



# Testing and Certification Regulation

## TÜV SÜD Group

### Scope:

This Testing and Certification Regulation (TCR) applies to the TÜV SÜD Group (see [www.tuvsud.com/tcr](http://www.tuvsud.com/tcr)), e.g. the following legal entities:

TÜV SÜD America Inc.  
TÜV SÜD Auto Service GmbH  
TUV SUD BAPT UNLIMITED  
TUV SUD Certification and Testing (China) Co., Ltd.  
TÜV SÜD Czech s.r.o.  
TÜV SÜD Energietechnik GmbH Baden-Württemberg  
TUV SUD Hong Kong Ltd.  
TUV SUD Indonesia (PT. TUV SUD Indonesia)  
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  
TUV SUD PSB Pte. Ltd.  
TÜV SÜD Rail GmbH  
TÜV SÜD SFDK Laboratório de Análise de Produtos Eireli  
TUV SUD South Asia Pvt. Ltd.

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



The Testing and Certification Regulation applies to:

- the testing and/or certification of products, processes, services and projects (hereinafter collectively referred to as products),
- the auditing and certification of management systems (hereinafter referred to as system).

In as far as clients have concluded multiple contracts for obtaining a certificate (separate contract partner(s) for the service contract and the certification contract with the latter being the TSC to which the contract-relevant Certification Bodies is/are affiliated), the provisions of the TCR will apply to the contractual relationship between the “Certification Body TSCs” and the client.

This Testing and Certification Regulation shall replace previous versions. They will become effective on May 1st 2021 and remain valid until a new version is issued.

In case of doubt, the German version shall be authoritative for work related to Certification Bodies according to ISO/IEC 17000ff located in Germany. For all other Certification Bodies, the English version shall be authoritative. Certification Bodies are independent third parties that confirm the conformity of products, processes, services, systems or persons within the scope of certification schemes.

This Testing and Certification Regulation are governed by the law of the country of the TSC which includes the Certification Body relevant for the requested service.

This Testing and Certification Regulation comprise a number of modules; in general module A applies to all TSC; the remaining modules apply as appropriate and may amend, replace or denote as not applicable any regulations in other modules (Module A gets completed by Modules B1/B2. Modules A and B get completed/changed/replaced by the relevant Module C).

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

The full version of the Testing and Certification Regulation covers the Modules A, B1, B2 and C1 to C7.

For certain areas combinations of particular Modules are available.



<b>Contents</b>	<b>Page</b>
Module A) General regulations	4
Module B1) Special regulations for product testing and certification	15
Module B2) Special regulations for management system auditing and certification	20
Module C1) Special regulations and conditions for the field of medical devices by TÜV SÜD Product Service GmbH (TÜV SÜD PS)	26



## Module A) General regulations

### A-1. General

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

The client knows that to ensure independence, impartiality and objectivity, the Certification Body and/or TSC cannot combine the testing and certification services that form the subject matter of the contract with consulting services regarding the subject matter of testing and/or certification.

The client undertakes to inform the Certification Body without delay of any consulting services by TSC or a TSC affiliated company received by the client.

Any jeopardizing of the Certification Body's independence, impartiality and objectivity on the grounds of consulting services will entitle TSC to terminate this contract without notice for important reasons as set forth in Section A-1.8 II.

A-1.2 A certificate only becomes valid after all financial and technical requirements in connection with the test/audit and product/system certification have been fulfilled. If a certificate is awarded subject to certain requirements, the certificate holder undertakes to satisfy these requirements within the defined deadlines. If the requirements are not fulfilled within the defined deadlines, the certificate will be deemed withdrawn on expiry of said deadlines and will have to be returned by the certificate holder to the issuing TSC without delay.

A-1.3 Prior to placing an order, the client shall provide TSC with the name of any other organization that tested/audited/certified the same product or system in a similar way or is in the process of doing so. With each order the client agrees to accept the current version of this Testing and Certification Regulation as part of the contract. Existing contractual relationships are governed by the respectively valid versions of this Testing and Certification Regulation.



TSC reserves the right to make changes to the Testing and Certification Regulation with effect for the future at any time. In this case, TSC will notify the client of these changes. The client has the right to terminate the contractual relations with TSC in text form within one month after receiving the amendment notification. Otherwise the changes to the Testing and Certification Regulation shall be deemed to be accepted by the client.

The currently valid versions of this Testing and Certification Regulation is available at the TSC of the relevant Certification Body or will be provided free of charge on request.

