



Testing, Certification, Validation and Verification Regulations

TÜV SÜD Group

Applicability:

These Testing, Certification, Validation and Verification Regulations (hereinafter referred to as “TCVVR”) apply to all companies of the TÜV SÜD Group (hereinafter referred to individually or collectively as “TSC” or “TÜV SÜD company”).

This includes in particular the following TSC:

- TÜV SÜD Auto Service GmbH
- TÜV SÜD America Inc.
- TUV SUD Asia Ltd.
- TUV SUD BABT Unltd.
- TUV SUD Certification and Testing (China) Co., Ltd.
- TÜV SÜD Czech s.r.o.
- TÜV SÜD Danmark ApS
- TÜV SÜD Energietechnik GmbH Baden-Württemberg
- TUV SUD Hong Kong Ltd.
- TÜV SÜD Industrie Service GmbH
- TUV SUD Korea Ltd.
- TUV SUD (Malaysia) Sdn. Bhd
- TÜV SÜD Management Service GmbH
- TÜV SÜD Nederland B.V.
- TÜV SÜD Product Service GmbH
- TÜV SÜD PSB Philippines Inc.
- TUV SUD PSB Pte Ltd.
- TÜV SÜD Rail GmbH
- TÜV SÜD SFDK Laboratório de Análise de Produtos LTDA
- TUV SUD South Asia Pvt. Ltd.
- TÜV Technische Überwachung Hessen GmbH



These TCVVR (see www.tuvsud.com/tcr) in the version 1st of January 2024 replaces the previous version dated 1st of May 2021. In the previous version, these TCVVR were referred to as “TCR” or “Testing and Certification Regulations”. The new version becomes part of the contract with the client* in accordance with A-1.4 either after its acceptance (for new contracts) or information of the change by the respective TSC (for existing contracts). During the transition phase, both versions will remain available and valid accordingly.

For the application of these TCVVR, the terms and definitions according to the glossary apply.

Terms and definitions included therein are marked with an asterisk (*) at the point of their first use in the TCVVR as a reference to the glossary.

The TCVVR apply to:

- testing* and certification* of products, processes, systems, services and persons (hereinafter referred to as “objects of conformity assessment”* or “objects of certification”*);
- auditing* and certification* of management systems;
- validation* and verification* of information (hereinafter referred to as “claims”).

Conformity assessment bodies*, such as certification bodies*, testing laboratories*, inspection bodies or validation/verification bodies*, are hereinafter also generally referred to as “CAB”.

Inspections* as conformity assessments* beyond evaluation activities in the context of certification are excluded from the scope.

Insofar as a client has concluded multiple contracts for obtaining a certificate* or an attestation of conformity* (e.g. separate contract partners to which the contractually relevant certification bodies are affiliated for the service contract and the certification contract), the more specific provisions for the specific order shall take precedence in the event of contradictions.

These TCVVR shall be governed by the law applicable at the registered office of the CAB relevant to the respective service in the respective TSC.

Insofar as these TCVVR are available in several language versions, in the event of inconsistencies or contradictions between the language versions, the German version shall prevail. If the German version is not available, the English version shall prevail.

These TCVVR comprise several modules, where Module A generally applies to all TSC. The remaining modules apply as appropriate and may supplement, replace or denote as not applicable any provisions in other modules. Modules B1/B2/B3/B4 supplement Module A. Modules A and B are supplemented/modified/replaced by the relevant Module C.

The full version of these TCVVR covers Modules A, B1 to B4 and C1 to C7.

In the context of the C Modules, any references to the certification body or TSC shall be construed as references to the relevant certification body. In the event of conflicts between the respective C Module and other provisions of these TCVVR, the C Module shall prevail.



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Module A General terms and conditions

A-1. General terms and conditions

A-1.1 These TCVVR apply to testing, certification, validation, verification, and EU conformity assessment procedures performed by TSC.

The client knows that to ensure independence and impartiality, TSC cannot combine contractual conformity assessments with consultancy regarding the object of conformity assessment*.

The client shall notify the CAB immediately of any consultancy received that was provided by TSC or affiliated companies/bodies.

Any jeopardizing of its impartiality and independence on the grounds of consultancy will entitle TSC to terminate this contract for cause according to paragraph A-1.5 II.

A-1.2 In accordance with the TSC's Code of Conduct, TSC reserves the right to reject applications for conformity assessments on a case-by-case basis, especially if there is a conflict with legal requirements, the TÜV SÜD brand, TSC quality standards or corporate image.

A-1.3 Before placing an order, the client shall provide TSC with the name and results of any other organization that has tested, audited, validated, verified or certified the same object of conformity assessment based on a similar or identical order in the past or is currently in the process of doing so.

A-1.4 With each placement of an order, the client accepts the respective current version of these TCVVR as the content of the contract. Existing contractual relationships are subject to the respective valid version of the TCVVR.

TSC reserves the right to make changes to the TCVVR at any time with effect for the future and undertakes to notify the client about such changes. In this event, the client has a special right of termination, which shall be exercised in textform* within six (6) weeks after receipt of the information about the change. If the special right of termination is exercised, the contractual relationship with the respective TSC shall be terminated effective at the end of the following month. Otherwise, the contractual relationship shall be continued under the modified conditions. TSC shall notify the client in its communication on the TCVVR's modifications about the consequences of its silence.

The currently valid versions of these TCVVR are available at the relevant CAB-TSC or will be provided free of charge on request.



A-1.5 Any certificate and attestation of conformity is subject to the existence of a valid contract or order covering the performance of the respective conformity assessment.

