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 TCVVR 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 B3 Special terms and conditions for certification of persons

B3-1. The client shall commission TSC to perform assessment and certification according to a scheme and provide all required information. TSC reviews the application to make sure that the applicant meets the requirements for the certification scheme.

B3-2. TSC shall perform the assessment at its own discretion or consider other bodies' assessments if deemed equivalent within the framework of the certification scheme.

B3-3. The client shall be obligated to fulfill the examination requirements and relevant conditions of the applicable scheme (such as regarding re-certification, suspension or withdrawal of certification).

B3-4. TSC shall perform examination of the person to be certified and may make the results of this examination available to authorized bodies (such as public authorities, accreditation bodies or scheme owners). Any conflicting agreement shall be invalid.

B3-5. TSC shall assess the results and conclusions regarding certification according to the applicable scheme and issue a certificate to all certified persons, which shall take the form of a letter, card or other medium. The certificate shall contain the information according to ISO/IEC 17024:2012, 9.4.8.

B3-6. When the first certificate is issued, the client automatically becomes a partner in the TÜV SÜD certification system and remains a partner as long as at least one certificate is valid. The re-certification period shall be determined according to ISO/IEC 17024:2012, 9.6.3.

B3-7. The certified person shall make claims regarding certification only with respect to the scope for which certification has been granted. The certified person shall not use the certification in such a manner as to bring TSC into disrepute, and shall not make any statement regarding the certification which TSC considers misleading or unauthorized. Certificates shall not be used in a misleading manner.

B3-8. If certification is suspended, the certified person shall refrain from further promotion of the certification while it is suspended. If certification is withdrawn, the certified person shall return any certificates issued by TSC and refrain from use of any references to certified status, and specifically to TSC.

B3-9. For re-certification in accordance with the scheme applied, TSC shall confirm continued competence of the certified person and ongoing compliance with current scheme requirements by the certified person. In accordance with the certification scheme, TSC shall consider at least the following:

- on-site assessment;
- professional development;
- structured interviews;
- confirmation of continuing satisfactory work and work experience records;
- examination;
- checks on physical capability in relation to the competence concerned.

Module B4 Special terms and conditions for validation and verification of information (claims)

B4-1. The client shall commission TSC with the validation or verification of a claim according to a programme and provide all required information, including their own results or results generated by external parties, which TSC should take into account as part of its validation/verification activities. TSC shall, at its own discretion, perform a pre-engagement review of the information received from the client before concluding the agreement on the provision of validation/verification activities. For this, TSC may conclude a separate agreement with the client.

B4-2. Depending on the result of the pre-engagement review, TSC either declines to perform validation or verification or concludes an agreement with the client on validation or verification of a claim within its scope in accordance with the programme to be applied.

B4-3.- The client shall be obligated to fulfill the requirements of the applicable programme and make all necessary arrangements for the conduct of the validation/verification, including provisions for examining documentation and access to all relevant processes, areas, records, and personnel and to accommodate the presence of observers. If the programme provides for unannounced validation/verification activities, the client is required to make the necessary arrangements for this.

B4-4. TSC shall prepare a plan for conducting validation/verification on site and using other procedures (e.g. remote methods) and shall communicate it to the client including any revisions deemed necessary in the course of the activities.

B4-5. TSC shall review the results and conclusions regarding confirmation of the validated/verified claim and issue a validation/verification statement in the form of an attestation of conformity according to the programme applied. The validation/verification statement reflects only the situation at the time it is issued and is not issued with a defined period of validity. Therefore, no regular surveillance activities to maintain the validity of the one-time statement will take place. The validation/verification statement shall contain the information according to ISO/IEC 17029.

B4-6. The client shall be obligated to immediately communicate to TSC new facts or information that have been discovered after the validation/verification statement has been issued and that could materially affect it. Should TSC become aware of such new facts or information, it may notify the authorized bodies (e.g. public authorities, programme owners, other interested parties).

B4-7. If a validation/verification statement becomes invalid as a result of new facts or information, TSC shall be authorized to take action, including repeating relevant steps of the validation/verification performed, revision, withdrawal or revocation of the statement.

B4-8. Unless the programme specifies otherwise, TSC communicates the status of a specific validation/verification statement upon request (such as “confirmed”, “not confirmed” or the applicable level of assurance, such as “reasonable level of assurance”).

B4-9. The client shall not refer to a validation/verification statement issued by TSC in a manner that is misleading with regard to the statement of conformity or the scope of the validation/verification or that appears to be a product certification.

B4-10. For issuing a mark of conformity for validated/verified claims, the following requirements apply:

- performance of validation/verification by TSC as a third-party activity;
- confirmation of conformity of the claim to be validated/verified with the requirements defined with a reasonable level of assurance and no limitations;
- identification of the issue date of the validation/verification statement;
- contractual commitment of the client to the application of a programme providing for regularly recurring validation/verification or contractually agreed lines of communication and enforceable actions in the event of new facts or information that are discovered after the validation/verification statement is issued and could materially affect it.