- A-1.4 The Certification Body of the relevant TSC evaluates the documents submitted by the testers/auditors. It decides whether a certificate is to be issued and handles disagreements/appeals concerning certification. Complaints management procedures have been established for each certification process.

Appeals and complaints shall be addressed directly to the Certification Bodies of the respective TSC. The Certification Bodies maintain documented appeals and complaints management procedures. A description of these procedures is made available to the public.

Costs born by the evaluation of such appeals or complaints may be borne by the client.

The Certification Body will forward to the certified clients in question any complaints about certified products or systems received by TSC within an appropriate period of time.

- A-1.5 Certificates, certificates of conformity, test certificates based on EU Directives and EU Regulations, standards or other criteria always relate to the version of the relevant directives, regulations, standards or other criteria valid on the date of issue of the certificate unless otherwise stated on the certificate.

The Certification Body only issues a certificate or other attestation if the product or system at the time of certificate issue fulfills all certification-relevant legal requirements, applicable standards, and other certification-relevant criteria. The date on which the order is placed and/or the contract concluded is irrelevant in this regard.

A certificate or attestation may be issued in hard copy and/or in digital form.

A granted certificate makes no statement concerning the marketability of a certified product unless otherwise stated on the certificate.



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

Certificates only relating to EU Directives and EU Regulations do not entitle the holder to use a TÜV SÜD certification mark unless otherwise stated on the certificate or determined by the certification scheme.

Any CE marking with the number of Notified Body is only allowed, as long as the use is granted by a valid certificate.

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

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

A.-1.8 Each certificate is subject to the existence of a valid certification contract/order.

The certification contract/order may be terminated in whole or in part, if specific regulations of the certification contract/order not define any other periods of notice:

I. by termination **without cause**

- a. for system certifications: with three (3) months notice to the next scheduled audit due date (for the surveillance or the recertification audit respectively) by the certificate holder or TSC.
- b. for product certifications: with two (2) months notice to the end of the respective calendar year.
- c. System certification based on EU Directives and EU Regulations are handled by TSC according to A-1.8 I.a.

II. by termination **for cause**.

A-1.9 If the validity of a certificate ends or if the certificate is revoked, withdrawn or expires irrespective of the reason, the underlying certification contract/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 expiry.



- A-1.10 The expiry of the certification contract/order will not affect any existing claims against the client, e.g. unsettled receivables. All costs and expenses for upcoming surveillance or auditing/testing of the certified system or product already incurred can be claimed.
- A-1.11 The requirements of this Testing and Certification Regulation will apply during the term of the certification contract/order and for three (3) years thereafter (grace period). If only part of the certification contract/order is terminated, the grace period will also apply to the terminated part.
- A-1.12 Should any individual provision of this Testing and Certification Regulation or any part of any provision be or become void or unenforceable, the validity of the remaining Testing and Certification Regulation hereof shall remain unaffected. In such case the void and/or unenforceable provisions shall be replaced by corresponding provisions coming as close as possible to the sense and spirit and purpose of the void and/or unenforceable provision.
- A-1.13 The certificate holder shall ensure that the TSC can audit/inspect the manufacturing facility and other sites specified by the manufacturer as well as critical subcontractors and/or key suppliers and the relevant warehouses of authorized representatives, importers, and branches at any time during regular working hours, including as unannounced audits, at the cost of the certificate holder.

The TSC has the right to take free samples of the certified products for testing to the extent necessary at all of the above sites, including sites owned by parties other than the certificate holder.

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

- A-2.1 A certificate expires automatically or is deemed to be withdrawn if
- A-2.1.1 the indicated period of validity expires or if the contractual basis for use of the certificate and/or certification mark otherwise ceases to apply,
- A-2.1.2 insolvency proceedings are opened over the certificate holder's assets or the opening of such proceedings is refused for lack of assets and the certificate holder fails to inform the responsible Certification Body in writing and within one month of its application for insolvency proceedings,
- A-2.1.3 the certificate holder permanently discontinues business operations without a legal successor,



