



Testing and Certification Regulations

TÜV SÜD Group

Scope:

These Testing and Certification Regulations apply to the TÜV SÜD Group.

Specifically for the following business units/companies:

- TÜV SÜD Industrie Service GmbH
- TÜV SÜD Management Service GmbH
- TÜV SÜD Product Service GmbH
- NavCert GmbH

Hereinafter referred to as TSC (TÜV SÜD Company).

The Testing and Certification Regulations apply to:

- the testing and certification of products
- the testing and certification of services (hereinafter referred to as products)
- the testing and certification of projects (hereinafter referred to as products)
- the auditing and certification of management systems (hereinafter referred to as system)

These Testing and Certification Regulations shall become effective on May 1, 2008 and remain valid until a new version is issued.

In case of doubt, the original german version shall be authoritative.



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A) General terms and conditions

(Parts B and C include special provisions which amend, replace or cancel paragraphs included in part A, where appropriate)

1. General

- 1.1 These Testing and Certification Regulations apply to tests, audits, conformity assessment procedures as per EC directives and certification carried out by TSC. The services offered by TSC also include information on normative requirements or approval procedures.
- 1.2 With receipt of the first certificate, the client automatically becomes a TÜV SÜD certification-system partner and remains so for as long as at least one certificate is valid. Apart from the above, certificates do not become valid until all TSC requirements in connection with the test/audit and product/system certification have been satisfied.
- 1.3 With each order the client acknowledges the validity of the current version of the General Terms and Conditions of Business, agreed fees and/or schedules of fees and these Testing and Certification Regulations. Existing contractual relationships are governed by the respectively valid versions of these documents. Prior to placing an order, the client shall inform TSC whether the product or system to be tested/audited has already been audited/tested in a similar way by another organization. Up-to-date versions of the General Terms and Conditions of Business, the Price List and Testing and Certification Regulations can be accessed on the Internet under www.tuev-sued.de.
- 1.4 The Certification Body evaluates the documents submitted by the testers/auditors. It decides whether a certificate is to be issued and handles disagreements concerning certification via the complaint procedure.
- 1.5 Certificates, certificates of conformity, test certificates based on EC directives relate to the version of the relevant directive valid on the date of issue of the certificate. Such certificates do not entitle the holder to use a TÜV SÜD certification mark. Any CE marking that may prove necessary falls under the responsibility of the persons indicated in the relevant Directive.
- 1.6 Auditors/representatives of the respective accreditation bodies are entitled to participate in TSC witness audits on the business premises of the client/manufacturer or his/her subcontractor.
- 1.7 TSC also provides reports as computer documents. In this case, the hard copy of the test/audit report represents the legally binding document.



2. Certificate expiry or withdrawal

2.1 A certificate expires if and when

2.1.1 the indicated period of validity expires;

2.1.2 the certificate holder terminates the certificate or his/her membership in the certification system at the end of the year by giving written notice by October 31 at the latest (in the case of system certificates: at least 3 months prior to certificate expiry);

2.1.3 the certificate holder objects in writing to amendments to the General Terms and Conditions of Business, these Testing and Certification Regulations or the Price List within 6 weeks after such amendments have come into effect or within 6 weeks after the certificate holder has had the possibility of taking note of them;

2.1.4 proceedings are opened under the Insolvency Code with regard to the assets of the certificate holder or an application for the opening of such proceedings is refused for lack of assets;

2.1.5 the certificate holder discontinues his/her business operations;

2.1.6 the legal requirements, the requirements of an accreditation body or the codes of practice on which the certificate is based change, unless the certificate holder demonstrates, within a certain defined period, through re-testing or re-auditing carried out by TÜV SÜD at the certificate holder's expense that the product or system is in line with the new codes of practice;

2.1.7 the underlying (basic) certificate becomes invalid.

2.1.8 the certificate holder is obliged to withdraw the product/certified service from the market.