The contract or order may be terminated in whole or in part by the client or TSC as follows, unless the underlying special terms and conditions define other periods of notice:

I. by **termination without cause**

- a) for management system certifications:
with three (3) months' notice before the next scheduled certification audit*;
- b) for system certifications:
according to EU directives and EU regulations, A-1.5 I. a) similarly applies to TSC;
- c) for product certifications, including process and service certifications:
with two (2) months' notice before the end of the respective calendar year;
- d) for the certification of persons:
with two (2) months' notice before the end of the respective calendar year;
- e) for validations and verifications:
with two (2) months' notice before the completion of the validation/verification activities.

II. by **termination for cause**.

A-1.6 The client shall comply with the requirements of the relevant scheme* and make all necessary arrangements for performing the conformity assessment; in particular for document review, for access to all relevant processes, areas, records and personnel, and for accommodating observers. If unannounced conformity assessment activities* are specified in the scheme, the client shall make the necessary arrangements.

A-1.7 The client shall cooperate with TSC in a timely manner and to the extent required (e.g. measures regarding nonconformities, provision of documents, information and test samples, accommodating audits).

The client shall ensure that TSC and, if necessary, the personnel of authorized bodies (such as public authorities, accreditation bodies* or scheme owners during witness audits or integrity audits) can audit or inspect both the client's manufacturing and operating sites and those of critical subcontractors identified by the client (such as critical suppliers*, warehouses of authorized representatives, importers) during ordinary business hours, even without prior notice, at the client's expense. TSC shall also have the right to take random samples at the client's expense to the extent necessary for the audit or inspection.



A-1.8 Where on-site activities (such as audits or inspections) conducted by TSC personnel require personal protective equipment, TSC and the client shall agree upon supply of such equipment in advance of any visit.

In addition, the client shall ensure that the necessary safety precautions (in particular regarding occupational and operational safety) are observed on site in order to guarantee that TSC personnel can work safely. Otherwise, TSC may interrupt the on-site activity at the client's expense and shall be released from its obligation to perform until appropriate conditions are provided.

A-1.9 To the extent permitted by the respective scheme, TSC may perform conformity assessment activities, such as audits, remotely in full or in part, using suitable information and communication technologies.

A-1.10 The CAB of the TSC concerned reviews the results of the personnel involved in the conformity assessment activities.

The CAB decides on the granting of the certificate or issuing of the attestation of conformity and handles any disagreements, complaints* or appeals* regarding the conformity assessment.

Complaints and appeals shall be addressed directly to the respective CAB of the TSC. CABs have documented processes for handling complaints and appeals.

A description of the relevant processes is publicly available.

Costs resulting from such a process for handling a complaint or an appeal may be charged to the client to the extent that they exceed the usual level.

A-1.11 Statements of conformity* (in particular certificates, validation or verification statements) are issued only after all technical and financial requirements regarding the conformity assessment have been fulfilled.

A-1.12 Certificates and attestations of conformity always refer to the version of the normative documents* applicable at the time they were issued, unless otherwise stated.

Statements of conformity issued with certificates or attestations of conformity shall always be referred to in full (i.e. including pertinent annexes, specified scopes or other references) by the client.

If the client makes certificates or attestations of conformity or copies thereof available to others, the documents shall be reproduced in their entirety or as specified in the scheme.

A statement of conformity may be issued in hard copy and/or in digital form.

The client shall at all times reference the pertinent annexes of the certificate or attestation of conformity.



A certificate, including all certificate duplicates, is non-transferable and remains the property of TSC.

The owner of a validation/verification statement shall always refer to the information issued with the statement (e.g. scope and applied programmes, system boundaries, intended users, level of assurance, conclusions and comments). The validation/verification statement, including any duplicates, reflects only the situation at the time it is issued and is not transferable.

Certificates and attestations of conformity do not entitle the holder or owner to use a TÜV SÜD mark of conformity* unless otherwise stated on the certificate or attestation of conformity or specified by the scheme.

Any use of a mark of conformity and CE marking* in connection with the number of the notified body* is only allowed as long as the use is granted by a valid certificate or attestation of conformity.

- A-1.13 In the event of expiry*, withdrawal* or revocation* of a certificate, irrespective of the reason, the underlying certification contract or order for this certificate will also expire automatically without requiring separate termination. This does not apply if the contracting parties have agreed on continuing the contractual relationship prior to its automatic termination*. This, however, does not affect the terminated certificate.
- A-1.14 This termination will not affect any existing claims against the client, e.g. unsettled receivables. Any costs and expenses for upcoming surveillance of the object of certification already incurred can be claimed.
- A-1.15 The requirements of these TCVVR will apply during the term of the contract or order on the performance of the respective certification or validation/verification activities and for three (3) years thereafter (grace period). If only part of the contract or order is terminated, the grace period will also apply to the terminated part.
- A-1.16 Should any individual provision of these TCVVR or any part of any provision be or become void and/or unenforceable, the validity of the remaining TCVVR shall remain unaffected. In such case, the void and/or unenforceable provision shall be replaced by a corresponding provision coming as close as possible to the sense and spirit and purpose of the void and/or unenforceable provision.



A-2. Termination, reduction or suspension of certificates and attestations of conformity

A-2.1 General regulations applicable to certificates and attestations of conformity

A-2.1.1 Withdrawal

TSC may also withdraw a certificate or attestation of conformity at the request of the client.

A-2.1.2 Revocation

TSC may revoke a certificate or attestation of conformity if there is a not insignificant violation of an essential obligation on the part of the client and relevant normative documents stipulate a revocation or if there is a corresponding request from the competent authority, accreditation body or scheme owner.

A-2.1.3 Reduction and suspension

Certificates or attestations of conformity may furthermore be reduced in time (i.e. shortened in validity), limited technically, or suspended temporarily by TSC for the reasons stated under A-2.2.2 and A-2.3. As an interim measure of protection, the suspension* may also already be combined with the request under A-2.2.2.1 or A-2.3.1, provided this is proportionate.

