Testing and Certification Regulations

TÜV SÜD Group

Scope:

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

Specifically for the following companies:

Company	**Web site**
TÜV SÜD Automotive GmbH	www.tuev-sued.de
TÜV SÜD America Inc.	www.tuvam.com/tools/custforms.cfm
TÜV SÜD Czech	www.tuv-sud.cz
TÜV SÜD Industrie Service GmbH	www.tuev-sued.de
TÜV SÜD Management Service GmbH	www.tuev-sued.de
TÜV SÜD Product Service GmbH	www.tuev-sued.com\ps_regulations
TÜV SÜD PSB Pte Ltd.	www.tuv-sud-psb.sg
TÜV SÜD Rail GmbH	www.tuev-sued.de
NavCert GmbH	www.tuev-sued.de
BABT	www.babt.com

Hereinafter solely and jointly referred to as TSC (TÜV SÜD Company).

The Testing and Certification Regulations apply to:

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

These Testing and Certification Regulations shall replace previous versions and become effective on 1st July 2011 and remain valid until a new version is issued.

In case of doubt, the German version shall be authoritative for work related to Certification Bodies located in Germany. For all other Certification Bodies the version in English shall be authoritative.

These Testing and Certification Regulations apply under the legal system of the relevant Certification Body's location as appropriate for the requested service.

These Testing and Certification Regulations are formed of a number of sections; in general section A applies to all TSC; The remaining sections apply as appropriate and may amend, replace or declare regulations to be not applicable in other sections.

In the context of C-parts the references to Certification body or TSC shall be construed as references to the concerned certification body. If there are any conflicts between the respective C-part and other sections of this document the respective C-part shall take precedence.

Contents **Page**

A) General regulations

A-1. General

A-1.1 These Testing and Certification Regulations apply to tests, audits, conformity assessment procedures as per EC directives, or on basis of other appointments as well as all other certification activities carried out by TSC. The services offered by TSC also include information on normative requirements or approval procedures.

A-1.2 On issue 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. A certificate only becomes valid after all financial and technical requirements in connection with the test/audit and product/system certification have been fulfilled. If a certificate is awarded subject to certain requirements, the certificate holder undertakes to satisfy these requirements within the defined deadlines.

A-1.3 Prior to placing an order, the client shall inform TSC of the name and relevant activities of any other organization which has already tested/audited/certified or is in the process of testing/auditing/certifying the same product or system in a similar way. With each order the client agrees to comply with the current version of these Testing and Certification Regulations as terms of the contract. Existing contractual relationships are governed by the respectively valid versions of these Testing and Certification Regulations.

Up-to-date versions of these Testing and Certification Regulations can be accessed on the Internet as listed under the specific TSC on the table on page 1 or can be sent on request.

A-1.4 The Certification Body of the relevant TSC evaluates the documents submitted by the testers/auditors. It decides whether a certificate is to be issued and handles disagreements/appeals concerning certification via the appropriate procedure.

Appeals and Complaints shall be addressed directly to the Certification Bodies of the respective TSC. The Certification Bodies maintain documented procedures governing the handling of Objections and 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.

A-1.5 Certificates, certificates of conformity, test certificates based on EC Directives, standards or other criteria relate to the version of the relevant Directives, standards or other criteria valid on the date of issue of the certificate.

Unless otherwise agreed in writing, the Certification Body only issues a certificate or another attestation if the product or system fulfills all certification-relevant legal requirements, applicable standards, and other certification-relevant criteria at the time of its issuance.

The time of placing the order or conclusion of the contract is irrelevant in this regard.

The holder must at all times associate the certificate with any annexes issued with it. The certificate (and any duplicate certificates) is not transferable and shall remain the property of TSC.

Certificates only relating to EC-directives do not entitle the holder to use a TÜV SÜD certification mark. Any CE marking that may prove necessary falls solely under the responsibility of the persons indicated in the relevant Directive.

A-1.6 The client shall ensure that auditors/representatives of the respective authorities (e.g. regulatory appointment body, accreditation body or certification scheme owner) are entitled to participate in so called observed and witness audits on the business premises of the client/manufacturer and/or their subcontractor/supplier.

A-1.7 Where on-site activities (e. g. audits, inspections) conducted by TÜV SÜD personnel require personal protective equipment, TÜV SÜD and the client shall agree upon supply of such in advance of any visit.