2.2 The Certification Body may withdraw a certificate without notice or declare it invalid if

2.2.1 further use of a certification mark/certificate is no longer justified, i.e. no longer meaningful within the market context or is prohibited by law; in such cases, TSC will provide an alternative mark, if possible;

2.2.2 misleading or unauthorized advertising is conducted, in particular, specifically in connection with certification marks or certificates, or certification marks or certificates are misused, or legal requirements not met when a product is marketed;



- 2.2.3 the certificate holder, despite receiving reminders to that effect, fails to pay outstanding invoices to TSC. Failure to make partial payments may also lead to withdrawal of all certificates;
- 2.2.4 the certificate holder files a petition for the initiation of insolvency proceedings, third parties initiate compulsory execution proceedings relating to the certificate holder's rights arising from the certificate. The certificate holder shall notify TSC immediately of such measures;
- 2.2.5 the certificate holder violates these Testing and Certification Regulations, unless such violation is only due to negligence or insignificant acts.
- 2.3 In addition, the above reasons also entitle the Certification Body to restrict, revoke or suspend system certificates for a certain period.
- 2.4 The Certification Body is entitled to publish details of the withdrawal, expiry, declaration of invalidity, restriction and suspension of a certificate; continued advertising or other use of the certificate/mark or the name of TSC is prohibited in all such cases. A certificate that has been withdrawn has expired or has been declared invalid shall be returned to the Certification Body and/or destroyed upon the Certification Body's written request. License fees paid in advance shall not be reimbursed; fees that have not yet been paid are fully payable in such cases.
- 2.5 Apart from cases of willful intention and gross negligence, TSC shall not be liable for any disadvantages arising for the client from non-issue, withdrawal, expiry, restriction or suspension of a certificate.

3. Advertising; publishing of certificates, certification marks and test reports; information

- 3.1 A certificate or mark referring to a management system may only be used to promote the system concerned. A product certificate (in as far as a mark is approved) or a product mark may only be used to promote the certified product.

Product-related advertising using a TSC mark is not permissible in cases where a mere certificate of conformity or management system certificate has been issued. In the non-regulated area, TSC certification marks document voluntary certification, which is identified accordingly.

The certificate holder assumes full and complete responsibility for the use of his/her certificate, certification mark or test report. Specifically, when promoting a product which has been voluntarily tested, all advertising must indicate this voluntary aspect as well as the standard or entity that has issued the standard.



Test/audit reports prepared by TSC may only be quoted with their exact and complete wording, giving the date of issue. Use of the test report prepared by TSC or the name of TSC for advertising purposes is subject to written approval. The size of certification marks and company logos may only be changed, if the resultant shape is geometrically similar.

- 3.2 TSC is entitled to publish the names of certificate holders, tested products and audited management systems and the like for consumer information and advertising purposes.

4. Retention of test samples and documentation

As far as clients are in possession of test samples and pertinent documentation, they must retain them for a period of 10 years after expiry of the certificate or marketing approval.

System certification documentation shall be retained for the term of validity of the certificate plus a minimum of 3 years.

All other legal provisions going beyond the above shall remain unaffected.

Claims for damages against TÜV SÜD or TSC shall be excluded, in particular if the client fails or is unable to provide a test sample/document returned to or retained by him in an unchanged condition.

5. Violation of Testing and Certification Regulations

TSC is entitled to claim payment of a contractual penalty of up to EUR 250.000 in the case of culpable violations of these Testing and Certification Regulations by the certificate holder. This applies more specifically if a product labeled with the certification mark is offered for sale or marketed prior to the issue of the certificate, if unauthorized advertising takes place or if a certificate or certification mark is misused.

The certificate holder is liable for costs charged to TSC by an accreditation body or costs directly incurred by the Certification Body or the test laboratory in connection with activities resulting from culpable violation on the part of the certificate holder, in particular violation of these Testing and Certification Regulations. This applies in particular if TSC's activities were the result of instructions issued by a supervisory authority or similar instructions and if such instructions proved to be justified.