A-2.1.4 Costs and expenses

TSC may also charge any costs and expenses incurred in connection with the termination*, reduction* or suspension and caused by the client, including those charged to TSC by authorized bodies (such as public authorities, accreditation bodies or scheme owners).

A-2.1.5 Other consequences

Termination, reduction or suspension of a certificate or attestation of conformity may be published by the CAB of the respective TSC.

A terminated certificate or attestation of conformity shall be immediately canceled, destroyed or returned at the discretion of the CAB.

Further advertising or other use of the certificate or the attestation of conformity and the marks of conformity is not permitted.

TSC shall not be liable for any disadvantages incurred by the client or third parties as a result of the lawful termination, reduction or suspension.



A-2.2 Special regulations for certificates

A-2.2.1 Expiry

A certificate becomes void when

- its designated validity period has expired;
- the underlying main certificate has terminated.

A-2.2.2 Withdrawal

TSC may withdraw a certificate with effect for the future if there is an important reason that makes it unacceptable for TSC to continue, even taking into account the legitimate concerns of the client.

A-2.2.2.1 An important reason shall be deemed to exist in particular if the client breaches the contract, these TCVVR and related applicable normative documents in a not insignificant manner and does not remedy the breach – despite receipt of a corresponding request with an appropriate remedy period and simultaneous threat of withdrawal.

Such a breach shall be deemed to have occurred in particular if

- a) the certification requirements are not or no longer fulfilled, in particular, but not exclusively, if
 - the client provides incorrect information to TSC or conceals important facts relevant for certification;
 - characteristics relevant for certification do not or no longer correspond to the certified sample;
 - users, operators or third parties are exposed to significant risks or the object of certification has to be recalled from the market due to a public authority's orders;
 - requirements underlying the certificate change (e.g. requirements specified by applicable normative documents, by the state of the art of technology, by a public authority, accreditation body or scheme owner) and the client does not substantiate within a set time through re-testing or re-auditing that the object of certification complies with the new requirements;
- b) the contractual basis for the use of the certificate ceases to exist (e.g. because the client permanently discontinues its business operations without having a legal successor);
- c) specified requirements or conditions were violated, if the certificate was issued under such;



- d) the client does not provide the required cooperation (such as corrective action regarding nonconformities, provision of documents and information, enabling audits, etc.) at all, or in a timely manner, or sufficiently; if, for example
 - testing or auditing of facilities or product testing is not made possible;
 - the products or documents are not made available within the specified period;
- e) the client causes or tolerates the misuse, misleading or otherwise inappropriate use of TSC certificates, certification marks, attestations of conformity; or reports of results;
- f) serious allegations against the client become known which are relevant to the certification and the client is unable to refute the allegations to TSC's satisfaction within a reasonable time;
- g) the client does not fulfill due payment claims within the set period despite receipt of a reminder.

A-2.2.2.2 An important reason shall also be deemed to exist if the further use of a certificate or a related certification mark is no longer legally permissible or, at TSC's reasonable discretion, no longer justifiable with regard to its informative value on the market. In this case, TSC shall either provide an adequate alternative or compensate the client for damages proven to be causally inflicted by TSC. The provisions of A-2.2.2.1 shall apply alternatively and remain unaffected by this clause.

A-2.3 Special regulations for attestations of conformity, including validation/verification statements

If new facts or information are discovered after the issue date that require revision, withdrawal, or revocation of the attestation of conformity (e.g. verification statement), the issued attestation of conformity is invalid.

TSC may revoke an attestation of conformity if there is an important reason that makes it unreasonable for TSC to continue, even taking into account the legitimate concerns of the client.

A-2.3.1 An important reason shall be deemed to exist in particular if the client breaches the contract, these TCVVR and related applicable normative documents in a not insignificant manner and does not remedy the breach – despite receipt of a corresponding request with an appropriate remedy period and simultaneous threat of revocation.



Such a breach shall be deemed to have occurred in particular if

- a) the requirements for conformity assessment (e.g. inspection or verification) are not fulfilled, in particular, but not exclusively, if
 - the client has provided incorrect information to TSC or has concealed important facts relevant for the conformity assessment;
 - users, affected persons or third parties are exposed to considerable risks;
- b) specified requirements or conditions were violated, if the attestation of conformity was issued under such;
- c) the client causes or tolerates the misuse, misleading or otherwise inappropriate use of attestations of conformity, marks of conformity, or reports of results of TSC;
- d) serious allegations against the client become known which are relevant for the conformity assessment and the client is unable to refute the allegations to TSC's satisfaction within a reasonable time;
- e) the client does not fulfill due payment claims within the set period despite receipt of a reminder.

A-2.3.2 An important reason shall also be deemed to exist if the further use of an attestation of conformity or a related mark of conformity is no longer legally permissible or, at TSC's reasonable discretion, no longer justifiable with regard to its informative value on the market. In this case, TSC shall either provide an adequate alternative or compensate the client for damages proven to be causally inflicted by TSC. The provisions of paragraph A-2.3.1 shall apply alternatively and remain unaffected by this clause.

A-3. Use of certificates and certification marks, use of attestations of conformity and marks of conformity other than certification marks

A-3.1 Use of certificates and certification marks

A-3.1.1 Granting of rights of use

During the validity of a certificate, the client may use it in commercial transactions in accordance with these TCVVR. If the respective scheme provides for the issuance of a certification mark, the client shall also be granted the non-exclusive right, limited in time to the validity of the underlying certificate, to use the mark in commercial transactions and in particular for advertising purposes. In doing so, only the mark related to the respective certification may be used. The right of use lapses upon termination of the underlying certificate.



A-3.1.2 Terms of use

A-3.1.2.1 In the case of certifications that do not represent a legal obligation, the advertising shall refer to the voluntary nature of the certification, the requirements of the certification scheme, and the normative basis or scheme owner.