- A-2.1.4 the requirements (e.g. of a regulatory authority, accreditation body or certification scheme owner, codes of practice etc.) on which the certificate is based have changed and the certificate holder is unable to demonstrate within a defined time period at the certificate holder's expense that the product or system conforms to the new requirements through TSC re-testing or re-auditing,
- A-2.1.5 the underlying (main) certificate becomes invalid,
- A-2.1.6 the certificate holder is obliged to withdraw the product/certified service from the market,
- A-2.1.7 the product or system has been inadvertently assigned to the wrong basis of evaluation under the scheme rules, e.g. an incorrect class as per the relevant EU Directive and EU Regulation on which conformity assessment is based,
- A-2.1.8 defects or nonconformities are detected in the products or systems; products fail to conform to the certified samples or key prerequisites pertaining to the certified product/system are not or no longer fulfilled.
- A-2.2 The Certification Body in the respective TSC is entitled to suspend, withdraw or revoke a certificate at its own discretion with or without notice, in particular if
- A-2.2.1 further use of a certification mark/certificate is no longer justified, i.e. not or no longer meaningful within the market context or is prohibited by law; in such cases, TSC will provide an alternative certification mark, if possible,
- A-2.2.2 the certificate holder engages in, initiates or tolerates
- misleading or otherwise unacceptable advertising, in particular with the certification mark, the certificate or the test report,
  - misuse of certificates, certification marks or test reports, or
  - violation of legal provisions when marketing a product tested by a TSC.
- A-2.2.3 the certificate holder fails to pay outstanding invoices within 4 weeks to TSC, despite receiving reminders in text form to that effect,
- A-2.2.4 the certificate holder files for insolvency or similar proceedings under foreign law outside of Germany or the opening of such proceeding is rejected for lack of assets,





A-2.2.5 the certificate holder violates this Testing and Certification Regulation and/or the related part of the contract/order, unless such violation is insignificant in nature or represents only minor negligence,

TSC is entitled but under no obligation to grant the certificate holder a period of grace to remedy the violation.

A-2.2.6 the relevant Certification Body forms the opinion that

- the certified product or system does not or no longer comply or no longer complies with the underlying certification requirements or standards, or
- fails to fulfill its purpose as defined by the manufacturer, or
- is exposing users, operators or third parties to considerable risks, or
- fails to adapt the product or system to the applicable version of the relevant standard or certification requirement within the period of time allowed to the certificate holder by the Certification Body; or
- the certificate holder is in violation of any certification-related conditions/obligations.

A-2.2.7 the certificate holder makes incorrect statements to TSC or withholds from TSC important facts that are relevant for certification,

A-2.2.8 it becomes evident after certificate issue that the certificate holder failed to fulfill the certification requirements from the outset,

A-2.2.9 the certificate holder objects to changes in this Testing and Certification Regulation and/or a relevant part of the contract/order (e.g. the relevant current rates and fees) within a 6-week period of appeal after such amendments have come into effect,

A-2.2.10 inspection or auditing of facilities or product testing is not made possible or the products or documents are not made available within the specified time. This also applies if follow-up-services, surveillance measures or audits cannot be carried out within a timeframe of 4 weeks (unless otherwise specified by the Certification Body) despite a text form request to this effect or if nonconformities are not eliminated within the agreed period through appropriate corrective actions.

A-2.3 Certificates can also, be restricted or suspended with regards to time and content for the reasons noted above (A-2.1 and A-2.2).



A-2.4 The Certification Body of the respective TSC is entitled to publish details of the expiry, withdrawal, revocation, restriction, and suspension of a certificate. Continued advertising or other use of the certificate/certification mark or the name of TSC is prohibited in all such cases. A certificate that has expired, has been withdrawn, or has been revoked shall immediately be returned to the Certification Body and/or destroyed or, if being a digital certificate, permanently deleted upon the Certification Body's request.

License fees paid in advance shall not be reimbursed; those not yet paid shall be paid in full.

A-2.5 Apart from cases of willful intention and gross negligence, TSC shall not be liable for any disadvantages arising for the client from non-issue, expiry, withdrawal, revocation, restriction, or suspension of a certificate.

### **A-3. Use of certificates, certification marks and test reports in business transactions**

#### **A-3.1 Granting rights of use**

During their certificates' terms of validity clients are entitled to use their certificates in their business transactions as set forth in this Testing and Certification Regulation. If the respective certification criteria and procedures provides for the issue of a certification mark, clients will also be granted the limited, non-exclusive right to use the certification mark in their business transactions and in particular their advertising during the period of validity of the underlying certificate. In this context, clients may only use the certification mark assigned to the respective certification. The right of use will expire on expiry, withdrawal, revocation, restriction or suspension of the underlying certificate.

#### **A-3.2 Terms of use of certification marks and certificates**

A-3.2.1 Certification marks and certificates shall not be misused or used in a misleading manner that may jeopardize the trust of the public in the TSC's certification marks or certificates. Certification marks and certificates shall only be used in unchanged form; in particular, they shall not be modified in content by adding, deleting, or covering by shades or watermarks. The role of the TSC as an independent third party shall not be compromised by the use and visual presentation of certification marks.