B1) Terms and conditions for product testing and certification

1. Testing

- 1.1 The client shall submit a test order to TSC and supply the required test samples and documentation free of charge. TSC shall, at its own discretion, carry out the tests either in their own test laboratory or externally, and prepare a summary report.
- 1.2 Following the test, TSC shall dispose of the test samples for a flat-rate charge per sample or, at the client's express request, return them to the latter at his/her expense. TSC will not store test samples but may require the client to do so. If a test is interrupted for more than one month, TSC shall also return the sample or store it for a flat-rate charge for each month or part-month that elapses up to continuation of the test.
- 1.3 TSC is entitled to make the test file, if necessary along with the test sample, accessible to any authorized (e.g. accreditation) bodies. Any agreement to the contrary is invalid.
- 1.4 TSC shall not assume any liability if test samples are mislaid or damaged either in the course of testing or due to burglary, theft, lightning, fire, water etc..
- 1.5 TSC does not offer consultancy services for product design and development or system establishment.

2. Certification

After successful completion of product testing, TSC will award a certificate either with or without authorization to use a certification mark. If product certification does not include manufacturing surveillance, the product must not be labeled with a certification mark. The following regulations apply to product certification that includes the issue of a certification mark:

- 2.1 In addition to a positive product testing result, initial inspection of the manufacturing site must not raise any objections. Continued use of the certification mark will depend on regular inspections (follow-up service, see below).
- 2.2 Certificate holders may use the marks defined in the certificate. The certificate shall be valid only for the certificate holder and for the products and manufacturing sites listed in the certificate. The certificate holder must not transfer the certificate to third parties nor may third parties use the certificate or certification mark.



Should a product certificate expire or become invalid, the products listed on the certificate may no longer be marketed using the certification mark. Holders of withdrawn or expired certificates must either remove the certification mark from all accessible products or destroy the products and enable the Certification Body to verify these measures.

2.3 TSC certification marks may only be used for products that conform to the successfully tested type and the specifications included in the test report or supplementary agreements. The required documents (e.g. certificate of conformity, operating and assembly instructions) are to be enclosed with the product in the appropriate language of the country of destination.

2.4 Additional characteristics for individual certification marks

2.4.1 The modular TÜV SÜD mark allows various fields of testing to be covered by a single certification mark.

If a product is manufactured at several manufacturing sites with different qualifications, the qualification level of the respective manufacturing site may only be used if different designations are given to the models. Otherwise only the level of qualification which applies to all manufacturing sites may be used for advertising.

2.4.2 Certificates based on the product safety law (GS mark) have been limited to a period of 5 years, the validity can be extended.

2.5 Holders of certification marks must constantly monitor the manufacturing of products that have been awarded the mark to ensure conformance to test requirements. They must also carry out the specified tests and inspections, document any complaints in connection with certified products and the correction of nonconformances. The Certification Body must be immediately notified of any changes made to the products after certification. If the certificate concerned is to be maintained, the Certification Body may request the manufacturer to prove observance of codes of practice or may require an additional test to be carried out by the test laboratory.

2.6 As a minimum requirement, every product must be identified by a label clearly indicating the name of the manufacturer or importer and type designation, so that the identicalness of the approved type with the serially manufactured product can be ascertained. If a product submitted for testing does not satisfy the test requirements and if products corresponding to this test sample have already been distributed for sale, the modified test sample submitted for testing may only be certified if it bears another type designation.

2.7 Inspection of manufacturing sites in the case of certificates including authorization to use a certification mark (follow-up service), market observation.



2.7.1 In order to ensure maintenance of the product characteristics on which a certificate has been based, the Certification Body will regularly inspect manufacturing and testing facilities as well as quality assurance measures at the certificate holder's expense. Alternatively, for certification including the right to use a mark, random checks based on module C of the Council Resolution 93/465/EEC may be agreed prior to issue of the certificate. If the system of the respective manufacturing site has been certified by TÜV SÜD, the follow-up service may also be incorporated in the surveillance/repeat audit pertaining to the system.

To ensure production quality, additional pre-shipment inspection may be agreed, in which samples from the products to be shipped are checked for conformance to the tested and certified type.