B4-11. Only marks of conformity as included in the respective validation/verification statement and in conjunction with the validated/verified claim shall be used.

B4-12. The client shall be responsible for controlling the use of the mark of conformity and ensure that the mark of conformity is only used in conjunction with the client’s identity and the specific validated/verified claim.

B4-13. If the validation/verification statement is revised, withdrawn or revoked, or at the end of the period defined by the programme, or after one (1) year at the latest, a mark of conformity issued in conjunction with the specific validated/verified claim shall no longer be used. Marks of conformity already affixed shall be removed or made permanently unrecognizable.

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.

Module C2 Special terms and conditions for services by TÜV SÜD Management Service GmbH (TÜV SÜD MS)

These special terms and conditions (Module C2) supplement or amend Modules A and B as follows.

The following modules of the TCVVR apply to TÜV SÜD MS services. In the event of conflict, the following order of precedence is applied to the modules:

- Module C2 – Special terms and conditions for services by TÜV SÜD MS
- Module B2 – Special terms and conditions for management system auditing and certification
- for product certification, in addition, Module B1 – Special terms and conditions for product testing and certification
- for validation and verification, in addition, Module B4 – Special terms and conditions for validation and verification of information (claims)
- Module A – General terms and conditions

Clients are bound by the requirements specified in the underlying standards and by the accreditation bodies and/or scheme/standard owners. Clients shall obtain information on these requirements and any changes implemented by the scheme/standard owner.

The key requirements (with no claim to completeness) will be made accessible to clients on the following website http://www.tuvsud.com/ms-gtc-tcvvr.

C2-1. -> A-3. Use of marks of conformity, logos or other protected marks of scheme/standard owners

In as far as the respective scheme/standard owner expressly permits use of its marks of conformity, logos or other protected marks, the client shall consult the guidelines on their use and strictly observe them. The client shall be solely responsible for correct use. TÜV SÜD MS expressly grants no rights to marks of conformity, logos or other protected marks of the scheme/standard owner.

C2-2. -> A-4. Disclosure of information to/by accreditation bodies, public authorities or scheme owners

Accreditation bodies, public authorities, or scheme owners are authorized to publish certain certification-related information, such as the name of the client, the scope and the certification status, on their websites, databases or platforms.

Accreditation bodies, public authorities, or scheme owners are also authorized to disclose certain certification-related information if this is required for recognition of the standard by a third party, such as Deutsche Akkreditierungsstelle (DAkkS) or the Global Food Safety Initiative (GFSI). The same applies where such disclosure is required by the applicable standard or a public authority, for example.

C2-3. -> A-1.8, B2-6.1
Complaints/appeals

In addition to A-1.8 and B2-6.1, the following applies to services by TÜV SÜD MS:

Complaints and appeals regarding TÜV SÜD MS testing, certifications, validations/verifications can be submitted using the following online form: http://www.tuvsud.com/en-ms-feedback.

C2-4. Additional special terms and conditions apply to the services referred to:

C2-4.1 -> B2-6.2 Information obligations for clients holding occupational health and safety certification

In addition to the information obligations set forth in B2-6.2 TCVVR, holders of occupational health and safety (OHS) management system certifications (in particular according to ISO 45001) shall notify TÜV SÜD MS's certification body of any serious incidents or violations of OHS regulations that require the involvement of the competent authority. Such notification shall be made without delay, but within three (3) working days at the latest (unless individual standards provide for shorter periods) in text form (by e-mail to MS-PCM-SMS@tuvsud.com).

C2-4.2 -> B2-6.2 Information obligations for clients holding food / feed certification

In addition to the information obligations set forth in B2-6.2 TCVVR, the client shall notify TÜV SÜD MS's certification body of any circumstances that may affect the validity of certification. Such notification shall be made without delay, but within three (3) calendar days at the latest (unless individual standards provide for shorter periods) by e-mail to FoodAlarm@tuvsud.com. Such circumstances particularly include product recalls and/or regulatory and/or legal proceedings in the area of product safety or other legal issues.

C2-4.3 -> B2-6.2, C2-4.2
Information obligations for clients holding GMP+ certification

With respect to the GMP+ standard, the following shall also be observed:

In the event of signals or perceived facts relating to feed which affect feed and/or food safety, such as exceeding the maximum permitted levels of undesirable substances or other nonconformities or irregularities with regard to aspects of feed safety beyond the control of the participant and having potential consequences for other businesses, the client shall send an EWS (Early Warning System) report to TÜV SÜD MS (by e-mail to FoodAlarm@tuvsud.com) and GMP+ International (using the EWS reporting form on the website www.gmp-plus.org or by e-mail to ews@gmpplus.org) within twelve (12) hours after confirmation of the contamination.