A-3.1.2.2 Certificates and certification marks shall not be misused or used in a misleading or other manner that could jeopardize public confidence in TSC's certificates and certification marks. TSC's role as an independent third party shall not be compromised by the presentation of certification marks.

A-3.1.2.3 A certificate or a certification mark may only be used to advertise the specific object of certification.

The impression that the certification applies to objects that are outside the scope of the certificate shall not be conveyed.

A-3.1.2.4 Product-related advertising with a certification mark is not permitted if only a management system certificate or an attestation of conformity have been issued.

A-3.1.2.5 If certificates or certification marks only refer to specific aspects of an object of certification, the advertising shall not give the impression that the object of certification has been certified in its entirety.

A-3.1.2.6 The client is fully responsible for the permissible use and the permissibility of any statements regarding the certificate or mark issued for an object of certification. This also applies, in particular in the area of product certifications, to the correct use by the client's customers, provided this use is permissible.

A-3.1.2.7 When advertising with certificates and certification marks, the client is advised to ensure transparency so the public addressed is informed easily and sufficiently about the nature of the TSC services underlying the certificates and certification marks.

A-3.2 Use of attestations of conformity and marks of conformity other than certification marks

A-3.2.1 Granting of rights of use

After an attestation of conformity is issued, the client may use it in commercial transactions in accordance with these TCVVR. If the respective scheme provides for the issuance of a mark of conformity, the client shall also be granted the non-exclusive right to use the mark in commercial transactions and in particular for advertising purposes in accordance with these TCVVR for a maximum period of one (1) year after issuance of the associated attestation of conformity. In this context, only the mark of conformity associated with the respective attestation of conformity may be used.



A-3.2.2 Terms of use

A-3.2.2.1 In the case of conformity assessments that do not represent a legal obligation, the advertising shall refer to the voluntary nature of the conformity assessment, the requirements of the conformity assessment scheme, and the normative basis or scheme owner.

A-3.2.2.2 Attestations of conformity and marks of conformity shall not be misused or used in a misleading or other manner that could jeopardize public confidence in TSC's attestations of conformity and marks of conformity. TSC's role as an independent third party shall not be compromised by the presentation of marks of conformity.

A-3.2.2.3 An attestation of conformity or a mark of conformity may only be used to advertise the specific object of the conformity assessment.

The impression that the statement of conformity applies to objects that are outside the scope of the attestation of conformity shall not be conveyed.

A-3.2.2.4 If attestations of conformity or marks of conformity only refer to specific aspects of an object of conformity assessment, the advertising shall not give the impression that the object of conformity assessment has been assessed in its entirety.

A-3.2.2.5 The conformity assessment client is fully responsible for the permissible use and permissibility of any statements regarding the attestation of conformity or mark issued for an object of conformity assessment. This also applies to the correct use by the client's customers, provided this use is permissible.

A-3.2.2.6 When advertising with attestations of conformity and marks of conformity, the client is advised to ensure transparency so that the public addressed is informed easily and sufficiently about the nature of the TSC services underlying the attestations of conformity and marks of conformity.

A-3.3 Use of reports of results including test reports

Results of conformity assessment activities (such as test reports* or audit reports), which have not been issued in the form of a certificate or attestation of conformity, may not be used by the client for advertising purposes and may not be reproduced either in part or in full. References to reports of results or names of TSC for promotional purposes are not permitted.

Exceptions to this are cases in which the responsible CAB of TSC has expressly approved this in advance in text form*, or the respective conformity assessment provides for the report's use, or disclosure is required due to statutory, regulatory or accreditation requirements.



If reports of results of conformity assessment activities are used for advertising purposes with TSC's approval, the client shall not attach to the reports any statements or interpretations that go beyond their actual content, in particular no falsifying or misleading statements or interpretations that could cast doubt on TÜV SÜD's neutrality. The client shall at all times ensure that TSC's results are reproduced correctly and without distortion.

This applies in particular to all communication activities, advertisements, notices, sales documents, etc., in digital media, audio features or print media initiated by the client.

If TSC reports of results may be used as set out above, their wording shall be unchanged and complete and their date of preparation stated.

Under no circumstances, however, shall TSC reports of results be used to state or imply that TSC specifically recommends the client, its product or system.

A-3.4 Consequences of unauthorized use

If claims are asserted against TSC or the respective CAB by third parties due to use of the certificate, the attestation of conformity or the mark of conformity by the client in violation of the contract, the client shall be obligated to indemnify TSC or the CAB against all claims of third parties upon first request. The same shall apply if claims are asserted against TSC or the CAB by third parties as a result of advertising statements made by the client.

A-3.5 Specifications for the presentation of certification marks and other marks of conformity

A-3.5.1 The client may only use the mark and may under no circumstances use the TÜV SÜD logo ("TÜV SÜD octagon", see header) or the claim of the TÜV SÜD Group (at present: "Add value. Inspire trust.").

A-3.5.2 Neither the content nor the design of the mark of conformity provided by TSC may be changed. It shall be recognizable as such and its size shall be visibly smaller than that of the client's company. The information included in the mark shall be clearly legible even if the mark is displayed at reduced size.

A-3.5.3 The mark of conformity shall stand alone and may not be associated with any other elements (e.g. the client's company logo, statement or graphics). In particular, the impression shall not be given that the client or its employees are members of the TÜV SÜD Group or that the mark is the client's trademark or logo.

A-3.5.4 If TSC changes the design of a mark of conformity, the client is obligated to use the new version of the mark of conformity exclusively. Unless TSC has set another deadline for the changeover and communicated it to the client in text form, the change to the new version of a mark of conformity shall be completed within six (6) months at the latest.



A-3.6 Information obligations before media publications

If the client plans to mention TSC or a TSC service in a press release, in professional articles or social media posts, TÜV SÜD AG's press office (presse@tuvsud.com) shall be informed about it in time.

Furthermore, the written consent of TSC shall be obtained before publication.