A-3.2.2 A certificate or a certification mark referring to a management system may only be used to promote the system concerned. A product certificate or product certification mark (in as far as a certification mark is approved) may only be used to promote the certified product as described on the certificate.



The use of certificates and/or certification marks must not give the impression of certification applying to activities outside the scope of certification.

- A-3.2.3 Product-related advertising using a certification mark is not permissible in cases where only a certificate of conformity or management system certificate has been issued.
- A-3.2.4 Where certification marks or certificates refer only to certain partial aspects of a product or system, advertising must not give the impression of certification of the entire product or system.
- A-3.2.5 Full responsibility for correct use of the certificate and/or certification mark and for the correctness of all statements about the certified system/product rests with the certificate holder. In the case of product certification this also applies to correct use/advertising by the customers of the certificate holder.
- A-3.2.6 It is recommended that clients, when using certification marks and certificates in their advertising, take steps to ensure that the target groups addressed by advertising can inform themselves easily, adequately and transparently of the content of the TSC services underlying the certification marks or certificates.

### **A-3.3 Requirements regarding the visual presentation of certification marks**

- A-3.3.1 Clients may use certification marks only and may under no circumstances use the TÜV SÜD logo ("TÜV SÜD – Octagon", logo see headline) or the slogan of the TÜV SÜD Group (at present: "Add Value, Inspire Trust.").
- A-3.3.2 Neither the content nor the design of the certification mark provided by TSC may be changed. It must be recognizable as certification mark and its size must be clearly smaller than that of the company logo of the client/certificate holder. The information included in the certification mark must be clearly legible even if the certification mark is displayed at reduced size.
- A-3.3.3 The certification mark must stand alone and may not be associated or combined with any other element (e.g. the client's company logo, statement, or graphics). The use of the certification mark in particular must not give the impression that the client/certificate holder or its employees are members of the TÜV SÜD Group or that the certification mark is the client's trademark/customer logo. Certification marks shall not be used in a non venerable manner.



#### **A.3.4 Use of TSC test reports**

Unless expressly approved beforehand in text form by the relevant Certification Body/relevant TSC or where use of the report is an integral part of the underlying certification procedure or disclosure is required on the basis of legal, regulatory or accreditation-related requirements, the following shall apply:

Reports by TSC may not be published/reproduced in part or in full in particular for advertising purposes.

If test reports, audit reports or other reports are used with the approval of the TSC, the client shall not complement said reports by adding any statements or interpretations that go beyond the reports' actual contents. In particular, clients shall not add any distorting or misleading statements or interpretations that could give rise to doubts in the impartiality of TÜV SÜD. Clients must ensure at all times that the test results of the TSC are reproduced correctly and not distorted.

The same applies to communication activities, advertisements, confirmations, communications, sales collaterals etc in digital, audio and print media.

In cases in use of the reports prepared by TSC is approved, said reports may only be quoted verbatim and with their complete wording, giving the date of issue.

TSC reports may never be used to claim or imply that TSC particularly recommends the product or system to customers.

#### **A-3.5 Information obligation before press publications**

If the customer plans to mention a TSC or a TSC testing and/or certification in a press release, in particular in a professional articles and social media posts, the press office of the TÜV SÜD AG ([presse@tuvsud.com](mailto:presse@tuvsud.com)) shall be informed about it in time.

This shall not replace a necessary prior consent of TSC.

#### **A-3.6 Consequences of impermissible use**

The client undertakes to indemnify TSC or the respective TSC Certification Body at first request against all claims by third parties arising as a result of the client's use of the certification mark, certificate or TSC report contrary to the terms of this contract. The same applies to all claims by third parties against TSC /TSC Certification Body arising as a result of advertising statements made by the client.



Any cost arising from such issue will be billed to the client.

#### **A-4. Publication of certificates, certification marks and test reports**

TSC can publish the names of the certificate holders, tested products, audited systems, etc. for consumer information or if required by the certification procedure or by relevant law. TSC shall be entitled to grant authorized bodies (e.g. authorities, accreditation bodies or certification scheme owners) direct access to the certification-relevant documentation at any time.

All further information about clients, certified products and systems are subject to confidentiality unless the disclosure of such information is requested by court or an authorized body or otherwise mandatory by law or for the certification procedure. This obligation of non-disclosure 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 must 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 area, whichever is the longer.

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

All other legal provisions extending beyond shall remain unaffected.