C2-4.4 -> B2-6.2, C2-4.2
Information obligations for clients holding FAMI-QS certification

With respect to the FAMI-QS standard, the following additional requirements apply:

In the event of a (suspected) feed safety incident, the client shall notify TÜV SÜD MS (by e-mail to FoodAlarm@tuvsud.com), and also the FAMI-QS Secretariat by e-mail to notification@fami-qs.org, using the reporting form intended for this purpose.

C2-4.5 **Assessment of compliance with approval-related requirements as set forth in Regulation (EU) No 2018/858, Regulation (EU) No 167/2013, Regulation (EU) No 168/2013, the 1958 UNECE Agreement and the German regulation for authorization of vehicles for road traffic (StVZO) within the framework of the type approval procedure at the Federal Motor Transport Authority (KBA)**

With respect to the KBA standard, the following additional requirements apply:

TÜV SÜD MS may notify KBA of the relevant content/results of each procedure. This includes information on, among others:

- issue, reductions (time or content), changes, suspension, expiry, revocation or withdrawal of KBA certificate amendments and/or KBA confirmations of verification;
- major nonconformities regarding approval-related requirements at the audited client, unless the audited client implements effective and adequate corrections and corrective actions immediately;
- final refusal of KBA certificate amendment and/or KBA confirmation of verification.

C2-4.6 **Certification in accordance with the Accreditation and Approval Regulation for Employment Promotion (Akkreditierungs- und Zulassungsverordnung Arbeitsförderung, AZAV)**

For the approval of individual courses and seminars, the requirements for product certification according to B1 TCVVR and ISO/IEC 17065 are also binding.

Module C3 **Special terms and conditions for certification by TUV SUD BABT Unltd. (TUV SUD BABT)**

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

In the context of UKCA certification by TUV SUD BABT, any references to EU Directives, EU Regulations and the CE marking in Modules A, B1 and B2 shall be replaced with UK regulations and the UKCA marking.

C3 -> A **Module A**

C3-1. -> A-1.3 The first paragraph of A-1.3 is supplemented as follows:

An order is deemed to be a completed TUV SUD BABT application form.

C3-2. -> A-1.17 The following provisions are inserted as an additional paragraph A- 1.17:

The client shall notify TUV SUD BABT immediately of any safety-related corrective actions and notices associated with the design and/or manufacturing of the relevant product applicable to products bearing the identification number CE 0168.

The client shall notify TUV SUD BABT immediately of any incidents associated with products bearing the identification number CE 0168 which pose a severe risk to public health or safety and where the incident may affect device certification.

C3-3. -> A-2.6 The following provisions are inserted as an additional paragraph A- 2.6:

Where a certificate is withdrawn without the holder's consent, TUV SUD BABT shall immediately notify the holder.

C3-4. -> A-3.1 is supplemented as follows:

Any TUV SUD BABT certificate holder shall follow the rules and requirements for the use of TUV SUD BABT certification marks as specified in these fundamental TCVVR.

C3-5. -> A-1.18 The following provisions are inserted as an additional paragraph A- 1.18:

The client or their UK Responsible person shall, without undue delay:

- inform the TUV SUD BABT of all relevant vigilance incident information, in particular manufacturer incident report (MIR), field safety corrective action, field safety notice, periodic summary report and trend report;

- provide TUV SUD BABT with a risk analysis for every field safety corrective action at the same time as he has provided it to the national competent authority;
- provide TUV SUD BABT with a final vigilance report;
- inform TUV SUD BABT of any limit or prohibition imposed by any regulator on the use or marketing of a device certified by TUV SUD BABT.

C3-6. -> A-1.7 For medical devices certification, the following provisions are inserted after the first section:

All documentation for conformity assessment shall be provided in English.

C3-7. -> A-5 For medical devices certification, the following provision replaces A- 5:

Document retention periods:

For non-implantable medical devices, the TUV SUD BABT certificate holder shall retain documents pertaining to the certified system or product for the expected lifetime of the device or at least ten (10) years, after the last product has been manufactured (for when the expected lifetime of the device is less than ten (10) years).

For implantable medical devices, the TUV SUD BABT certificate holder shall retain documents pertaining to the certified system or product for the expected lifetime of the device or at least 15 years, after the last product has been manufactured (for when the expected lifetime of the device is less than 15 years).

C3 -> B1 Module B1

C3-8. -> B1-1.2 is replaced as follows:

The client shall

- provide technical documentation appropriate to the particular certification procedure to enable conformity assessment of the test samples with the standards to be used for evaluation;
- send, upon request and free of charge, to the certification body representative test samples of the certifiable products from manufacturing for which the client has applied for a certificate, or shall otherwise make these samples available to TUV SUD BABT for the purpose of examination and testing.

