

GENERAL RULES FOR PRODUCT CERTIFICATION

1. GENERAL PROVISIONS

- 1.1** The Product Certification Body TSÚ Piešťany, š. p. (hereinafter referred to as „PCB TSU“) offers the customers applying for certification (hereinafter referred to as „client“) its services in the field of certification of products, as an evidence of the fulfilment of requirements stipulated in the relevant normative documents through an independent third part. PCB TSU does not provide the consulting related to design and development of products.
- 1.2** These General Rules apply to the conformity assessment procedures according to the „New Approach “ European Directives to which TSÚ Piešťany, š. p. has been notified as well as for the voluntary certification performed by PCB TSU.
- 1.3** After receiving the certificate the clients becomes a partner in the TSÚ Piešťany, š.p. certification system and remains as such at least until the expiration date of the certificate. In addition the certificate is valid only when all requirements of PCB TSU related to conformity assessment/certification are met.
- 1.4** Any documents, reports and certificates, provided by PCB COCV and the copyright contained therein shall be and remain the property of TSÚ Piešťany, š.p. and the client shall not alter or misrepresent the contents of such documents in any way.
- 1.5** PCB TSU is the contact place in case of any problems, complaints and appeals.
- 1.6** The certificates issued according to European Directives refer to the state of the relevant European Directive as amended in the time the certificate was issued. The CE label is within the scope of responsibility of persons listed in the respective European Directive. The certificates issued according to normative documents refer to the state of the relevant normative document as amended in the time the certificate was issued.

2. CERTIFICATION PROCESS

2.1 Submission and review of Application

- 2.1.1** PCB TSU requires the client to fill out the Application Form and enclose technical documentation. The Application shall be signed by the authorized representative of the client. The current version of Application Forms are available on the Internet, at <http://www.tsu.sk/index.php?l=en&p=3&ps=2>. If the product to be a subject of conformity assessment was or is a subject of a comparable contract at another Notified Body, the client shall inform PCB TSU of the fact prior to the contract conclusion.
- 2.1.2** PCB TSU conducts a review of the information given in the Application to ensure that:
- the information about the client and the product is sufficient for the conduct of the certification process
 - any known difference in understanding between the certification body and the client is resolved, including agreement regarding standards or other normative documents
 - the scope of certification sought is defined
 - the means are available to perform all evaluation activities
 - PCB TSU has the competence and capability to perform the certification activities

2.1.3 If the result of the review is positive, PCB TSU sends to the client the contract or „Confirmation of Application” and establishes the evaluation plan and evaluation team. It is always ensured that the persons, who have been involved in the design, supply and assembly or maintenance of the product in a way which is in a conflict with their impartiality or in the past two years were employed by a subject involved in the above mentioned activities, are not included in the evaluation team.

2.2 Product evaluation

2.2.1 The evaluation of the product (testing, audits, inspections) shall be basically performed in specified procedures which consider the technical complexity for the particular product groups and the extent of possible risk related to the use of products, and according to relevant specifications. The particular procedures are specified in the internal documentation of PCB TSU.

2.2.2 The client shall supply necessary test samples, including documentation to PCB TSU and quality management documentation if required. PCB TSU carries out the evaluation or assigns evaluation to units within TSÚ Piešťany, š. p. If external resources (except TSÚ Piešťany, š. p.) are intended to be used for evaluation activities, PCB TSU informs the client of the fact in advance.

2.2.3 PCB TSU informs the client of all non-conformities. If the client expresses interest in continuing the certification process, PCB TSU provides information regarding the additional evaluation tasks needed to verify that nonconformities have been corrected.

2.3 Review of evaluation results and certification decision

The certification decision is based on the review of the information and evaluation results gathered during the evaluation process, or on other important information. If the decision making is based on information outside the source of evaluation, the information is communicated to the client together with information on the evaluation process and the client is given a chance to comment it.

The certification decision is made solely by PCB TSU and it is guaranteed that the review and decision is made by the persons who have not been involved in the evaluation process.