A-1.8 If a hard copy of a test/audit report is produced in addition to a computer copy, the hard copy test/audit report represents the legally binding document.

A.-1.9 Each certificate is subject to the existence of a valid certification contract/order.

The certification contract/ order/ membership in the certification-system may be terminated in whole or in part: if the individual contractual regulations, the respective guidelines/rules/procedures, or the guidelines/regulations of the Certification Bodies or other respective authorities (e.g. regulatory appointment body, accreditation body or certification scheme owner) do not define other periods of notice.

I. by termination **without cause**

a. for system-certifications: with three (3) months notice to the next scheduled audit date (for the surveillance respectively the recertification audit) by the certificate holder or the TSC.

b. for product-certifications: with two (2) months notice to the end of the respective calendar year by the certificate holder or with one (1) year notice to the end of the respective calendar year by the TSC.

c. System Certificates based upon EC directives are handled by TSC following I.b.

II. by termination **for cause** at the terminating party´s choice with or without notice, in particular (but not only) in case the certificate issued on the basis of the certification contract/ order may be withdrawn, revoked or restricted according to the following regulations in paragraphs A-2.1 – A-2.3.

Terminations have to be made in writing.

If the validity of a certificate ends – for whatever reason – the underlying certification contract/ order with respect to such certificate ends accordingly at the same time.

In case where the holder's last remaining certificate is no longer active, the membership of the holder in the certification-system of TÜV SÜD is suspended.

Any outstanding fees are still due. Any costs incurred for imminent surveillance or auditing/testing of the certified system or product may still be billed.

The requirements of these Testing and Certification Regulations stay valid until three (3) years after the end of the certification contract/ order and/or in the case of expiration, revocation or withdrawal of a certificate the related part of the contract/order.

A-1.10 Should any individual provision of this Testing and Certification Regulations or any part of any provision be or become void or unenforceable, the validity of the remaining Testing and Certification Regulations hereof shall in no way be affected. In such case the void and/or unenforceable provisions shall be replaced by relative provisions coming as close as possible to the sense and spirit and purpose of the void and/or unenforceable provision.

A-2. Expiry, withdrawal, revocation, restriction or suspension of certificates

A-2.1 A certificate expires automatically or is deemed to be withdrawn if

A-2.1.1 the indicated period of validity expires;

A-2.1.2 the certificate holder becomes subject to bankruptcy laws or makes any arrangements with their creditors; or who has a receiver or administrator appointed for their business and the certificate holder does not inform in writing the relevant Certification Body within 4 weeks.

A-2.1.3 the certificate holder discontinues the relevant business operations;

A-2.1.4 the legal requirements, the requirements of respective authorities (e.g. regulatory appointment body, accreditation body or certification scheme owner) 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 requirements or the codes of practice;

A-2.1.5 the underlying (basic) certificate becomes invalid.

A-2.1.6 the certificate holder is obliged to withdraw the product/certified service from the market.

A-2.2 The Certification Body in the related TSC is entitled to withdraw or revoke a certificate at its own choice with or without notice if

A-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;

A-2.2.2 misleading or unauthorized advertising is conducted, 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; or such misuse is tolerated by the certificate holder;

A-2.2.3 the certificate holder fails to pay outstanding invoices within 4 weeks to TSC, despite receiving reminders to that effect. Failure to make partial payments may also lead to withdrawal of all certificates;

A-2.2.4 the certificate holder files for insolvency or similar proceedings or the opening of such proceeding is rejected for lack of assets;

A-2.2.5 the certificate holder violates these Testing and Certification Regulations and/or the related part of the business contract/order, unless such violation is due to isolated careless or insignificant acts.

TSC has the right but no obligation to give the certificate holder a respite to fix the violation;

A-2.2.6 the Certification Body forms the opinion that the certified product or system does not comply with the standard, or with any amended or new edition of the standard within the period of time allowed to the holder by the Certification Body to adapt the product or system, or that the holder has breached any of the conditions endorsed on the certificate;

A-2.2.7 the certificate holder makes untrue statements to TSC or withholds important facts from TSC relevant to the basis for the certification;

A-2.2.8 the certificate holder fails to comply with these Testing and Certification Regulations and/or a related part of the business contract/order (e.g. the relevant actual prices and fees) 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;

A-2.2.9 it comes out that the certificate holder did not fulfil the requirements for the certificate issue right from the start.