Where TUV SUD BABT is satisfied that all the requirements of the testing and certification and the appropriate standards are met, TUV SUD BABT shall issue a certificate.

Except where specified elsewhere in this document, clauses of B1 only apply to product certification that includes issuing a TSC certification mark (such as “BABT approved” or the BABT tick marks).

C3-9. -> B1-2.7 Is not applicable for medical devices certification.

C3-10. -> B1-2.4 For medical devices certification, is supplemented as follows:

QM Certificates issued under UK Medical Devices 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 re-certification audit (with regard to content and duration) is necessary at least every five (5) years.

C3-11. -> B1-2.4 For medical devices certification, is supplemented as follows:

TSC shall be entitled to carry out audits at short notice and unannounced audits at the expense of the certificate holder.

Unannounced audits may be conducted without specific cause and do not substitute a regular audit.

Unannounced audits can also be carried out on the company premises of critical subcontractors and/or a critical supplier.

The certificate holder must contract with its critical subcontractors and/or critical suppliers along the supply chain to ensure that TSC has access to the premises of the respective companies at all times.

Within the context of such unannounced audits, but also during surveillance audits, TUV SUD BABT may check and test recently produced adequate samples, preferably taken from the ongoing manufacturing process at the expense of the certificate holder.

Transport, insurance, logistics, customs etc. of the samples to TSC shall be arranged by, and at the expense of, the certificate holder.

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

C3-12. -> B2-5.8 For medical devices certification, second paragraph is not applicable.

C3-13. For medical devices certification, Module B is supplemented as follows:

TUV SUD BABT must be informed in due time of any planned change to the approved device type or of its intended purpose and conditions of use. Additionally, TUV SUD BABT must be informed about planned changes that could affect the safety and performance of the device or the conditions prescribed for use of the device. The manufacturer shall also inform TUV SUD BABT of any planned change with respect to an ancillary substance incorporated in a device, in particular related to its manufacturing process.

In cases where the manufacturer uses derivatives of tissues or cells of human origin the manufacturer must notify TUV SUD BABT about any planned change with respect to non-viable tissues or cells of human origin or their derivatives incorporated in a device, in particular relating to their donation, testing, or procurement.

All information related to any planned change submitted to TUV SUD BABT must be adequately relevant and specified. TUV SUD BABT is entitled to ask for additional information relating to such change at any time.

C3-14. For medical devices certification, Module B is supplemented as follows:

The manufacturer shall inform in due time TUV SUD BABT of any plan for relevant changes to the quality management system. All information related to any planned change must be adequately relevant and specified. TUV SUD BABT is entitled to ask for additional information relating to such changes at any time.

Module C4 **Special terms and conditions for product testing and certification by TÜV SÜD America Inc. (TÜV SÜD America)**

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

C4 -> A **Module A**

C4-1. -> A-1.10 is supplemented as follows:

Clients may escalate appeals to the Standards Council of Canada (SCC) if they disagree with the appeal decision made by the TÜV SÜD America certification body regarding conformity with accreditation criteria for SCC accredited product certifications. The Standards Council of Canada (SCC) is the final stage of appeal.

C4 -> B1 **Module B1**

C4-2. -> B1-2.1 is replaced as follows:

In addition to a positive product testing result, the initial visit of the manufacturing site shall not raise any objections. A certificate entitling the holder to use a certification mark shall not be issued until the initial visit has been completed successfully. Continued use of the certification mark shall depend on regular reviews (for follow-up service, see below).

C4-3. -> B1-2.9 The following provisions are inserted as an additional paragraph B1- 2.9:

The following additional provisions apply to the US Environmental Protection Agency (EPA) ENERGY STAR® Program:

C4-3.1 -> B1-2.9.1

Testing results shall be provided to the EPA, if applicable.

C4-3.2 -> B1-2.9.2

Certified products may be subject to testing. Costs associated with procurement, transport and testing of the selected product shall be the sole responsibility of the certificate holder. Samples shall be purchased from the open market unless otherwise agreed with TSC. If requested, the certificate holder shall provide at least three (3) retail outlets where the product can be purchased “off the shelf”. TSC reserves the right to arrange for verification testing at an EPA recognized testing laboratory of its choice. TSC personnel shall conduct or witness any testing that must be performed at the certificate holder’s manufacturing site.

C4-3.3 -> B1-2.9.3

Testing results may be challenged in accordance with the EPA ENERGY STAR® requirements. A representative sample shall be retested at no charge to the certificate holder with the results being reported to the EPA. The certificate holder shall be notified if a challenge of test results is submitted.