2.7.2 The certificate holder shall ensure that the Certification Body can inspect the manufacturing and business premises and warehouses listed on the certificate (in the case of certificate holders abroad, also the warehouses of their German representatives and branches; in the case of importers, this also applies to warehouses) at any time during standard business hours and without prior notice. Certificate holders must also ensure that the Certification Body can take the required number of samples of certified products free of charge for testing purposes, even if the manufacturing and business premises are not their own.

2.7.3 The certificate holder shall immediately inform the Certification Body of any relocation of a manufacturing plant, transfers of manufacturing plants to another company/company owner or changes in the manufacturing process that may affect the certified product. In these and other special cases, the Certification Body may demand that the product is identified by a predefined inspection mark, in addition to the certification mark, so that products from different periods of manufacturing can be identified. Should there be a change in the manufacturing site, TSC must inspect and approve the new production facility before the products manufactured there can be labeled with a certification mark.

2.7.4 The Certification Body is entitled to take samples of products identified by a certification mark from the market for testing purposes. If the certificate requirements are not satisfied, e.g. because of unauthorized modifications that have resulted or may result in certificate withdrawal, the certificate holder shall bear the costs of re-testing/inspecting the product and/or the manufacturing site.

2.7.5 The certificate holder shall inform the Certification Body immediately of any damage or other events arising from certified products.



- 2.8 Further certificates may be issued in addition to an existing (basic) certificate, if, for example, the product is to be launched on the market under another name than that appearing on the (basic) certificate, or if – with the approval of the holder of the (basic) certificate – a certificate relating to this product is to be issued to a third party. The content and validity of such certificate shall be dependent on the (basic) certificate.
- 2.9 The Certification Body may withdraw a certificate without notice or declare it invalid, if
- 2.9.1 defects or nonconformances are detected in the products or in quality assurance, products do not conform to the certified samples or key prerequisites pertaining to the certified product/system are not or no longer fulfilled;
- 2.9.2 a product is not or no longer covered by the document on which evaluation was based (e.g. directive, standard) or have been inadvertently assigned to the wrong basis of evaluation or to an incorrect class as per the relevant EC directive on which testing is to be based;
- 2.9.3 a product no longer satisfies basic requirements, thus exposing users, operators or third parties to considerable risks, or fails to fulfill its purpose as defined by the manufacturer, and such defects are not corrected within a reasonable period of time;
- 2.9.4 Inspection of production, testing and storage facilities or product testing by the test lab are not possible or the products themselves not made available within the specified time. This also applies if follow-up services or surveillance audits cannot be carried out within 4 weeks despite a written request to this effect or if nonconformances are not eliminated within the agreed period through appropriate corrective action;



B2) Terms and conditions for management system auditing and certification

1. General

TSC carries out management system (hereinafter referred to as "system") auditing and certification in the regulated area, incl. EU directives.

The requirements of accreditation bodies will be fulfilled, especially in the regulated area including EC directives. This means a. a., that for a certification of a system in the area of product based EC directives the audited and certified company shall have at least one type examination or design-dossier based on the specific EC directive.

The product related system certification makes sure, that the product will be produced continuous and unchanged against the certified type.

The terms and conditions outlined below satisfy the requirements of the relevant laws and standards other the associated Guidelines.

TSC does not offer consultancy services relating to management system establishment.

2. Preliminary system assessment, pre-audit

On request, TSC offers the following services which can also be independent of a certification procedure:

- 2.1 Based on management system documentation, improvement potential in the system description is pointed out in a preliminary assessment as compared with the requirements of the respective legal basis or standard. The client receives a report on the results of the assessment.
- 2.2 The aim of the pre-audit, the on-site and total scope of which is defined jointly with the client, is to draw attention to weak points in the system. In general, a pre-audit is carried out by a single auditor, who should be a member of the audit team that will perform the (certification) audit. The auditor informs the client of the results in a closing meeting; if requested, TSC prepares a pre-audit report. Only one (1) pre-audit may be carried out.