A-4. Publication of certificates, attestations of conformity and marks of conformity

For consumer information or if required by the program or the relevant normative documents, TSC may publish the mandatory information, such as the names of certificate holders or validation/verification clients and also of certified objects and validated/verified claims. TSC may grant authorized bodies (such as public authorities, accreditation bodies or scheme owners) direct access to the relevant documentation at any time.

Any further information about clients and objects of certification or validation/verification is subject to confidentiality unless the disclosure of such information is requested by a court or authorized body or otherwise mandated by law or procedure. This non-disclosure obligation applies equally to all employees and agents of TSC.

A-5. Retention of test samples and documentation

As far as clients are in possession of test samples and pertinent documentation, they shall retain them for a period of ten (10) years after expiry of the certificate or after the last product covered by the certificate is placed on the market, whichever comes last.

Management system certification documentation shall be retained for the term of validity of the certificate plus a minimum of three (3) more years.

Documents related to the certification of persons shall be retained for the term of the certificates plus ten (10) more years.

Validation and verification documents shall be retained for a minimum of three (3) more years after the validation/verification statement is issued.

Provisions of the normative documents extending beyond these requirements shall remain unaffected.

Claims for damages against TSC shall be excluded, in particular if clients fail or are unable to provide a test sample or document returned to or retained by them in unchanged condition.



A-6. Contractual penalty

TSC may demand an appropriate contractual penalty at its reasonable discretion for each case of culpable breach by the client regarding the contract, these TCVR or related applicable normative documents, which in the event of a dispute shall be subject to review by the court having jurisdiction. In determining the contractual penalty, TSC shall, at its reasonable discretion, take into account, among other things, the nature and gravity of the breach and the fact that the client should not be left with any financial benefit from the breach or whether the client has already been penalized in some other way.

Based on previous cases, it can generally be assumed that TSC will impose contractual penalties of EUR 5,000 to EUR 10,000 for significant violations and EUR 10,000 to EUR 50,000 for serious violations.

A serious violation may exist, in particular, in the event of intentional and repeated violations, if a product bearing a mark of conformity is placed on the market before the certificate or attestation of conformity is issued, if a certificate or attestation of conformity is falsified or if an object of conformity assessment is advertised with a certificate or attestation of conformity alleged to be present, although it does not conform to it.

Excluded from the contractual penalty are cases of non-acceptance, delayed acceptance of the service, delay in payment and the client's dissolution of the contract.

The possibility of asserting further claims for damages in addition to the contractual penalty shall remain unaffected, as shall the enforcement of any additional claims for injunctive relief.



Module B1 Special terms and conditions for product testing and certification

B1-1. Testing

B1-1.1 The client shall commission TSC with testing and supply the necessary test samples and documentation free of shipping charges. TSC shall, at its own discretion, perform testing either in their own testing laboratory* or externally, and prepare a report.

B1-1.2 Following the testing, TSC shall dispose of the test samples at a flat-rate charge or, at the clients' 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 testing is interrupted for more than one month, TSC may also return the test sample or store it at a flat-rate charge applied to each month begun until testing continues.

B1-1.3 TSC may make the test file and, if necessary, the test sample, accessible to authorized bodies (such as public authorities, accreditation bodies or scheme owners). Any conflicting agreement shall be invalid.

B1-1.4 Transport, insurance, logistics, customs, etc., of the samples to TSC shall be arranged by, and at the expense of, the client.

B1-1.5 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 or transport, etc.

B1-1.6 No consultancy will be supplied on product development or management system establishment.

B1-1.7 TSC evaluates measurement results to make statements of conformity with a specified requirement by taking into account measurement uncertainty as far as provided for in the statutory requirements, applied schemes and normative documents applicable to the testing.

In this context, statutory requirements prevail over normative requirements. Clients' contractual requirements are taken into account only if they are not in conflict with statutory or normative requirements.

If no such provisions apply, measurement uncertainty is not considered in the evaluation of measurement results.



B1-2. Certification

When the first certificate is issued, the certificate holder automatically becomes a partner in the TÜV SÜD certification system and remains a partner as long as at least one certificate is valid.

The fact that a certificate was issued makes no statement on the marketability of a certified product unless otherwise stated on the certificate.

After successful completion of product testing, TSC will issue a certificate either with or without the right to use a certification mark. If product certification does not include manufacturing surveillance, the product shall not be labeled with a certification mark.

The following regulations apply to product certifications including certification marks and to certifications granting the right to carry the CE marking in connection with the number of the notified body.

B1-2.1 Positive results of both product testing and the initial visit of the manufacturing site are required for the use of a certification mark (licensure). Regular reviews (follow-up service, see B1-2.6) are required to maintain the validity of the certificate (according to the licensure).

B1-2.2 The certificate holder shall only use the certification marks defined in the certificate for the specific models listed on the certificate.

The certificate holder shall be responsible for surveilling the use of the certification marks and shall ensure that they are only used in conjunction with the certificate holder's identity and the specific certified model number.

The certificate holder shall not transfer the certificate rights to third parties.

As soon as a product certificate is void, the products listed on the certificate shall no longer be placed on the market using the certification mark or the CE marking in connection with the number of the notified body.

Holders of withdrawn or revoked certificates shall in addition either remove the certification mark from all products accessible, make the certification mark permanently unrecognizable or destroy the products and enable the TSC to verify these measures at the certificate holder's expense.

B1-2.3 TSC certification marks shall only be used for products in conformity with the type or model successfully tested and the specifications included in the certificate or supplementary agreements. The required documents (such as attestation of conformity, operating and assembly instructions) shall be enclosed with the product in the language of the country of destination unless otherwise specified by applicable regulations.



B1-2.4 Holders of certification marks shall implement ongoing surveillance of the manufacturing of products bearing the certification mark to ensure conformity with the requirements applicable for testing. They shall also perform specified control testing and document any complaints in connection with certified products. The client shall take appropriate action with respect to such complaints and any defects found in products that affect conformity with the requirements for certification.