C4-4. -> B1-2.10 The following provisions are inserted as an additional paragraph B1- 2.10:

Special regulations for product inspections (field evaluation)

C4-4.1 -> B1-2.10.1

The certificate/mark holder shall document any complaints in connection with the certified/inspected products and take corrective action if the approved product is subsequently found to be nonconforming or hazardous. TSC shall be notified immediately of any changes made to products and of any recalls or safety-related incidents and potential hazards after certification/inspection. If TSC identifies a serious safety issue, the certification/inspection body shall direct the certificate holder to publish a public notice and/or institute a recall for a certified product, or, for an inspected product, block the marked product. TSC shall notify the competent governmental authority if no action is taken.

C4-4.2 -> B1-2.10.2

The mark is only applicable to the individual product inspected and shall not be transferred to another product. The mark is void if removed.

C4-4.3 -> B1-2.10.3

The Standards Council of Canada is the final stage of appeal for Canadian product inspections related to accreditation requirement issues.

Module C5 **Special terms and conditions for TUV SUD PSB Pte Ltd. (TUV SUD PSB)**

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

C5 -> A **Module A**

C5-1. -> A-3.1 is supplemented as follows:

Any TUV SUD PSB certificate holder shall follow the rules and requirements for the use of TUV SUD PSB certification marks further detailing the provisions of these TCVVR.

C5 -> B1 **Module B1**

C5-2. -> B1-1.2 is replaced as follows:

Together with the test order and the test samples, the client shall provide any recent test reports, design and material specifications, and any other relevant supporting documents.

C5 -> B2 **Module B2**

C5-3. -> B2-5.8 The last paragraph of B2-5.8 is replaced as follows:

If nonconformities are identified in the audit that are serious enough to make certification appear unrealistic, even if the appropriate corrective action is taken, TSC shall notify the client of these nonconformities. The client may terminate the certification audit. If the certification audit is terminated, the certification fee shall not be refunded.

Module C6 **Special terms and conditions for TUV SUD South Asia Pvt. Ltd. (TUV SUD South Asia)**

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

C6 -> A **Module A**

C6-1. -> A-2.2 The following provisions are inserted as an additional paragraph A- 2.2:

If the certificate holder does not take appropriate corrective action and undergo on-site correction to resolve major nonconformities, the certificate may be suspended/terminated as of the date of withdrawal or within 180 days from last day of on-site audit whichever comes first (certification/surveillance/repeat, etc.).

C6-2. -> A-1.7 is supplemented as follows:

The accreditation body's terms require surveillance of the on-site audits performed by the certification body's auditors within the framework of witness audits. Sometimes, witness audits are performed by accreditation bodies. The accreditation body or scheme owner selects the client. All certified clients and prospective certification clients shall agree to cooperate with certification and accreditation bodies, the scheme owner or public authorities etc. to perform witness audits.

C6-3. -> A-3.5 is supplemented as follows for further clarification of the TCVVR:

Use of the certification mark for marketing purposes by the certified client shall be in line with TÜV SÜD South Asia's procedure (Use of Certificates and Logo, TSSA_CCU_20), which is available at the certification body.

C6 -> B **Module B**

C6 -> B2 **Module B2**

C6-4. -> B2-1. is supplemented as follows:

Management system audits rely on random sampling. The audit result depends on the quality of the samples selected. The audit does not absolve sites from ensuring that the requirements of the management systems are met in their entirety. Therefore, the audit result does not indicate that individual sites completely fulfill all quality and other requirements.

The number of auditor days and accreditation-related arrangements according to the quotation shall apply subject to the approval of the certification body.

C6-5. -> B2-4. is supplemented as follows:

According to NABCB, TUV SUD South Asia is not authorized to perform pre-audits for any standards. If any kind of pre-audit is conducted for a client, this client cannot be certified for two (2) years from the date of pre-audit.

C6-6. -> B2-5.2.1
is supplemented as follows:

As a rule, in all certification schemes, audits stage 1 are performed on site, if reviewed and agreed with the certification body. For food safety management system stage 1, the review and evaluation of management system documentation necessarily takes place on site.

If nonconformities are identified during the audit that are serious enough to make granting a certificate appear unrealistic, even after reasonable corrective action is taken, TSC shall notify the client of these nonconformities and the client may terminate the certification audit. If the certification audit is terminated, the certification fee shall not be refunded.

C6-7. -> B2-5.4 is supplemented as follows:

Special audits / unannounced audits (for OHSMS):

If TUV SUD South Asia becomes aware of a serious accident or a violation of regulations by the certified organization, a special audit shall be scheduled outside of the normal cycle to investigate if the OHS management system is not compromised and did function effectively.

C6-8. -> B2-5.7 is supplemented as follows:

Repeat audits shall be conducted 60 days ahead of the due date to ensure there is enough time for the client to submit an action plan and for reviewing the report.

C6-9. -> A-4. is supplemented as follows:

The certification body may make information about issued, revoked, withdrawn and suspended certificates available to the public on its website www.tuvsud.com.