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

#### **A-6. Violation of Testing and Certification Regulation**

TSC is entitled to claim payment of a contractual penalty of up to EUR 50.000 in each single case of each culpable violation of this Testing and Certification Regulation by the certificate holder. This applies specifically if a product labeled with the certification mark is offered for sale or marketed prior to the issue of the certificate, if unauthorized advertising takes place or if a certificate, certification mark or the CE marking with Notified Body number is used improperly.



Furthermore, the TSC is entitled to bill any costs or expenses born by a suspension or cancellation of a certificate.

The certificate holder is liable for costs charged to TSC by authorized bodies (e.g. regulatory authority, accreditation body or certification scheme owner) or costs directly incurred by the Certification Body or the test laboratory resulting from culpable violation on the part of the certificate holder, in particular violation of this Testing and Certification Regulation.

This applies in particular if TSC's activities were the result of instructions issued by a supervisory authority or similar instructions and if such instructions proved to be justified.



## **Module B1) Special regulations for product testing and certification**

In line with the TSC “Code of Ethics”, TSC reserves the right to reject applications for testing and/or certification on a case-by-case basis in particular if they are in conflict with legal requirements, the TÜV SÜD brand, the TSC quality standards and corporate image.

### **B1-1. Testing**

B1-1.1 The client shall submit a test order to TSC and supply the required test samples and documentation free of charge. TSC shall, at its own discretion, carry out the tests either in their own test laboratory or externally, and prepare a summary report.

B1-1.2 Following the test, TSC shall dispose of the test samples for a flat-rate charge per sample or, at the 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 a test is interrupted for more than one month, TSC may also return the sample or store it for a flat-rate charge for each month or part-month that elapses up to continuation of the test.

B1-1.3 TSC is entitled to make the test file and, if necessary, the test sample, accessible to authorized bodies (e. g. regulatory authority, accreditation body or certification scheme owner). Any agreement to the contrary is invalid.

B1-1.4 Transport, insurance, logistics, customs etc. of the sample(s) 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, damages due to transport issues etc.

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

B1-1.7 The evaluation of measurement results by TSC in order to make a statement of conformity, is done by taking into account measurement uncertainty as far as this is regulated for the respective test through regulatory requirements, applicable schemes and standards.



In this context, regulatory requirements have precedence over normative requirements. Contractual requirements from customer side are being observed only, if they are not in conflict to regulatory or normative requirements.

If none of these perqui-sites apply, measurement uncertainty is not taken into account during the evaluation of measurement results.

## **B1-2. Certification**

On issue of the first certificate, the certificate holder automatically becomes a TÜV SÜD certification-system partner and remains partner as long as at least one certificate is valid.

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

The following regulations apply to product certification that includes the issue of a certification mark or certificates that bore the right to carry the CE-Marking with the number of Notified Body:

**B1-2.1** A positive result of product testing and a positive result in the initial audit of the manufacturing site is required for issuing a license for the use of a certification mark. The continued use of the certification mark will depend on regular inspections (follow-up-service, see B1-2.7) and a valid certificate (respective license).

**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 controlling the use of the certification mark and ensure that the certification mark is 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.

Should a product certificate become invalid, the products listed on the certificate shall not be made available on the market using the certification mark or in case of CE-marking with the Notified Body number.





Holders of withdrawn or revoked certificates must 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 on their own cost.

- B1-2.3 TSC certification marks may only be used for products in conformity to the type or model successfully tested and the specifications included in the test report(s) or supplementary agreements. The required documents (e. g. certificate of conformity, operating and assembly instructions) are to be enclosed with the product in the appropriate language of the country of destination as not otherwise required by applicable laws.
- B1-2.4 Additional characteristics for individual certification marks
- If a product is manufactured at several manufacturing sites with different qualifications (e. g. with or without ISO 9001), the qualification level of the respective manufacturing site may only be used if different designations are given to the models. Otherwise only the level of qualification which applies to all manufacturing sites may be used for advertising.
- B1-2.5 Holders of certification marks must constantly monitor the manufacturing of products that have been awarded the certification mark to ensure conformance to requirements tested. They must also carry out the specified tests and inspections, document any complaints in connection with certified products and the correction of nonconformities. The Certification Body must be immediately notified of any changes made to the products, recalls or safety related incidents after certification. If the certificate concerned is to be maintained, the Certification Body may request the manufacturer to prove compliance with standards and/or codes of practice or may require an additional test to be carried out by a qualified test laboratory.
- B1-2.6 As a minimum requirement, every product must be identified by a non-destructible marking clearly indicating the name of the manufacturer or importer and type designation, so that the identity with the approved type with the serially manufactured product can be proved. If a product submitted for testing does not satisfy the test requirements and if products corresponding to this test sample have already been distributed for sale or have been the subject of a certification mark misuse, the modified test sample may only be certified if it bears another type designation.
- B1-2.7 Inspection of manufacturing sites in the case of certificates including authorization to use a certification mark (follow-up-service), market surveillance:



B1-2.7.1 In order to ensure maintenance of the product characteristics on which a certificate has been based, the Certification Body will regularly inspect manufacturing and testing facilities as well as quality assurance measures at the certificate holder's expense. Alternatively, for certification including the right to use a certification mark, random checks based on modules of the Council Decision 768/2008/EC may be agreed prior to issue of the certificate. If the quality management system of the respective manufacturing site has been certified by TSC, the follow-up-service may also be incorporated in the surveillance/re-certification audit pertaining to the system.

To ensure production quality, additional pre-shipment inspection may be arranged, in which samples from the products to be shipped are checked for conformity with the tested and/or certified type respectively the sample as provided.

B1-2.7.2 The certificate holder shall immediately inform the TSC of any relocation of a manufacturing plant, transfers of manufacturing plants to another company/company owner or changes in the manufacturing process that may affect the production of the certified product. In these and other special cases, the Certification Body may demand that the product is identified by a predefined control mark, in addition to the certification mark, so that products from different periods of manufacturing can be identified. Should there be a change in the manufacturing site, TSC must inspect and approve the new production facility before the products manufactured there can be labeled with a certification mark. The holder shall inform the TSC of any changes to the holder's details.

B1-2.7.3 The Certification Body is entitled to pick samples of products identified by a certification mark from the market for testing purposes. If the certificate requirements are not satisfied, e. g. because of unauthorized modifications that have resulted or may result in restriction, suspension or withdrawal of the related certificate, the certificate holder shall bear the costs of re-testing/inspecting the product and/or the manufacturing site.

B1-2.7.4 The certificate holder shall inform the Certification Body immediately of any damage or other events arising from certified products.

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

- a. For the same (main) certificate holder if he seeks to have certified a product under another name than that appearing on the (main) certificate,



- b. For certificate holders differing from the (main) certificate holders, if he also seeks to have a product certified under another or same name than that appearing on the (main) certificate. Prerequisite is the approval of the (main) certificate holders and their confirmation of equality of design of the product with that from the (main) certificate.

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



## **Module B2) Special regulations for management system auditing and certification**

### **B2-1. General**

TSC carries out management system (hereinafter referred to as "system") auditing, verification and certification in the non-regulated and regulated area, including according to EU Directives and EU Regulations.

TSC does not perform consultancy services relating to management system establishment, including customer-specific training and internal audits on the subject matter of the certification.

### **B2-2. Due date for audits**

The due date for the next certification, re-certification or surveillance audit is determined by the specific certification scheme; it is usually 12 months after the last day of the most recent regular audit carried out.

### **B2-3. Audit on site**

The customer or certificate holder shall ensure in a reasonable manner (contractually, if needed) that TSC is enabled to perform the audit on site at the certification-relevant premises and shall have access to these premises at any time

### **B2-4. Remote audits**

If permitted by the applicable specific certification scheme, TSC is entitled to conduct audits remotely by using a videoconferencing tool.

### **B2-5. Preliminary system assessment, pre-audit**

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

**B2-5.1** Based on management system documentation, areas of concern in the description of the system are pointed out in a preliminary assessment as compared with the requirements of the respective legal basis or standard. The client receives a report on the results of the assessment.

**B2-5.2** The aim of the pre-audit, the on-site and total scope of which is defined jointly with the client, is to draw attention to areas of concern in the system. The auditor informs the client of the results in a closing meeting; if requested, TSC prepares a pre-audit report. Only one (1) pre-audit may be carried out.



B2-5.3 Pre-audits are not allowed for TÜV SÜD South Asia under any standards as per NABCB. If pre-assessment is conducted in any means, such clients cannot be certified for next 2 years from the date of pre-audit.

## **B2-6. Certification procedure**

### **B2-6.1 Preparation for certification audit**

After the client has accepted in text form the quotation submitted by TSC, the client appoints an Audit Representative, who is responsible for the certification procedure; TSC informs the client of the auditors assigned (audit team or lead auditor). Requirements outlined in the applicable standards and regulations pertaining to unauthorized consultancy on the part of auditors are observed.

In order 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 availability, qualification, impartiality, etc.

In addition and in as far as there are no conflicting legal regulations, e. g. regulations under the data privacy law, clients can request appropriate background information on each member of the audit team.