The certification body shall be notified immediately of any changes made to products after certification and of any recalls or safety-related incidents. The certification body may request the manufacturer to demonstrate compliance with standards and codes of practice or require additional testing by a qualified testing laboratory to maintain certification.

B1-2.5 As a minimum requirement, every product shall be identified by an indestructible marking clearly indicating the name of the manufacturer or importer and a type designation to establish that the series product placed on the market is identical to the approved type. If a product submitted for testing does not satisfy the testing requirements and products corresponding to this test sample have already been distributed for sale or have been the subject of a certification mark misuse, the modified test sample may only be certified if it bears another type designation.

B1-2.6 Manufacturing site visits for certificates including the right to use a certification mark (follow-up service) and market surveillance

B1-2.6.1 To retain the product characteristics on which the certificate is based, the certification body will regularly inspect manufacturing and testing facilities and quality assurance measures at the certificate holder's expense. Alternatively, for certification including the right to use a certification mark, random sample testing based on the modules of Decision No 768/2008/EC of the European Parliament and of the Council may be agreed upon before the certificate is issued. If the quality management system of the respective manufacturing site has been certified by TSC, the follow-up service may be incorporated in the surveillance/re-certification audit pertaining to the management system.

To ensure manufacturing quality, additional pre-shipment inspections may be agreed upon, to assess the conformity of the samples ready for shipment with the tested, certified, or provided type.



- B1-2.6.2 The certificate holder shall immediately notify TSC of any relocation of a manufacturing site, transfer of a manufacturing site to another company or company owner or any change in the manufacturing process, including the management system, that may affect the production of the certified product. In such and other special cases, the certification body may request the product to be identified using a specified marking or applying a specified method, in addition to the certification mark, so that products from different manufacturing periods can be identified. If a different manufacturing site is used, TSC shall visit and approve the new manufacturing site before the products manufactured there are labeled with a certification mark. The certificate holder shall immediately notify TSC of any changes to the holder's details, such as:
- legal, commercial, organizational status or ownership;
 - organization and management (such as key managerial, decision-making, or technical staff);
 - contact address.
- B1-2.6.3 The certification body can pick samples of products identified by a certification mark from the market for review purposes. If the certification requirements are not satisfied (e.g. because of unauthorized modifications that have resulted or may result in reduction, suspension, withdrawal or revocation of the related certificate), the certificate holder shall bear the costs of re-testing the product and/or re-visiting the manufacturing site.
- B1-2.6.4 The certificate holder shall notify the certification body immediately of any damage to certified products or any incidents related to them.
- B1-2.7 In addition to an existing (main) certificate, further certificates may be issued:
- a) to the (main) certificate holder if they seek to have a product certified under a different product designation than the one appearing on the (main) certificate;
 - b) to a different certificate holder if they seek to have a product certified under the same or a different product designation than the one appearing on the (main) certificate. This requires the approval of the (main) certificate holder, who also needs to confirm that the product's structure is identical with that of the product associated with the (main) certificate.
- The content and validity of such certificates are based on the (main) certificate.
- B1-2.8 For the purpose of publishing certificates, TSC may also publish images of the certified products if this is required by law or by the certification scheme. TSC assumes no liability for damages of any kind resulting from the publication of images of the certified products.



Module B2 Special terms and conditions for management system auditing and certification

B2-1. General

TSC audits and certifies management systems or audits and certifies systems according to EU-Directives and EU-Regulations (both hereinafter referred to as “management systems”).

TSC does not perform management system consultancy services, including client-specific training.

B2-2. Due date for audits

The due date for the next audit is determined based on the relevant normative documents. As a rule, audits take place periodically twelve (12) months after the last day of the most recent regular audit.

B2-3. On-site audit

The client shall ensure appropriately (contractually, if applicable) that TSC can perform the on-site audit at the premises relevant to certification and can gain access to these premises at any time.

B2-4. Preliminary system assessment, pre-audit

On request, TSC offers the following services, which can also be provided independently of certification procedures.

B2-4.1 In a preliminary assessment, selected documents are reviewed to identify weaknesses in the system. The client receives a report on the results of the assessment.

B2-4.2 The aim of the pre-audit, the total and on-site scope of which is specified jointly with the client, is to point out weaknesses in the management system. The auditor informs the client of the results in a closing meeting; on request, TSC prepares a pre-audit report. Only one (1) pre-audit may be performed.

B2-5. Certification procedure

B2-5.1 Preparation for certification audit

After commissioning TSC, the client appoints an audit representative who is responsible for the certification procedure and provides their details. TSC in turn informs the client of the auditors assigned. Rules outlined in the applicable standards and regulations pertaining to unlawful consultancy on the part of auditors are observed.

To ensure an independent audit, the selection of the audit team is solely up to TSC. The decision in each individual case will be based on several factors such as competence, availability, impartiality, etc.

In addition and in as far as there are no conflicting legal regulations, such as privacy laws, clients may request appropriate background information on each member of the audit team.



B2-5.2 Certification audit

The client shall ensure that authorized staff members are available to answer questions. The client grants auditors access to the respective units of the audited organization and any records related to the system.

B2-5.2.1 Initial certification audit

The initial certification audit shall be performed in two stages: stage 1 and stage 2.

Stage 1 / review and assessment of client's preparedness

The client shall provide any requested management system documents (such as manual, procedures, work and test instructions, records) to TSC for review and assessment.

If the same or a similar scope of the management system has already been certified by another certification body, the client shall additionally provide the following documents:

- a copy of the previous certificate;
- all audit reports of the current certification cycle;
- information on any unresolved nonconformities;
- information on complaints relevant to certification and action taken;
- information on any legal compliance issues.