3. Certification procedure

3.1 Preparation

3.1.1 Opening meeting

At the client's request, the following points can be discussed in advance:

- objective, benefits and prerequisites of certification
- steps in the certification procedure with respect to contents and time
- legal basis, standard governing the audit, audit scope
- cost estimate

3.1.2 Contract: preparation for certification audit

Usually, the auditing and certification contract has a 3-year term of validity (certain Directives may define other terms of validity). Contract validity will be extended automatically by another 3 years, unless the contract is terminated in writing by the client or TSC observing a 3-month period of notice to contract expiry.

After the client has accepted in writing the quotation submitted by TSC, the client's management appoints an Audit Representative, who is responsible for the certification procedure; TSC informs the client of the auditors assigned to the audit (audit team or lead auditor). Requirements outlined in the applicable standards and regulations pertaining to unauthorized consultancy on the part of auditors are observed. The client has the right to reject auditors. In addition and in as far as legal regulations do not stand in the way, clients are entitled to be informed of the certification procedures in which the auditors have participated over the last two years.

If external auditors are employed, the client will be sent any information necessary for assessment of the auditor's impartiality and exclusion of competition.

3.2 Certification audit

(An initial certification audit is carried out in (2) stages (stage 1 and stage 2 audit).)

3.2.1 Review and evaluation of management system documents / stage 1 audit

The client provides the Certification Body with all management system documentation concerning his/her system (manual and, if necessary, further documents such as documented procedures, work and test instructions) for review and assessment of compliance with the applicable Directives and Standards.



The Certification Body reviews the management system documentation – to the extent required also on site – the site-specific conditions of the client, the client's status and understanding of standard requirements/statutory and legal aspects and their specific implementation in management system documentation.

Based on the results of the stage 1 audit, the Certification Body assesses whether the level of management system implementation is sufficient for conducting a stage 2 audit and plans the process and priorities of the stage 2 audit. The details of the stage 2 audit will be agreed with the client.

The Certification Body documents the findings of the stage 1 audit and notifies the client thereof, including information about areas of concern which may be classified as non-conformities in the stage 2 audit.

The interval agreed between the stage 1 and stage 2 audit, will give the client sufficient time to eliminate any identified areas of concern (weaknesses).

3.2.2 On-site audit certification / stage 2 audit

Prior to the stage 2 audit, the client receives the audit plan, which has been coordinated with him/her, for information purposes. During the audit, clients demonstrate practical implementation of their documented procedures, while the auditors check and evaluate system effectiveness on the basis of the agreed standard or legal provisions. Clients grant auditors access to the respective units of the company and allow them to review all system-relevant records.

After audit completion, TSC informs the client of the audit result in a closing meeting and an audit report. Nonconformance reports countersigned by the Audit Representative include the required corrective action. In the case of nonconformance one (1) re-audit is possible; the costs being based on the time needed (current daily rate).

If nonconformances become evident during the audit that are so serious that certificate award appears unrealistic even after reasonable corrective action, TSC informs the client of the termination of the certification audit and recommends that the audit should be continued as a pre-audit. In such cases, TSC will charge for the costs incurred up to audit termination (including report).

3.3 Certification

If all requirements of the applicable standard are satisfied and all legal and official regulations observed, the Certification Body will issue a certificate, generally with a three (3)-year period of validity from the date of the certification decision.



3.4 Surveillance audit

Unless specific regulations, standards or EC resolutions require other periods of validity, a certificate is valid for three years, provided that annual surveillance audits are carried out at the company with positive results. These surveillance audits must be carried out within twelve months of the last day of the stage 2 audit at the latest, provided that no other date has been determined for specific regulations. In justified cases, the TSC shall be entitled to carry out audits at short notice (ad-hoc audits) at the expense of the certificate holder. The Certification Body specifies the conditions under which these audits announced at short notice will be carried out, and communicates them to the certified client. To prepare for the surveillance audit, the valid management manual and a list of all modifications that have been effected must be submitted to the auditor. In the surveillance audit, the auditor checks selected management system elements by sampling and prepares a report.

