate.
- 3.2.5 After a Certificate has been declared invalid it must be returned to the Certification Body.

#### **4 Publication of Test Reports and Certificates**

- 4.1 The Client may only pass on test reports and Certificates with their full wording and an indication of the date of issue. Publication or duplication of extracts is subject to the prior permission of the Certification Body.
- 4.2 The Certification Body reserves the right to publish a list of the Certificates.

#### **5 Obligations and Responsibility**

##### **5.1 Obligations and responsibility of the Certification Body**

The Certification Body undertakes to treat all information made accessible to it with respect to the Client's company as confidential and to assess it only for the agreed purpose. Documents of the company will not be passed on to third parties. Excluded from this provision is the detailed report to the arbitration body in the case of a dispute. The Client may release the Certification Body from its obligation of secrecy.

The Certification Body shall be liable under statutory provisions towards the Client or third parties only in the case of wilful action or gross negligence. Any other claims are excluded.

If the QA system is modified or updated, the Certification Body will review the planned changes and decide whether a new audit is necessary for the modified QA system. It will notify the client of its decision. The notification will contain the results of the review and the reasons for the decision.

##### **5.2 Obligations and responsibility of the Client**

The Client shall make available to the Certification Body the documents which describe the quality assurance system (for further use or examination purposes) and shall grant the auditors access to the relevant departments in the company. The Client also undertakes to proceed in accordance with the certified quality assurance system.

The Client shall notify the Certification Body of planned updates in the quality assurance system.

#### **6 Violation of the Testing and Certification Regulations**

The Certification Body shall be entitled to demand a contractual penalty of up to EUR 5,000 in the case of non-compliance with the Testing and Certification Regulations and especially if the Notified Body's identification number is used illegally.

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The Notified Body's identification number shall also be deemed to have been used illegally if products bearing a mark are offered for sale or placed on the market before the Certificate is issued or if inadmissible advertising is conducted.



## **7 Coming into Force and Amendment of the Testing and Certification Regulations**

- 7.1 The Testing and Certification Regulations shall come into force as from 01.08.2002.
- 7.2 When new Testing and Certification Regulations are drawn up, the present Regulations shall cease to be valid after a transitional period of 6 months.
- 7.3 As required the Client shall be notified when new Testing and Certification Regulations come into force or the present ones become ineffective. This shall normally be done in conjunction with the testing activity following the date the new Testing and Certification Regulations come into force.

## **8 Complaints / Place of Jurisdiction**

The Client may lodge complaints against decisions of the Certification Body. The complaints shall be submitted to the Head of the Certification Body and handled in each case by the superior body against which the complaint is lodged.

The place of jurisdiction for both parties to the contract shall be Munich.