The TSC shall

- review the management system documentation;
- determine preparedness for the stage 2;
- review the client's status and understanding regarding requirements of the normative documents;
- obtain necessary information regarding the scope of the management system including the sites, processes, equipment, levels of controls and applicable statutory and regulatory requirements;
- plan the stage 2, including confirmation of requirements for the audit team;
- evaluate if the internal audits and management reviews are being performed, and that the level of implementation of the management system substantiates that the client is ready for stage 2.

To achieve the objectives mentioned above, parts of stage 1 can be performed on site.



TSC documents the audit conclusions with regard to fulfillment of the stage 1 audit objectives and readiness for the stage 2, and communicates them to the client, including identification of any areas of concern that could be classified as nonconformities during the stage 2.

Based on the results of the stage 1, TSC plans the performance and focus of the stage 2. The details of the stage 2 will be agreed with the client.

The interval agreed between the stage 1 and stage 2 audits will give the client enough time to resolve the areas of concern identified.

B2-5.2.2 Stage 2 / audit at the client's site

Before the stage 2, TSC shall provide the client with an audit plan* that has been agreed upon with the client.

The auditors evaluate the implementation, including effectiveness, of the management system. At least the following shall be audited:

- information and evidence about conformity to all requirements of the applicable management system standard or other normative documents;
- performance monitoring, measuring, reporting and reviewing against key performance objectives and targets;
- the client's management system ability and its performance regarding meeting of applicable statutory, regulatory and contractual requirements;
- operational control of the client's processes;
- internal audits and management review;
- management responsibility for the client's policies.

TSC provides the client with an audit report on the stage 2.

B2-5.3 Certification

If all requirements of the applicable requirements of normative documents and all statutory and regulatory requirements are fulfilled, TSC will issue a certificate, generally valid for three (3) years from the date of the certification decision, unless specific normative documents or individual arrangements according to the certification contract require other periods of validity.

B2-5.4 Surveillance audit

Surveillance audits are conducted regularly (in general annually) during the validity period of a certificate and serve to assess whether the certified management system continues to fulfill the requirements.

For the preparation of the surveillance audit, the required documents (such as the valid management system manual and a list of any changes made) shall be submitted to TSC upon request.



Each regular surveillance audit shall include:

- internal audits and management review;
- a review of actions taken on nonconformities identified during the previous audit;
- complaints handling;
- effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective system;
- progress of planned activities aimed at continual improvement;
- continuing operational control;
- review of any changes;
- use of certification marks and/or any other reference to certification.

TSC provides the client with an audit report on the surveillance audit.

B2-5.5 Special surveillance audits and special audits

If required by the specific certification scheme or in justified individual cases, TSC shall be authorized to conduct short-notice or unannounced audits* at the client's expense. These audits do not replace a regular surveillance audit according to B2-5.4.

B2-5.6 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 to the client to provide documents and records (on paper or electronic media);
- other means of monitoring the client's performance.

B2-5.7 Recertification audit

Recertification audits are conducted well in advance of certificate expiry to maintain certification. If such a recertification audit is successful, a new certificate will be issued.

The purpose of the recertification audit is to review the continued conformity and effectiveness of the management system as a whole.



During the recertification audit, a review of the management system's performance over the entire most recent certification cycle is performed. Stage 1 may be necessary where there have been significant changes to the client's management system.

In preparation for the audit, the client shall provide TSC with all requested documents relating to the management system.

B2-5.8 Audit report and nonconformities

After audit completion, TSC shall inform the client of the audit result in a closing meeting and an audit report. Nonconformity reports are countersigned by the audit representative, if this is required by the applicable scheme or requested by TSC. The client will document the required corrections and corrective actions. If nonconformities are identified, a re-audit may be performed. The costs will be based on the actual time needed. The same applies to any necessary additional assessment of corrective actions as documented in the nonconformity report.

If nonconformities are identified in the audit that are serious enough to make granting or maintaining a certificate appear unrealistic, even if the necessary corrective action is taken, TSC shall notify the client of the termination of the audit and recommend, if applicable, that the audit should be continued as a pre-audit. TSC will charge the costs incurred (including the report).

B2-6. Supplementary terms and conditions

B2-6.1 The client is obligated to ensure that the certificate or certification mark is used in line with the TCVVR provisions. TSC may check the use.

TSC investigates and evaluates both complaints from third parties and indications of possible incorrect elements that come to its attention elsewhere. The same applies to changes in the client's organization.

If required by the applicable certification scheme, TSC shall notify the client of significant changes in the certification scheme.

B2-6.2 The client shall satisfy all TCVVR requirements and supply all information required for auditing.

The client shall notify TSC immediately, but no later than after one (1) month or within a shorter period expressly specified by the respective certification scheme, in text form of all relevant changes in their management system, of any modifications in their organization or any other significant events that affect the management system or its compliance with the requirements for any of the certifications.



These changes may concern, among others (the following list is not exhaustive):

- legal or organizational status;
- commercial status, ownership or possession;
- organization and/or management (including individual changes in key staff);
- contact address and site addresses;
- scope of operations under the certified management system;
- major changes to the management system and processes including planned changes.

In addition, the client shall document internal and external complaints relating to the management system and the corrective action taken and provide such information during the audit.

Despite the fact that as a rule, TSC notifies the client of due surveillance/recertification audits, the client is also responsible to request such audits to maintain the validity of the certificate at least three (3) months before they become due within the 12-month cycle.

- B2-6.3 Changes in the underlying normative documents shall apply, considering any transition periods.
- B2-6.4 Integrated management systems shall allow specific aspects of the individual systems to be identified.



Module C1 **Special terms and conditions for EU Notified Bodies in the medical device field and for TÜV SÜD Product Service GmbH (TÜV SÜD PS) as certification body for quality management systems according to ISO 13485**

These terms and conditions supplement or amend Modules A and B1 and B2 as follows:

The regulations according to this section apply to the entire conformity assessment activities of TSC as an EU Notified Body in the field of medical devices as well as to certifications of quality management systems according to ISO 13485 by TÜV SÜD PS.