A-2.3 In addition to the reasons noted in the above cases (A-2.1 and A-2.2) certificates may with regards to time and content be restricted, or suspended.

A-2.4 The Certification Body of the related TSC is entitled to publish details of the expiry, withdrawal, revocation, 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 expired, has been withdrawn, has been revoked shall be immediately returned to the Certification Body and/or destroyed upon the Certification Body's written request. License fees paid in advance shall not be reimbursed; those not yet been paid shall be paid in full.

A-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, expiry, withdrawal, revocation, restriction or suspension of a certificate.

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

A-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 only a certificate of conformity or management system certificate has been issued. In the non-regulated area, TSC certification marks document optional certification, which is identified accordingly. The correct marking and related communication is not in the responsibility of TÜV SÜD.

The certificate holder assumes full and complete responsibility for the use and the legitimacy of all statements concerning the issued certificate, certification mark or test/audit report about a certified system/product as well as for the correct application/publicity by their customers.

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/audit report prepared by TSC or the name of TSC for advertising purposes is in any case subject to prior written approval.

A-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.

The Certification Body shall keep all other records about clients and certified products and systems confidential unless instructed to the contrary by a court or respective authority (e.g. regulatory appointment body, accreditation body or certification scheme owner). All employees of TSC and their agents are bound by confidentiality requirements to this effect.

A-3.3 Clients

A-3.3.1 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);

A-3.3.2 upon certificate suspension, expiry, revocation or withdrawal, shall discontinue use of their advertising materials containing reference to their certification status, in line with the instructions of the Certification Body;

A-3.3.3 shall amend all their advertising materials if their scopes of certification have been reduced;

A-3.3.4 shall not make or permit any misleading statements about their certifications;

A-3.3.5 shall not use any certification documentation or parts thereof in a misleading manner or permit such use;

A-3.3.6 shall not make or permit any reference to their management system certification which may imply product (including services) or process certification by the Certification Body (note: this includes laboratory test, calibration or inspection reports etc.);

A-3.3.7 shall not make or permit an implication that certification applies to activities outside the certification scope;

A-3.3.8 shall not use or permit use of their certifications in a manner discrediting the Certification Body and/or the certification scheme or jeopardizing public confidence.

A-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 ten (10) years after expiry of the certificate or after the last product is placed on the market area covered by the certificate, whichever is longer.

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

A-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 respective authorities (e.g. regulatory appointment body, accreditation body or certification scheme owner) or costs directly incurred by the Certification Body or the test laboratory 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) Special Regulations for product testing and certification

B1-1. Testing

B1-1.1 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.

B1-1.2 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 their 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 may 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.

B1-1.3 TSC is entitled to make the test file, if necessary along with the test sample, accessible to respective authorities (e.g. regulatory appointment body, accreditation body or certification scheme owner). Any agreement to the contrary is invalid.

B1-1.4 TSC shall not assume any liability if test samples are lost or damaged either in the course of testing or due to burglary, theft, lightning, fire, water etc..

B1-1.5 TSC does not offer consultancy services for product design and development or system establishment.

B1-2. 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:

B1-2.1 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).

B1-2.2 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.

Should a product certificate expire, has been withdrawn or has been revoked, the products listed on the certificate may no longer be marketed using the certification mark. Holders of withdrawn, revoked 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.

B1-2.3 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.

B1-2.4 Additional characteristics for individual certification marks

B1-2.4.1 If a product is manufactured at several manufacturing sites with different qualifications (e.g. with or without ISO 9001), 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.

B1-2.4.2 Certificates based on the product safety law (GS mark) have been limited to a period of 5 years, the validity can be extended.

B1-2.5 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 nonconformities. 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 compliance with standards and/or codes of practice or may require an additional test to be carried out by a qualified test laboratory.

B1-2.6 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 or have been subject of a certification mark misuse, the modified test sample may only be certified if it bears another type designation.

B1-2.7 Inspection of manufacturing sites in the case of certificates including authorization to use a certification mark (follow-up service), market observation:

B1-2.7.1 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/re-certification 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.

B1-2.7.2 The certificate holder shall ensure that the Certification Body can inspect the manufacturing and business premises listed on the certificate and the relevant warehouses of their representatives, importers and branches 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.