### **B2-6.2 Certification audit**

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

#### **B2-6.2.1 Review and evaluation of management system documents / stage 1 audit**

Clients shall provide the Certification Body with all requested management system documentation concerning their systems (manual and, if necessary, further documents such as documented procedures, work test instructions, records, etc.) for review and assessment of compliance with the applicable Directives, Regulations and Standards. If the system is already certified by another body to the same or an appropriate standard then the client shall include a copy of the certificate with any scoping information, and details of the findings of the previous audit.



The Certification Body shall

- review the management system documentation,
- determine readiness for the stage 2 audit,
- review key performance or significant aspects regarding the scope and operation of the management system,
- collect necessary information regarding the scope and the related statutory and regulatory requirements of the client's operation,
- plan the certification (stage 2) audit, including confirmation of audit team requirements,
- check whether internal audits and management review are being performed and that the level of implementation substantiates the client's readiness for the stage 2 audit.

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

Where required by court order or other authorized bodies (e.g. regulatory authorities, accreditation body or certification scheme owner), TSC may request product samples in order to verify the implementation of the management system. Additional costs related to such additional testing shall be paid by the client.

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

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

#### B2-6.2.2 On-site certification audit / stage 2 audit

Prior to the stage 2 audit TSC shall provide the client with an audit plan, which has been agreed with the client. During the audit, clients demonstrate practical implementation of their documented procedures, while the auditors check and evaluate system effectiveness on the basis of the agreed legal provisions, standards or other criteria.



### B2-6.3 Certification

If all requirements of the applicable standard(s) are satisfied and all legal and official regulations observed, the Certification Body will issue a certificate, generally with a three (3)-year period of validity from the date of the certification decision, unless specific directives/schemes, regulations, standards or individual arrangement in the certification contract require other periods of validity.

### B2-6.4 Surveillance audit

Surveillance audits are conducted regularly (in general annually) during the validity period of a certificate and serve to verify the continued compliance with certification requirements (see above B2-2.).

For the preparation of the surveillance audit, the required documents, e.g. the valid management manual and a list of all effected amendments shall be submitted to the Certification Body upon request. In the surveillance audit, the auditor checks selected management system elements/processes to ensure that the management system continues to fulfill the requirements. The auditor will prepare a report.

### B2-6.5 Specific surveillance audits

If required by the specific certification scheme or in reasonable specific cases, TSC shall be entitled to conduct short-term or unannounced audits at the expense of the certificate holder. These audits do not compensate a regular surveillance audit according to B2-6.4.

### B2-6.6 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 addressed to clients to provide documents and records (hard copies or electronic media), and
- Other means of monitoring the performance of the certified client.



#### B2-6.7 Re-certification audit

Re-certification audits are carried out well in advance of certificate expiry to maintain the certification. If such a re-certification audit has been carried out successfully, a renewal certificate may be issued. Re-certification audits check overall system effectiveness by means of random sampling. To prepare for the audit, the valid management manual and all major amendments effected must be submitted to the auditor/audit team. In cases involving significant changes to the system, a stage 1 audit may first be required.

#### B2-6.8 Nonconformities

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

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

### **B2-7. Supplementary contractual terms**

**B2-7.1** The certificate holder is obliged to ensure that the use of the certificate or certification mark is according to the regulations of the TCR. The TSC is entitled to control the use.

The Certification Body reviews and evaluates complaints by third parties, issues causing concern or changes in the client's organization that comes to its knowledge. It informs the certificate holder of substantial changes to the certification and surveillance procedure.

**B2-7.2** The client shall satisfy all requirements pertaining to certification and supply all information required for auditing.

Certificate holders shall inform the Certification Body immediately, but at the latest within one (1) month in text form of all relevant changes in their systems and about any modifications in company structure/organization that affect the compliance of the management system, or any other significant events affecting compliance with the requirements for certification.





These changes may include but are not limited to:

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

In addition, certificate holders shall document internal and external complaints relating to their management systems as well as implemented corrective action and provide such information during the audit.

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

- B2-7.3 Changes in the standards, underlying codes of practise or other regulations shall apply as binding – under consideration of transition periods.
- B2-7.4 Integrated management systems must allow specific aspects of individual systems to be identified.



**Module C1) Special regulations and conditions for the field of medical devices by TÜV SÜD Product Service GmbH (TÜV SÜD PS)**

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

**C1 -> A Module A**

C1-1. -> A-1.4 The following provisions are inserted after the first section:

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

The second section is supplemented as follows:

This applies only to such cost that resulted from an extraordinary evaluation of such appeals or complaints. Applicant will be informed in advance about the bearing of costs for extraordinary evaluation.