Upon request, TUV SUD South Asia shall disclose the current status of the client to interested parties after appropriately investigating their motive. The client shall be notified of this in advance. Any other information, except for information that is made public by the client, shall be considered confidential.

The certification body shall notify the client in writing by e-mail or letter before disclosing any confidential information to an external party.

C6-10. -> B2-7. The following provisions are inserted as an additional paragraph B2- 7:

For integrated management systems, the specific requirements of the individual systems shall be identified and fulfilled.

For QMS, EMS, OHSMS, EnMS, ISMS, FSMS and MDQMS:

Applicable mandatory documents are NABCB criteria and documents of the International Accreditation Forum (IAF): MD 1 (Audit and Certification of a Management System Operated by a Multi-Site Organization), MD 2 (Transfer of Accredited Certification of Management Systems), MD 5 (Audit Time of QMS, EMS and OHSMS), MD 21 (OHSMS) & MD 22 (OHSMS), ISO 50003 (EnMS), ISO/IEC 27006 (ISMS), ISO 22003 (FSMS), MD 11 (Integrated Management Systems), MD 9 (ISO 13485) and other applicable documents.

Module C7 **Special terms and conditions for the area of grid compatibility, certification of power generating units (PGU), systems and storage systems (PGS) as well as for their components according to FGW e.V. Technical Guidelines Part 8 (TG 8) (published by Fördergesellschaft Windenergie, a German public association for the renewable energy sector) at TÜV SÜD Industrie Service GmbH (TÜV SÜD IS) and TÜV SÜD Product Service GmbH (TÜV SÜD PS)**

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

C7 -> A	**Module A**
C7-1. -> A-1.5	A-1.5 I: Not applicable to PGS certification.
C7-2. -> A-1.13	Only applicable to the certification of PGUs and components where a site visit to the manufacturing facility or other sites is required in accordance with FGW e.V. TG 8.
C7-3. -> A-5.	Only applicable to test samples for component certification. Also excluded from retention requirements are large-scale components such as flexible AC transmission systems (FACTS).
C7-4. -> A-6.	Only applicable to PGU and component certification.
C7 -> B	**Module B**
C7-5. -> B1-1.1	The provision of test samples for the certification of PGUs, PGSs and large-scale components will be agreed upon in a separate contract.
C7-6. -> B1-1.2	Only applicable if test samples are tested in a TSC laboratory or a laboratory commissioned by TSC.
C7-7.	The following deadlines shall be observed:
C7-7.1	The certification body shall be notified immediately and in textform within three (3) months of any change in the company name of the PGU manufacturer.
C7-7.2	Any change of the holder of the PGS certificate shall be submitted to the certification body in textform within three (3) months.
C7-7.3	Any modifications and additions to components affecting the certified characteristics of the power generating units, systems and storage systems shall be submitted to the certification body in textform within three (3) months. The certification body will then initiate an event-driven inspection in accordance with FGW e.V. TG 8.

C7-7.4 Any modifications to PGU and component simulation models affecting the certified characteristics of the power generating units, systems and storage units shall be submitted to the certification body in writing within three (3) months. The certification body will then initiate an event-driven inspection in accordance with FGW e.V. TG 8.

C7-7.5 Any modifications and additions to the software used that affect the certified characteristics of the power generating units, systems, storage units and components, and the associated changes in the software versions, irrespective of whether these changes represent a software revision, release, or update, shall be submitted to the certification body in writing within three (3) months. The certification body will then initiate an event-driven inspection in accordance with FGW e.V. TG 8.

C7-7.6 Confirmation by the certificate holder that there have been no modifications to the hardware and software or the PGU and component models and that no nonconformities regarding the performance of the PGUs/components were identified shall be submitted to the certification body in writing within three (3) months of the certification body's request as part of the scheduled surveillance every 18 months.

C7-7.7 Within three (3) months of the declaration of conformity being issued, the certificate holder shall submit to the certification body a legally enforceable written confirmation that the declaration of conformity for the PGS was issued.

Testing, Certification, Validation/Verification Regulations – TÜV SÜD Group

Glossary
2023-08-07

The terms and definitions given in ISO/IEC 17000; in addition and especially the following apply.