B1-2.7.3 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. The holder shall inform the Certification Body of any changes to the holder details.

B1-2.7.4 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.

B1-2.7.5 The certificate holder shall inform the Certification Body immediately of any damage or other events arising from certified products.

B1-2.8 In addition to an existing (basic) certificate further certificates may be issued

a. for the same (basic) certificate holder if he wants to certify a product under another name than that appearing on the (basic) certificate.
b. for a certificate holder different from the (basic) certificate holder, if he also wants to certify a product under another or same name than that appearing on the (basic) certificate. Prerequisite is the approval of the (basic) certificate holder and his confirmation of equality of structure of the product with the one from the (basic) certificate.

The content and validity of such certificates shall be dependent on the (basic) certificate.

B1-2.9 The Certification Body may in addition to the cases listed in A-2.2 also withdraw or revoke a certificate at its own choice with or without notice, if

B1-2.9.1 defects or nonconformities are detected in the products or in quality assurance systems, products do not conform to the certified samples or key prerequisites pertaining to the certified product/system are not or no longer fulfilled;

B1-2.9.2 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 based;

B1-2.9.3 a product no longer satisfies essential requirements of the corresponding directives, standards or other criteria, 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;

B1-2.9.4 inspection of production, testing and storage facilities or product testing by the test lab is 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 a timeframe of 4 weeks (if not otherwise specified by the Certification Body) despite a written request to this effect or if nonconformities are not eliminated within the agreed period through appropriate corrective action;

B2) Special Regulations for management system auditing and certification

B2-1. General

TSC carries out management system (hereinafter referred to as "system“) auditing and certification also in the regulated area e.g. EU directives.

The TSC does not perform consultancy services relating to management system establishment.

B2-2. Preliminary system assessment, pre-audit

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

B2-2.1 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.

B2-2.2 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. 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.

B2-3. Certification procedure

B2-3.1 Preparation

B2-3.1.1 Informational 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

B2-3.1.2 Preparation for certification audit

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 as e.g. obligations to observe confidentiality do not stand in the way, clients can request appropriate background information on each member of the audit team.

B2-3.2 Certification audit

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

The client shall ensure that appropriate staff are available to answer questions; clients grant auditors access to the respective units of the company and allow them to review all system-relevant records.

B2-3.2.1 Review and evaluation of management system documents/ stage 1 audit

Clients provide the Certification Body with all management system documentation concerning their systems (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. If the system is already certified by another body to the same or an appropriate standard then the client shall include a copy of the certificate with any scoping information, and details of the findings of the previous audit.

The Certification Body reviews the management system documentation – to the extent required which may include an on site audit – the site-specific conditions of the client, the client's status and understanding of appropriate standard, statutory and legal requirements 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).

B2-3.2.2 On-site certification audit / stage 2 audit

Prior to the stage 2 audit, clients receive the audit plan, which has been coordinated with them, 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 legal provisions, standards or other criteria.

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

If nonconformities 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).

B2-3.3 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.

B2-3.4 Period of validity of certificate / Surveillance audit

Unless specific directives/ schemes, regulations, standards or individual arrangement in the certification contract/order, require other periods of validity, a certificate is in principle valid for three (3) years after issue/decision of the certificate, provided that regularly required (normally annual) surveillance audits are carried out at the company with positive results.

The first surveillance audit 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 Certification Body upon request. In the surveillance audit, the auditor checks selected management system elements/processes to maintain confidence that the management system continues to fulfill the requirements. The auditor will prepare a report.

B2-3.5 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.

B2-3.6 Re-certification audit

If a successful re-certification audit is carried out in the company well in advance of certificate expiry, a renewal certificate may be issued. 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.

B2-4. Supplementary contractual terms

B2-4.1 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, issues causing concern or 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.

B2-4.2 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 immediately but not later than within one (1) month in writing of all relevant changes in their systems and about modifications in company structure/organization that affect the compliance of the management system, or any other significant events affecting compliance with the requirements for certification.

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 but are not limited to, for example:

- legal or organizational status;
- commercial status or ownership;
- organization and/or management (including individual changes in key personnel)
- contact address and the addresses of sites
- scope of operations under the certified management system, and
- major changes to the management system and processes including planned changes if requested by the Certification Body or scheme.