3.5 Further surveillance activities

- Further surveillance activities may include:
- Enquiries regarding certification aspects addressed by the Certification Body to certified clients
- Assessment of client information about their operations (e.g. advertising materials, web pages),
- Requests addressed to clients to provide documents and records (on paper or electronic media), and
- Other means of monitoring the performance of the certified client.

3.6 Re-certification audit

If a re-certification audit is carried out in the company well in advance of certificate expiry, certificate validity may be extended for a further period. In such cases, overall system effectiveness is checked by means of random sampling. To prepare for the audit, the valid management manual and a list of all modifications that have been effected must be submitted to the auditor/audit team.

In cases involving major changes to the system, a stage 1 audit may first be required.

4. Supplementary contractual terms

- ### 4.1
- As far as possible, the Certification Body is obliged to see that clients use certification correctly in advertising. The Certification Body reviews and evaluates complaints by third parties and changes in the client's organization that come to its knowledge. It informs the certificate holder of substantial changes to the certification and surveillance procedure as well as of any changes in the standards which are relevant for certification.



- 4.2 The client shall satisfy all reasonable requirements pertaining to certification and supply all reasonable information required for auditing.

Certificate holders shall inform the Certification Body in writing of all important changes in their systems and about modifications in company structure/organization that affect the management system. In addition, certificate holders shall document internal and external complaints relating to their management systems as well as implemented corrective action and provide such information during the audit. These changes may include, for example:

- legal or organizational status;
- commercial status or ownership;
- organization and/or management
- contact address and sites
- scope of operations under the certified management system, and
- major changes to the management system and processes

Despite the fact that TSC generally informs the certificate holder of due surveillance/repeat audits, certificate holders must request such audits at least three months before they become due within the 12-month-cycle in order to maintain the validity of a certificate.

- 4.3 In cases involving changes in the standards, regulations or codes of practice underlying certification the existing contractual documentation will be amended accordingly.

The number of auditor days cited in the quotation shall apply subject to the approval of the Certification Body.

- 4.4 Integrated management systems must allow specific aspects of individual systems to be identified.

- 4.5 The Certification Body shall make information about issued or withdrawn certificates available to the public.

- 4.6 Clients

- 4.6.1 shall comply with the requirements of the Certification Body with respect to referencing their certification status in communication media (e.g. Internet, brochures, advertising materials or other documents).

- 4.6.2 upon certificate suspension or withdrawal, shall discontinue use of their advertising materials containing reference to their certification status, in line with the instructions of the Certification Body



- 4.6.3 shall amend all their advertising materials if their scopes of certification have been reduced
- 4.6.4 shall not make or permit any misleading statements about their certifications
- 4.6.5 shall not use any certification documentation or parts thereof in a misleading manner or permit such use
- 4.6.6 shall not permit any reference to their management system certification which may imply product (including services) or process certification by the Certification Body.
- 4.6.7 shall not imply that certification applies to activities outside the certification scope.
- 4.6.8 shall not use their certifications in a manner discrediting the Certification Body and/or the certification scheme or jeopardizing public confidence
- 4.7 Objections shall be addressed directly to the Certification Bodies of the respective TSC. The Certification Bodies maintain documented procedures governing the handling of objections. A description of the procedure is made available to the public.
- 4.8 Complaints shall be addressed directly to the Certification Bodies of the TSC in question. The Certification Bodies maintain documented procedures governing Complaints Management. A description of these procedures is made available to the public.

The Certification Body will forward complaints about certified clients within an appropriate period of time to the certified clients in question.



C1) General and special terms and conditions for the field of medical devices, TÜV Product Service (TÜV PS)

(These terms and conditions complete or amend parts A and B as follows:)

Part A

1. General

- 1.2 A1.2 is amended by the following addendum: If a certificate is awarded subject to certain requirements, the certificate holder undertakes to satisfy these requirements within the defined deadlines.
- 1.6 A1.6 is amended by the following addendum: For the purpose of "observed audits" and "witness tests", the client shall grant ZLG and ZLS employees or representatives access to the operating facilities of the manufacturer and his/her subcontractor.
- 1.8 The following paragraph is inserted after A1.7: The customer undertakes to notify TÜV PS without delay of all incidents concerning a product with the identification number CE 0123 that are associated with the design and/or production of the product in question.