C1-2. -> A-1.11 The following provisions are inserted as additional section:

The manufacturer or the authorized representative shall inform the Notified Body of every relevant vigilance information, in particular manufacturer incident report (MIR), field safety corrective action, field safety notice, periodic summary report, trend report.

The manufacturer or the authorized representative shall provide the Notified Body with a risk analysis for every field safety corrective action at the same time as he has provided it to the national competent authority. In addition, the manufacturer or the authorised representative is obliged to provide the Notified Body with a final vigilance report.

C1-3. -> A-2.2 Is replaced as follows:

The Certification Body shall be entitled to restrict, suspend or withdraw a certificate at its own discretion with or without previous notice, taking Section C1-5. -> A-2.6 into account.

Unless a hearing is impossible in view of the urgency of a decision or fails to take place within 14 days after text form notification, the certificate holder must be given the opportunity to provide a statement (hearing), before a decision is made.

However, on a case-by-case basis, an individual period may be defined for the hearing process.



TÜV SÜD PS adheres to its legal information obligations as a Notified Body.

This applies in particular, if:

C1-4. -> A-2.4 Is replaced as follows:

Certificate expiries, revocations, withdrawals, restrictions, and suspensions may be published; in such cases, continued advertising or other use of the TSC name/certificate/certification mark is prohibited.

If certificates are issued under the Directives/Regulations on active implantable medical devices, medical devices or in-vitro diagnostic medical devices, the relevant products shall not be marked and placed on the market(s) with the CE-Marking and the identification number of the Notified Body with immediate effect, unless the Certification Body has given permission in text form. An expired, revoked, or withdrawn certificate must be returned to the Certification Body. Licensing fees paid in advance will not be reimbursed; in the above case, all outstanding fees must be paid in full.

C1-5. -> A-5. Is replaced as follows:

Clients must retain any test samples and pertinent documents in their possession for a period of minimum 10 years (15 years in case of implantable medical devices) after certificate or marketing-approval expiry.

Documents pertaining to the certified system or product must be retained for at least 10 years (15 years in case of implantable medical devices) after expiry of certification.

Any legal regulations exceeding the above requirements (e. g. for certificates as per EU Directives and EU Regulations) shall remain unaffected by the above provision.

TÜV SÜD PS may, in particular, not be held liable for damage or loss, if clients fail or prove unable to provide the test sample/document returned to or retained by them in its original state.



**C1 -> B1      Module B1**

C1-6. -> B1-1.1 Is replaced as follows:

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

C1-7. -> B1.2.8 Is not applicable

**C1 -> B2      Module B2**

C1-8. -> B2-3.2.2

On-site certification audit / stage 2 audit

Prior to the stage 2 audit TSC shall provide the client with an audit plan, which has been agreed with the client.

During the audit, clients demonstrate practical implementation of their documented procedures, while the auditors check and evaluate system effectiveness on the basis of the agreed legal provisions, standards or other criteria.

C1-9. -> B2-3.4 Is supplemented as follows:

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

C1-10.-> B2-3.4 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 by critical subcontractors and/or a key supplier.



The certificate holder must contract with its critical subcontractors and/or key 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, TÜV SÜD may check and test recently produced adequate sample(s), preferably taken from the ongoing manufacturing process at the expense of the certificate holder.

Transport, insurance, logistics, customs etc. of the sample(s) 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 crucial 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).

C1-11.-> B2-3.5 Is not applicable

C1-12. -> B2-3.6

Is supplemented as follows:

An on-site-audit shall be carried out in advance of expiry of the EU certificate to allow for continuous certification and may be carried out as an off site audit.

The application for extension of the certificate shall be submitted 6 months prior to expiry of the certificate.

C1-13. -> B2-3.7 Second paragraph is not applicable

C1-14. The Certification Body 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, the Certification Body 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 inform the Certification Body as well of any planned change with respect to an ancillary substance incorporated in a device, in particular related to its manufacturing process.



In case that the manufacturer uses derivatives of tissues or cells of human origin the manufacturer must notify the Certification Body 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 the Certification Body must be adequately relevant and defined. The Certification Body is entitled to ask for additional information relating to such change at any time.

- C1-15. The manufacturer shall inform in due time the Certification Body of any plan for relevant changes to the quality management system. All information related to any planned change must be adequately relevant and defined. The Certification Body is entitled to ask for additional information relating to such changes at any time.