The Certification Body will review the change and advise the certificate holder of any action required to continue the certification.

Despite the fact that TSC normally informs the certificate holder of due surveillance/re-certification audits, it is also in the responsibility of the certificate holders to request such audits at least three (3) months before they become due within the 12-month-cycle in order to maintain the validity of a certificate.

B2-4.3 changes in the standards, underlying codes of practise or other regulations shall apply – under consideration of transition periods – as binding contractual basis. The number of auditor days cited in the quotation shall apply subject to the approval of the Certification Body.

B2-4.4 Integrated management systems must allow specific aspects of individual systems to be identified.

B2-4.5 The Certification Body may make information about issued, revoked or withdrawn certificates available to the public.

C1) **Special Regulations and conditions for the field of medical devices, TÜV SÜD Product Service GmbH (TÜV PS)**

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

C1 -> A **Part A**

C1-1. -> A-1.11 The following paragraph is inserted as new A-1.11: The client undertakes to notify TÜV PS without delay of all field safety corrective actions and field safety notices concerning a product with the identification number CE 0123 that are associated with the design and/or production of the product in question.

C1-2. -> A-2.2 is replaced as follows: The Certification Body shall be entitled to restrict, suspend, revoke or withdraw a certificate at it's own choice with or without notice, taking Section C1-5. -> A-2.6 into account. This applies in particular, if:

C1-3. -> A-2.4 is replaced as follows: Certificate expiries, revocations, 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, revoked 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.

C1-4. -> A-2.5 The following paragraphs shall be inserted as further points after A-2.5:

C1-5. -> A-2.6 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 C1-2. -> A-2.2.

C1-6. -> A-2.7 TÜV PS adheres to its notification duties as per MPG (Medical Devices Act) § 18 (3).

C1-7. -> A-4 is replaced 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.

C1 -> B1 Part B1

C1-8. -> B1-1.1 is replaced as follows: 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.

C2) **Special regulations for the auditing and certification of specific management systems by TÜV SÜD Management Service GmbH (TÜV MS)**

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

C2 -> B2 **Part B2**

C2-1. -> B2 Additional terms and conditions of auditing, verification and certification apply to

C2-1.1 -> B2 VDA 6.x: VDA volume 6 "Basis for Quality Audits" and VDA volumes 6.1, 6.2 and 6.4. VDA volume 6 sets forth the requirements, rules and processes of audits carried out between automobile manufacturers and suppliers and third-party audits carried out by certification bodies and must be complied with by all parties involved. Other applicable documents supplementing the VDA 6.x volumes are the SI (sanctioned interpretations) published on the website of the VDA-QMC. www.vda-qmc.de.

C2-1.2 -> B2 ISO/TS 16949: The "Automotive certification scheme for technical specification ISO/TS 16949" is binding on all IATF-recognized certification bodies and must therefore also be complied with by every client aiming for ISO/TS 16949 certification. Other applicable documents supplementing the Automotive certification scheme for technical specification ISO/TS 16949 are the SI (sanctioned interpretations) published on the website of the IATF www.iatfglobaloversight.org

C2-1.3 -> B2 ISO 9001 and 14001: Applicable mandatory documents of the International Accreditation Forum (IAF): MD 1:2007 (Certification of Multiple Sites Based on Sampling), MD 2:2007 (Transfer of Accredited Certification of Management Systems), MD 5:2007 (Duration of QMS and EMS Audits)

C2-1.4 -> B2 BS OHSAS 18001: In accordance with the provisions of the Deutsche Akkreditierungsstelle (DAkkS), the "IAF Mandatory Document For Duration of QMS and EMS Audits“ (IAF MD 5:2009) also applies to the certification and auditing of occupational health and safety systems as per OHSAS 18001.

C2-1.5 -> B2 ISO 27001: ISO/IEC 27006

C2-1.6 -> B2 ISO 22000: ISO 22003

C2-1.7 -> B2 Food and feed standards: EN 45011

C2-1.8 -> B2 Certification as per the IFS International Featured Standards (including but not limited to IFS Food, IFS Logistics):

- TÜV SÜD Management Service GmbH is authorised by HTS (HDE Trade Services GmbH) to conduct IFS audits and certifications and such authorisation lapses in the event this Framework Agreement ceases between the TÜV SÜD Management Service GmbH and HTS

- TÜV SÜD Management Service GmbH is obligated and irrevocably authorised by the Market Participants to transmit to HTS the relevant (detailed) results from the IFS audits and certifications, independently of the results of the audit; this data will be deposited in an online database - the IFS portal - kept by HTS

- HTS is irrevocably authorised to make available the master data of the audited market participants who hold a valid certificate as well as basic data on passed audits without detailed information (e.g. the reached points) via the IFS portal.