2.4 Issue of certificate

In case of positive decision (if all nonconformities have been removed and corrective actions verified) the certificate is issued. The certificate is issued by PCB TSU (in case of the voluntary certification) or the TSÚ Piešťany, š. p. - Notified Body (in case of the conformity assessment according to „New approach “ European Directives). The certificate remains valid for five years, unless otherwise provided in the certification scheme or further applicable regulations/documents. The client is informed about the certification results (positive or negative) after certification decision.

2.5 Surveillance

- 2.5.1** To ensure the constant properties of the product on which the certificate is based, PCB TSU carries out regular inspections of the production and testing devices and the measures for quality assurance at the cost of the certificate holder.
- 2.5.2** The certificate holder shall provide the certification body with the option to inspect anytime, without a prior notification (in usual working hours) the production site, plants and warehouse (in foreign holders of the certificate also the warehouses of their Slovak representatives and subsidiaries, in importers also their warehouses) specified in the certificate and to take, free of charge, a necessary amount of products for which the certificate have been issued, for the purpose of inspection, even in case it is not holder's own production site and plant).
- 2.5.3** PCB TSU may take certified products from the market to perform checks. If the requirements, on which the certificate is based, are not met, e.g. due to unacceptable modifications which were or could be the reason to withdraw the certificate the certificate holder shall cover the expenses incurred at the product evaluation and/or at the inspection/audit of the production site.
- 2.5.4** The type and method of surveillance is given in the relevant certification scheme. In case of a conformity assessment procedure according to "New Approach" European Directive and the certificate was issued on behalf of TSÚ Piešťany, š.p. - Notified Body, the surveillance procedure is governed by the particular Directive. In other cases, the procedure is as mentioned in the following paragraph.
- 2.5.5** The common methods of surveillance applied by PCB TSU are as follows:
- on- site inspection – inspection of Factory Product ion Control
 - physical inspection and/or testing of samples taken from production line,
 - warehouse or market.
- Frequency is given in the particular certification scheme
- 2.5.6** In addition to regular surveillance, an irregular one may be performed :
- if the client falls to keep the conditions under which was granted the certificate or as a result of a complaint
 - if the client wishes to change the scope of the certificate
 - if changes announced within client's obligations are so extensive that the certificate has lost its applicability

2.6 Changes and modifications

The client shall inform PCB TSU, without delay, of changes that may affect its ability to conform with the certification requirements (e.g. changes of the legal or organizational status or ownership, organization and management, modifications to the product or the production method, major changes to the quality management system, production sites or contact address). This situation may make the continuation of the certificate dependent on the evidence provided by the manufacturer as for the observance of requirements under which the certificate has been awarded, or on an additional evaluation observance of requirements under which the certificate has been awarded, or on an additional evaluation.

3. TERMINATION, WITHDRAWAL AND SUSPENSION IF CERTIFICATION

3.1 The certificate shall terminate if:

- 3.1.1** the time specified in the certificate expired;
- 3.1.2** the certificate holder announced bankruptcy by the decision of court – the holder shall inform PCB TSU immediately about such decision;
- 3.1.3** the certificate holder interrupted his business activity and notified the state administration authorities and immediately also to PCB TSU;
- 3.1.4** the company was passed to another entity (so called “dissolution with successor”) or a third person takes over the rights of the certificate holder within the compulsory administration – the certificate holder shall inform PCB TSU immediately about the facts;
- 3.1.5** legal requirements, standards or normative documents, on which the certificate is based, have been changed or cancelled or invalid;

3.2 PCB TSU is entitled to suspend the certificate if:

- 3.2.1** The surveillance cannot be carried out in the regular time due to reasons caused by the client and at the same time the client asks to postpone the surveillance and PCB TSU decides positively after considering the reasons. The certificate shall be suspended until the regular surveillance is carried out on a fixed date. When the fixed time period expires, either the certificate shall be renewed provided the requirements for the product certificate validity are met, or the certificate shall be withdrawn.
- 3.2.2** The surveillance shows that the certificate holder does not apply anymore any of the conditions for the product certification and at the same time the certification body may rightly expect the remedy of variances within specified deadline, however no more than 3 months from the performance of the surveillance. If the date is not met due to reasons caused by the client, the certificate shall be withdrawn.
- 3.2.3** if the client requests the suspension (e.g. if the production is temporary halted)