Any law and regulations exceeding the provisions of this TCVVR (e. g. for certificates as per EU Directives and EU Regulations) including other normative Documents remain unaffected.

C1 -> A **Module A**

C1-1. -> A-1.7 is supplemented as follows:

All documentation for conformity assessment shall be provided in English and/or in German.

It's the client's obligation to provide TSC with current contact details (address, contact person, fax, e-mail) and to inform TSC without undue delay of any changes in respect. Any notice successfully sent by TSC to the last contact details provided by the client shall be deemed to have been received at the time at which it can normally be expected to be taken note of.

The obligations of the client in accordance with A-1.7 must in the area of medical devices be contractually secured by the client (e.g. technical / quality agreements) and proven to TSC upon request.

Within the scope of audits, TSC may inspect and test recently produced suitable samples (preferably from the continuous manufacturing process) at the client's expense.

Transport, insurance, logistics, customs etc. of the sample(s) to TSC shall be arranged by, and at the expense of, the client.

If visas are needed for unannounced audits, the certificate holder shall provide TSC with invitations to visit critical subcontractors or suppliers (invitations which leave the date of signature and the date of visit blank to be filled in at a later date by TSC).

C1-2. The client is obliged to inform TSC immediately of significant matters that may affect compliance with the terms of the certification.



In the case of planned significant changes to an approved medical device or significant changes to the quality management system, the TSC must be informed immediately. Furthermore, the client is prohibited from implementing significant changes without prior approval by the TSC. All information relating to planned significant changes submitted to the TSC shall be appropriately relevant and defined. The TSC may ask for further information regarding these changes at any time. Depending on the conformity assessment procedure and applicable regulatory requirements, the relevant information obligations on the part of manufacturers shall be observed.

Planned changes to the approved device require, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, the prior approval by TSC before implementation by the client (see e.g. MDR Annex IX 4.10, IVDR Annex IX 4.11).

The client shall in the scope of MDR and IVDR: Inform the TSC as Notified Body without undue delay of every relevant vigilance information, in particular manufacturer incident report (MIR), field safety corrective action, field safety notice, periodic summary report, trend report. In case of recalls or other field safety corrective action, the client shall provide the Notified Body with a risk analysis in each case at the same time as the national competent authority. In addition, the client is obliged to provide the TSC with a final vigilance report.

C1-3. -> A-2.2 is supplemented as follows:

For conformity assessment procedures according to MDR/IVDR (or pre-regulation MDD, AIMDD, IVDD), the statutory regulation applies in addition. According to this, the following applies:

Where the TSC finds that the requirements of normative documents are no longer met by the client, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any restrictions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the client within an appropriate deadline set by the TSC. The TSC shall give the reasons for its decision (see e.g. Art. 56 (4) MDR, Art. 51 (4) IVDR oder Art. 16 (6) MDD).

C1-4. -> A-2.2.2.1 is supplemented as follows:

The remedy period requirement in A-2.2.2.1 is also met if an opportunity for comment (hearing) is granted and a hearing period has elapsed unsuccessfully before a decision is made by the TSC. The hearing period will normally be 14 days after notification in text form. Irrespective of this, another reasonable period of time may be determined by the TSC in individual cases.

Furthermore, good cause for withdrawal of a certificate according to A-2.2.2.1 a) exists in particular if the medical device has been based on an incorrect assessment according to the provisions of the certification procedure which would prevent certification, in particular if devices have been assigned by the manufacturer to an incorrect risk class according to the applicable EU Directive and EU Regulation on which the conformity assessment procedure is based.

- C1-5. In the German version it is clarified here that, due to the specific diction of the Medical Device Regulation, in this context the German term “Widerruf” is used for withdrawal instead of the German term “Zurückziehung”, which is otherwise used in the TCVVR for withdrawal.
- C1-6. The TSC fulfils its legal information obligations as a Notified Body in connection with changes of status as well as refusal of a certificate (see Art. 56 para. 5 MDR / 51 para. 5 IVDR).
- C1-7. -> A-1.12 paragraph 9 is supplemented as follows:
Medical devices that no longer have a valid certificate are with immediate effect no longer to be labelled and placed on the market with the CE marking and the TSC identification number.
- C1-8. -> A-5. paragraph 1 is supplemented as follows:
The retention period of fifteen (15) years (instead of ten (10) years otherwise) applies to implantable medical devices in accordance with the statutory regulation.
- C1 -> B1 Module B1**
- C1-9. -> B1-1.1 is replaced as follows:
The client shall commission TSC with testing, and supply TSC with the necessary test samples, including pertinent documentation, free of shipping charges. TSC shall perform testing in-house in its laboratory or, following notification of the client (in text form), externally, and prepare a report.
- C1-10. -> B1-2.7 is not applicable.



C1 -> B2 Module B2

C1-11. -> B2-4 is not applicable.

C1-12. -> B2-5.3 is supplemented as follows:

QM Certificates issued under EU Directives/Regulations (for quality management systems) are valid for a maximum of five (5) years, as far as the regularly required surveillance audits (at least on annual basis) are carried out at the company with positive results.

For the maintenance and renewal of such certificates periodic performance of an audit as recertification audit (with regard to content and duration) is necessary at least every 5 years.

C1-13. -> B2-5.8 second paragraph is not applicable.

C1-14. -> B2-6.2 last paragraph is supplemented as follows:

For certificates in the sense of C1-12 above, the application for renewal/recertification by the client in the scope of the MDR and IVDR shall be submitted at least nine (9) months before the expiry of the certificate. For implantable medical devices of class IIb and class III at the latest twelve (12) months before expiry.