Fundamentals	
conformity assessment	demonstration that specified requirements are fulfilled Note: Conformity assessment follows a specified process (functional approach), which always includes a decision on conformity of the assessed object as conclusion based on the assessment results. The decision can be negative, i.e. the outcome of conformity assessment can be a statement that the specified requirements are not fulfilled. Results of individual activities, that are conducted in context of conformity assessment (e.g. testing, inspection, auditing) but do not contain a decision on conformity, can be issued (e.g. as analysis, audit report, test report, inspection report) without a statement of conformity.
object of conformity assessment	entity to which specified requirements apply Note: Examples for objects of conformity assessment are products, processes, services, systems, management systems, installations, facilities, projects, data, designs, materials, claims, persons, organisations, or any combination thereof.
normative documents	statement of specified requirements that apply to a specific object of conformity assessment Note: Normative documents can be, e.g., EU harmonisation legislation, laws, directives, standards, technical specifications, which contain specifications of detailed or general requirements. Certificates and attestations of conformity refer to the respective version of the normative documents taken as basis. This version can differ from the actual edition of the normative documents.
scheme, programme	set of rules and procedures that (i) describes the object of conformity assessment, (ii) identifies the specified requirements, and (iii) provides the methodology for performing conformity assessment Note: A person or organisation is responsible as scheme owner for development and maintenance of certification schemes or validation/verification programmes. A conformity assessment scheme can be managed within a conformity assessment system, which sets rules and procedures for the management of similar or related schemes.

	Schemes and systems can be operated at international, regional, national, sub-national, or industry sector level. The EU Legislative Framework (s. Regulation No 765/2008, Decision No 768/2008/EG, Blue Guide) provides various conformity assessment procedures, which are implemented in Directives and Regulations. These “modules” are based on the standards series ISO/IEC 17000 and vary from internal control of production, for simple products or products not necessarily presenting serious risks, to the most comprehensive module (full quality assurance with EU-design examination), where the risks are more severe, or the products and technologies are more complex.
conformity assessment activity	activity to demonstrate that specified requirements are fulfilled by the object of conformity assessment Note: Examples for conformity assessment activities are sampling, laboratory testing, document review, inspection, audit, evaluation, validation, verification, production control, site visits.

Conformity assessment bodies	
conformity assessment body, CAB	legal entity, or part of a legal entity, that performs conformity assessment activities (i.e. testing laboratory, inspection body, certification body, validation or verification body) and, if applicable, issues a statement of conformity
accreditation	third-party attestation related to a conformity assessment body, conveying formal demonstration of its competence, impartiality, and consistent operation in performing specific conformity assessment activities
accreditation body	authoritative body that performs accreditation Note: Within the EU, the authority of the national accreditation body is derived from government.
notified body	conformity assessment body designated by public authority to conduct specified conformity assessment activities Note: Designation is considered as an act of the designating authority, which can be the same body as the notifying authority. Only the act of notifying the EU Commission and the other Member States allows a “designated body” to become a “notified body”. A notifying authority is the governmental or public body that is tasked with designating and notifying conformity assessment bodies under Union harmonisation legislation.
entrusted body	legal entity, on which the authority to independently assume public responsibilities outside governmental administration has been transferred
testing laboratory	body that performs testing activities Note: Sampling, associated with subsequent testing, can be included in the performed activities.

certification body	conformity assessment body that issues statements of conformity independently from the provider of the object of certification and with no user interest in the object (third party) Note: Objects of certification can be products, processes, systems, services, persons, or management systems.
validation body	conformity assessment body that confirms claims (information, data, reports, declarations etc.) as plausible for a specific intended future use or application and issues a validation statement whether all specified requirements have been fulfilled
verification body	conformity assessment body that confirms claims (information, data, reports, declarations etc.) regarding their truthfulness and issues a verification statement whether all specified requirements have been fulfilled

Results of conformity assessment	
statement of conformity	statement, based on a decision on the conformity of an object of conformity assessment, that fulfilment of specified requirements has been demonstrated Note: The statement can be issued as certificate or as attestation of conformity.
attestation of conformity	issue of a statement of conformity, which is not outcome of a certification Note: Examples for attestations of conformity are test reports with the statement “test passed” or “test failed”, inspection reports or verification statements.
test report	accurate, clear, unambiguous, and objective provision of test results in a report, which includes agreed with the client and necessary for the interpretation of the results and all information required by the method used Note: Test reports can include a statement of conformity and thereby be an attestation of conformity.
product certification process certification service certification	third-party attestation related to products, processes, and services as objects of conformity assessment Note: A product is the result of a process (e.g. hardware, software, processed materials). A process is a set of interrelated or interacting activities that transforms inputs into outputs (e.g. welding engineering processes, manufacturing processes, food production processes). A service is the result of at least one activity necessarily performed at the interface between the supplier and the customer, which is generally intangible (e.g. repair, income statement for tax declaration, knowledge transmission).