- The Market Participant himself decides whether failed audits and the detailed results of passed and failed audits may be made available by HTS to wholesalers and retailers via the IFS portal

- IFS-certified companies are obliged to support audits carried out under the "IFS Integrity Program". Under the "IFS Integrity Program", the standard-setter HTS carries out activities in the field of complaints management and preventive actions to assure the quality of the IFS.

  (1) Within the scope of complaints management, the HTS may conduct "investigation audits" which are aimed at managing and investigating complaints referring to completed IFS audits. Investigation audits are carried out either at short notice or unannounced by an auditor commissioned by HTS.

  (2) Within the scope of preventive quality assurance activities, HTS conducts "surveillance audits" to monitor the quality of the completed IFS audits in a sampling approach regardless of whether or not a complaint has been made. The audits are selected at random and carried out by HTS.

  (3) In re-approval witness audits, a standard certification audit carried out by an IFS auditor is attended by an auditor employed or commissioned by HTS.

If the measures performed under the Integrity Program reveal a breach in the implementation of the standard requirements on the part of the IFS-certified company, the company may be billed for the costs of additional audits performed under the Integrity Program

C2-1.9 -> B2 Certification as per the GMP+ standard of GMP International:

Companies certified as per the GMP+ standard are permitted to use the GMP+ logo and must therefore strictly comply with the criteria defined by GMP+ International. Companies with a temporary acceptance are not permitted to use the GMP+ logo in any way.

Companies certified as per the GMP+ standard must cooperate in witness audits, parallel audits and additional audits (compliance audits, stricter supervision and repeat audits).

C2-1.10 -> B2 Certification as per the QS-Standard of QS Qualität und Sicherheit GmbH (Bonn, Germany):

Cooperation in witness audits: Q&S GmbH reserves the right to send an appointed person/organization to verify compliance with the certification standard. One way of verification is for Q&S GmbH and/or an auditor appointed by Q&S GmbH to perform a witness audit at the certified company.

Within the scope of QS certification, QS system participants are obliged to cooperate in witness audits at all times (see guideline for certification bodies, Sections 2.1.10., 3.2. and Chapter 4.).

C2-1.11 -> B2 Certification as per GLOBALGAP:

Producers or companies certified as per GLOBALGAP must support audits carried out under the GLOBALGAP integrity program "Certification Integrity Programme, CIPRO“. CIPRO audits are carried out by auditors commissioned by GLOBALGAP.

C2-1.12 -> B2 Certifications as per 70/156 EEC, Article 10 and Annex X and approval-related requirements of the Federal Motor Transport Authority of Germany (KBA

TÜV MS is permitted to publish the names of certificate holders. In cases involving certification procedures as per Council Directive 70/156/EEC and verification procedures as per the StVZO (Regulations Authorizing the Use of Vehicles for Road Traffic), TÜV MS will inform the accreditation body of the German Motor Transport Authority (Kraftfahrt-Bundesamt) about the issue, suspension, revocation, withdrawal and expiry of certificates, confirmations of verification or other confirmations that are coupled with an existing certificate.

C2-1.13 -> B2 Verification as per StVZO (Regulations Authorizing the Use of Vehicles for Road Traffic), Article 19(3) including Annex XIX, and the directive governing the procedure and confirmation of quality system verification in the manufacturing of vehicle components for which component expert opinions are prepared:

Verification confirmations may only be used by manufacturers in connection with the appropriate component expert opinion as per Article 19 StVZO in conjunction with Annex XIX.

C2-1.14-> B2 Certification as per the International Railway Industry Standard (IRIS): Requirements outlined in the standard in Chapter 1, 4.1 Preparation and request for IRIS certification:

In case of termination of the framework agreement between the certification body and IRIS Group, before the evaluation process has been carried out and while the IRIS certificate still displays a valid date, the client is not entitled to claim the IRIS certificate.