3.3 PCB TSU is entitled to withdraw the certificate if:

- 3.3.1** there is misleading or other unacceptable advertisement through the certificate or this is misused, or legal provisions have not been observed when the product was put on the market;
- 3.3.2** variances were found in the product, the products do not conform with the certified product, or the major prerequisites of the certified product are not ensured anymore;
- 3.3.3** the certificate holder rejects in writing the amendments to General Terms and Conditions, these General Rules or price list of PCB TSU within six weeks after they came in force, or he had the opportunity to get acquainted with them;
- 3.3.4** the product no more meets the basic requirements which makes the consumer, user or third persons to be exposed to an indispensable risk, or the product fails to meet the purpose designed by the manufacturer and this deficiency is not removed within the specified time;

- 3.3.5** the inspection of production and testing facilities and warehouses was nor possible as well as the inspection/testing of the products, or the products were not made available within the specified time period; the same shall applied if a surveillance audit was not or could not be carried out despite a written notification within 4 weeks (unless otherwise provided), due to reasons caused by the certificate holder and at the same time paragraph 3.2 of these General Rules is not applied; or variances were not removed by means of relevant measures in an agreed time despite a written notification;
- 3.3.6** receivables of TSÚ Piešťany, š.p. have not been paid by the certificate holder within specified time period (it applies also in case of incomplete payments);
- 3.3.7** the certificate holder breach valid General Terms and Conditions or these General Rules and this breach is not just small negligence or trivial offence;
- 3.3.8** if corrective actions and/or suspension had no effect
- 3.3.9** the certificate holder requests the withdrawal or back out of the contract
- 3.4** PCB TSU shall not be liable for damages which incurred to the client/certificate holder if a certificate is not granted, is withdrawn, suspended or its validity is terminated.

4. DUTIES AND RESPONSIBILITIES

4.1 Duties and responsibilities of the certification body

- 4.1.1** PCB TSU shall within its procedures observe the requirements arising from effective legislation.
- 4.1.2** PCB TSU shall keep all information on products and client's organization confidential and use it only for the agreed purpose. The client may relieve PCB TSU from these confidential obligations.
- 4.1.3** Presented documents shall not be passed to third persons, unless required by law or by a judicial, governmental or other regulatory body.
- 4.1.4** Warranties given by PCB TSU to the client or to third persons shall be governed by Slovak law.
- 4.1.5** PCB TSU is obliged to supervise as possible the correct use of certification for the advertising purposes of the certificate holder.
- 4.1.6** PCB TSU keeps updated database of the certified products and provides information, on request, about the certificate validity and the certificate authenticity.
- 4.1.7** PCB TSU informs the certificate holders and the public about all changes which are to be introduced in its product certification requirements. Information is provided by means of :
- written notifications about changes TSÚ
 - Piešťany, š.p. website