management system certification	third-party attestation related to management systems as objects of conformity assessment Note: A management system is a set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve those objectives.
certification of persons	third-party attestation related to persons as objects of conformity assessment
certificate	issue of a statement based on a decision by a certification body, that fulfilment of specified requirements has been demonstrated for an object of certification Note: Objects of certification can be products, processes, systems, services, management systems, or persons.
termination of certificate	ending of the validity of the certificate, either after a specified period (expiry) or before expiry of a specified period (withdrawal or revocation)
expiry of certificate	ending of the validity of the certificate after a period specified with issue of the certificate Note: In previous versions, this termination of a certificate is also called
withdrawal of certificate	ending of the validity of a certificate through cancellation of the certificate by the certification body that issued the certificate (e.g. if certification requirements are no longer fulfilled or upon request of the client)
revocation of certificate	ending of the validity of a certificate through cancellation of the certificate with retroactive effect by the certification body that issued the certificate
reduction of certificate	temporal limitation of the period of validity or technical limitation (e.g. on conditions) of the scope of a certificate
suspension of certificate	temporary restriction of the certificate as interim measure of protection until either final withdrawal or restoration of the certificate for all or part of the specified scope of attestation
mark of conformity	legally against unauthorized use protected mark issued by a conformity assessment body, indicating that an object of conformity assessment fulfils the applicable specified requirements Note: Marks of conformity that are issued by certification bodies, indicating that an object of certification fulfils the applicable specified requirements, are called “certification marks”. Other marks related to attestations of conformity can be, e.g., “inspection marks” or “verification marks”.
CE marking (fr: Conformité Européenne)	marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in EU harmonisation legislation Note: Depending on the conformity assessment procedure or the respective harmonisation legislation, the CE marking can be used in connection with the number of

	the notified body (e.g. „CE 0123“ for TÜV SÜD Product Service GmbH).

Conformity assessment activities	
testing	determination of one or more characteristics of an object of conformity assessment, according to a procedure Note: The output of testing can include comments (e.g. opinions and interpretations) about the test results and fulfilment of specified requirements. There can be overlap between the use of the terms “testing”, “test”, and “inspection”. The differentiation, however, is crucial for determining the standard applicable to the body performing the activity (e.g. ISO/IEC 17025, 17020 or 17065).
inspection	examination of an object of conformity assessment and determination of its conformity with detailed requirements or, on the basis of professsional judgement, with general requirements Note: There can be overlap between the use of the terms “testing”, “test”, and “inspection”. The differentiation, however, is crucial for determining the standard applicable to the body performing the activity (e.g. ISO/IEC 17025, 17020 or 17065).
audit	process for obtaining relevant information about an object of conformity assessment (e.g. management system, process, service) and evaluating it objectively to determine the extent to which specified requirements are fulfilled Note: Audits can be conducted on site or remotely (i.e. irrespective of the distance at any site except the site of the audited object). A combination of conducting an audit on site and remotely is possible. Audits can be conducted announced or unannounced.
unannounced audit	audit that is conducted without announcement, either planned or event driven
certification audit	audit carried out by a certification body for the purpose of certifying the client’s management system Note: Certification audits include initial, surveillance, re-certification audits, and can also include special audits.
audit programme	arrangements for a set of one or more audits planned for a specific time frame and directed towards a specific purpose Note: The latest possible dates of planned audits, announced and unannounced, are the due dates.
audit plan	description of the activities and arrangements for an audit
validation	confirmation of a claim (information declared by the client), through the provision of objective evidence, that the

	requirements for a specific intended future use or application have been fulfilled Note: Validation is applied to claims regarding an intended future use based on projected information (confirmation of plausibility).
verification	confirmation of a claim (information declared by the client), through the provision of objective evidence, that specified requirements have been fulfilled Note: Verification is applied to claims regarding events that have already occurred or results that have already been obtained (confirmation of truthfulness).

Client relation	
client	legal entity or individual as contractual partner of TSG who is, among other things, responsible for ensuring that the relevant requirements for conformity assessment are fulfilled, including the requirements applicable to the object of conformity assessment Note: Clients can be several persons together as joint debtors. The term “client” includes “applicant” as well as “certificate holder”. In management system certification, the client is the organisation whose management system is audited. In validation/verification, the client is the organisation or person requesting validation. In product certification, the client can be the manufacturer or the importer. In person certification, the client can be the person him- or herself.
critical supplier	supplier of crucial material, components, or services who significantly influence the conformity, safety, or performance of finished products by their activities (e.g. software provider) Note: In the context of the audit of medical device manufacturers, a critical supplier is a supplier of a product or service, the failure of which to meet specified requirements could cause unreasonable risk to the patient, clinician or others, or could cause significant degradation in performance. This can include suppliers of services, which are needed for compliance with quality management system or regulatory requirements, e.g. documentation service providers, internal audit contractors or Authorized Representatives.
appeal	request by the person or organization that provides, or that is, the object of conformity assessment to a conformity assessment body for reconsideration by that body of a decision it has made relating to that object
complaint	expression of dissatisfaction, other than appeal, by any person or organization to a conformity assessment body or an accreditation body, relating to the activities of that body, where a response is expected

text form	readable statement on a permanent data medium that identifies the person making the statement Note: A permanent data medium is any medium that allows for the recipient to store or safe a statement, which is addressed to him or her personally, such that it is accessible for an appropriate period, and that is suitable to reproduce the statement without any changes.