2. Paragraph A2 will have the following heading: Expiry or withdrawal of certificates

- 2.1 A certificate expires if and when
- 2.1.2 A 2.1.2 is amended as follows: the certificate holder terminates the certificate. Unless otherwise agreed with the TÜV PS Certification Body, the certificate will expire with immediate effect; TÜV PS shall be entitled to bill any costs incurred for imminent surveillance or auditing/testing of the certified system or product.
- 2.2 A2.2 is amended as follows: The Certification Body shall be entitled to restrict, suspend or withdraw a certificate, taking Section C 2.7 into account. This applies in particular, if:
- 2.2.3 A2.2.3 is amended as follows: the certificate holder fails to pay TÜV PS receivables within 4 weeks, despite reminders to this effect. Withdrawal of all certificates is also possible in cases involving partial default of payment.

The following text shall be inserted after A2.2.5:

- 2.2.6 a "competent authority" or court of law in a member state of the European Economic Area determines that a certificate is wrongfully issued or subsequently classifies a certificate as wrongfully issued or ascertains that the basis of certificate issue is lacking or no longer applicable;



- 2.2.7 co-operation based on mutual trust appears no longer possible on the basis of the conduct of the certificate holder, his/her employees or representatives; in this case, a 3-month period of notice must be observed prior to certificate withdrawal;
- 2.2.8 the certificate holder makes untrue statements to TÜV PS or withholds important facts from TÜV PS;
- 2.2.9 the notification is withdrawn; TÜV PS reserves the right to terminate the certificates affected thereby, especially if surveillance by the Notified Body is no longer possible.
- 2.3 A2.3 is amended as follows: Additionally, certificates may be restricted, revoked, suspended or made subject to certain requirements in the above cases.
- 2.4 A2.4 is amended as follows: Certificate expiries, withdrawals, restrictions and suspensions may be published; in such cases, continued advertising or other use of the TÜV PS certificate/mark or TÜV PS' name shall be prohibited. If certificates are governed by the Directives on active implantable medical devices, medical devices or in-vitro diagnostic medical devices, the relevant products must no longer be sold under ID No. 0123 with immediate effect, unless the Certification Body has given its written permission to do so for a certain defined period. An expired or withdrawn certificate must be returned to the Certification Body. Licensing fees paid in advance will not be reimbursed; in the above case, all outstanding fees must be paid in full.

The following paragraphs shall be inserted after A2.5:

- 2.6 When taking decisions concerning "certificate restrictions, suspensions or withdrawals", TÜV PS will apply the principle of proportionality
- 2.7 Unless a hearing is impossible in view of the urgency of a decision or fails to take place within 14 days after written notification, the certificate holder must be heard, before a decision is made concerning a measure as per 2.2.
- 2.8 TÜV PS adheres to its notification duties as per MPG (Medical Devices Act) § 18 (3).

4. Retention of test samples and documentation

A4 is amended as follows: Clients must retain any test samples and pertinent documents in their possession for a period of 10 years after certificate or marketing-approval expiry. Documents pertaining to the certified system or product must be retained for at least 5 years after expiry of certification. Any legal regulations exceeding the above requirements (e.g. for certificates as per EC directives) shall remain unaffected by the above provision. TÜV PS may, in particular, not be held liable damage or loss, if the client fails or proves unable



to provide the test sample/document returned to or retained by him/her in its original state.



Part B

Part B 1.1. is amended as follows:

- 1.1 The client shall commission TÜV PS to carry out the required tests and shall provide the latter with necessary test samples plus pertinent documentation to TÜV PS free of charge. TÜV PS will carry out the tests in-house in its laboratory or, after approval by the client, externally, and prepare a test report.

N.B.: The term "certificate" is to be replaced by the term "approval".

Replaces B2 / 3.1.2 (3)

If external auditors are employed by TÜV PS, the customer shall have the right to obtain all information necessary for assessment of their impartiality and exclusion of competition.