4.2 Duties and responsibilities of the client/certificate holder

- 4.2.1** The client shall ensure by way of suitable control (e.g. factory production control related to the product or production process) that the product characteristics confirmed in the course of certification/conformity assessment are maintained thereafter and the changes communicated by the certification body are implemented. Records of the factory production control shall be submitted on demand to PCB TSU. These records shall be kept for ten years.
- 4.2.2** The client shall make all necessary arrangements for the conduct of the evaluation, surveillance, examining documentation and records and access to relevant equipment, locations, areas, personnel and client's subcontractors.
- 4.2.3** The certificate holder is fully responsible for the acceptable use of the certificate, conformity assessment reports and audit/inspection/test reports.
- 4.2.4** The client/certificate holder shall make claims regarding certification consistent with the scope of certification.
- 4.2.5** The client/certificate holder shall not use its product certification in such a manner as to bring PCB TSU and Notified Body into disrepute and shall not make any statement regarding its product certification that the certification body may consider misleading or unauthorized.
- 4.2.6** Upon suspension, withdrawal, or termination of certification, the client/certificate holder shall discontinue its use of all advertising matter that contains any reference thereto and shall take actions and measures as required by the certification body.
- 4.2.7** The client/certificate holder may reproduce and provide copies of the certification documents only in their entirety.
- 4.2.8** The client shall keep a record of all complaints made known to it relating to compliance with certification requirements throughout the validity period of the certificate and make these records available to the certification body when requested. The client shall take appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for certification and document the actions taken. After the certificate expires, the records shall be archived for ten years and shall be made available on request for PCB TSU.
- 4.2.9** The client shall allow representatives of an accreditation body or regulatory authorities to take part in audits/inspections as observers to assess/supervise the performance of PCB TSU or TSÚ Piešťany, š.p. - Notified Body.

5. COMPLAINTS AND APPEALS (REMEDIES)

- 5.1** The client may file appeals against the result of the certification process/decision made and file a complaint against the certification activities and procedures of PCB TSU. The client shall file appeals or complaint in writing, with reasoning and proofs for the claim.
- 5.2** Appeals or complaints shall be decided by the Head of PCB TSU. In case that the client does not agree with the resolution, the appeals or complains will be submitted to the special committee constituted by the General Director of TSU.

- 5.3** To ensure that there is no conflict of interest, personnel who was involved in the certification activities related to the complaint or appeal shall not be used by the certification body to review or approve the resolution or decide of a complaint or appeal.
- 5.4** Details are given in PCB TSU Internal Guidelines and made available on request for any interested party.

6. MEANING, RULES AND CONDITIONS FOR THE USE OF CONFORMITY MARKS

USING THE IDENTIFICATION NUMBER OF THE NOTIFIED BODY TSU, PIEŠŤANY š.p.

TSU, Piešťany š.p. is the Notified body with identification number 1299

- 6.1** The identification number 1299 is used together with CE mark. Authorization to use this identification number is granted only to the manufacturer or to his authorized representative („holder“). Authorization is granted the certificate
- 6.2** The identification number 1299 together with CE mark shall be referred in accordance with the EU legislation (EU Directive, Regulation (EC) of the European parliament and of the council, etc. .)
- 6.3** The holder is not allowed to use the identification number 1299 on products where the certificate has been removed or has expired. The identification number 1299 may not be used either during the period of suspended validity of the certificate.
- 6.4** The holder is not allowed to use the identification number 1299 in such a manner that might be considered by NB as misleading or unauthorized.
- 6.5** The holder may not cede the authorization for using the identification number 1299 to other legal person.
- 6.6** In the case of unauthorized / misleading use or misuse of the identification number 1299 or of the certificate granting the authorization for using this number, the Notified body must carry out following measures according to the degree of severity:
- written notice to the holder with request for immediate remedial measures and with caution, that the omission of remedial measures or repeated incorrect / misleading use or misuse of the identification number 1299 or of the certificate will result in withdrawal of the certificate or suspension the certificate
 - withdrawal of the certificate
 - disclosure of trespass
 - other legal action where appropriate
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7. FINAL PROVISIONS

- 7.1** These General Rules may become an integral part of the Contract concluded between PCB TSU and the client or the Confirmation of Application. The General Rules shall become binding and enforceable for parties upon the execution of the contract or the Confirmation of Application.
- 7.2** The General Rules remain binding throughout the contractual relationship and for the period of validity of certificates issued.

7.3 Contractual arrangements or terms in Confirmation of Application have priority over those in the General Rules.

8. EFFECTIVENESS OF THE GENERAL RULES

These General Rules for Product Certification shall come into force on January 1, 2014.
(update and supplement on March 23, 2018)

On behalf of TSÚ Piešťany, š. p. :

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Body