

Výskumný ústav dopravný, a. s. Veľký Diel 3323, 010 08 ŽILINA



Autorizovaná osoba SKTC-125 | Autorizovaná osoba SK05 | Notifikovaná osoba 1358 Authorized Body SKTC-125 | Authorized Body SK05 | Notified Body 1358

INTRODUCTORY INFORMATION FOR CUSTOMER

(manufacturer, importer, distributors, authorized representative)

VÚD, a.s., Certification Body for Products (COV) carries out assessment and verification of constancy of parameters of construction products, determination of type of construction products, verification of subsystems and conformity assessment of constituents of European railway system interoperability and products from unregulated area - voluntary certification (hereinafter "product"), the conformity assessment process to the requirements, to which are the national rules applied.

CUSTOMER/MANUFACTURER according to the type of product, its purpose of use and declared properties in relation to the technical specification (STN - Slovak Technical Standard, hEN - Harmonized European Standard, SK Technical Approval, TSI - Technical Specification for Interoperability, National Reference Document: Slovak Republic - National rules applied in relation with introduction of railcars on market according to cl. 14 of Directive 2016/797/EU in Slovak Republic) takes decision for applicable procedure of assessment/verification of conformity of product in accordance with relevant Act or directive, regulation. For the conformity assessment / verification is needed to submit to the COV full technical and other product documentation in scope of relevant legislation (government regulations, directives, EU regulations, TSIs, NRD).

Generally according to product type is submitted:

- drawing documentation,
- product description, product types, declared properties and product classes, purpose of use of the product,
- product data sheet, technical description of product,
- technological regulation,
- safety data sheet,
- type tests (if they are already performed),
- list of standards, regulations according to which the manufacturer declares parameters of the product,
- manufacturer's company standards for the product;
- prospectus, product catalogue,
- the quality management system certificate (if the manufacturer has a quality system established),
- regulation of factory production control (FPC),
- extract from the business register of the manufacturer,
- verified manufacturer's authorization to represent him in the certification process, etc. (*in the case of a importer, distributors, authorized representative*),
- In case of providing the test report by other manufacturer approval of the manufacturer for its use in the certification process.

Documentation shall be submitted in Slovak language (or Czech or English language), in case of translation by a customer, such document shall include date of issue and the name and signature of the customer.

Above mentioned documentation must be submitted to the COV for the process of:

- assessment and verification of constancy of performance of construction product,
- assessment/verification of constituent/subsystem of interoperability,

- assessment of non-designated product (voluntary certification),
- assessment of conformity with the national rules
- issue of a certificate/certificate of verification (hereinafter "certificate"),
- issue of NoBo file, DeBo file, EC Assesment Report, Report on assessment/verification of construction product or constituent/subsystem of interoperability, or Report on type determination of construction product (hereinafter "report"),
- issue a decision, statement.

A/ Procedure of assessment/verification of the product:

- 1. The COV provides basic information on procedure of assessment/verification to the customer at a face-to-face meeting, by e-mail or by telephone.
 - Information will be provided to the customer by the COV manager, division director, or COV staff.
- 2. The customer shall submit an application for assessment / verification of the product parameters / for conformity assessment by the Designated Body (DeBo) in two copies by post or email with technical and other product documentation. COV registers the application,
 - if the application is formally complete, the COV accepts the application, draws up a draft contract for the customer,
 - if the application is incomplete, the COV will notify the customer by letter / e-mail of the incompleteness of the application and ask for its completion,
 - after completing the application, the COV accepts the application, prepares a draft contract for the customer.

Application templates are available at <u>www.vud.sk</u>, (Certification / Certification Body), by e-mail or by personnel of COV.

- 3. The COV draws up a draft Contractual Relationship based on the received application. The contract/Order with General terms and condition, together with the confirmed application shall be sent to the manufacturer for signature. After signing by the COV, the signed document by both contractual parties will be sent to the customer (eventually also the advance invoice if this is stipulated in the contract). The COV will perform:
 - Assessment and verification of constancy of performances of construction product (1, I, 2 +, II +, 3, III), in accordance with applicable Act or government regulation,
 - verification / assessment of the constituent / subsystem of interoperability in accordance with the applicable Directive and the TSI module,
 - conformity assessment of a non-designated product (COV-1v1, COV-2v1), in accordance with the product data sheet, Department Technical Regulations (TPR) or other technical specification.
 - conformity assessment by the DeBo that the subsystem complies with the national rules
 notified in accordance with Article 14 for each Member State in which the subsystem is
 intended to be authorised to be placed in service in accordance with Directive (EU) 2016/797
 of 11 May 2016 on the interoperability of the rail system within the European Union as
 amended.
 - 4. If required by the regulation, the authorized personnel of the COV/IO VÚD, a.s. (based on the order) shall perform an initial inspection/initial audit of the FPC at the place of production on the basis of the inspection/surveillance/audit plan, subsequently will be performed assessments/verifications of product parameters and after a positive assessment/verification, the COV issues to the manufacturer:
 - CERTIFICATE in accordance with related Act, directive or regulation,
 - NoBo File, DeBo File, Report,

or decision not to grant a CERTIFICATE.

The procedure of assessment / verification of the product is stated in the relevant decree, directive, regulation, NRD or TSI. The COV will issue a certificates, relevant files / reports, or a decision not to issue after payment of the final invoice by the manufacturer / applicant / authorized representative.

- 5. The customer shall issue a Declaration of Performance in accordance with relevant regulation.

 Templates of the Declaration of Performance will be provided by the COV.
- 6. The COV / IO VÚD, a.s. shall perform at the place of production periodic continuous surveillances/audits of the FPC within the validity of the certificate within period stated in the Contractual Relationship concluded between the COV and the customer since previous inspection/surveillance/audit (in accordance with hEN, TSI or Directive/Regulation).

7. The customer is obligatory during the validity of certificate:

- employ declaration on parameters/conformity (hereinafter as "Declaration", only) solely in compliance with the requirements of the Directive / Regulation / Act;
- disallow improper use of the Certificate, Declaration and of the mark CE and improper referring to the objective materials in advertising materials;
- not to refer to the Certificate after being cancelled or expired in any declaration or advertising materials;
- the files/reports or the Certificates may be reproduced or published, advertised, etc., in any manner only as a whole, otherwise upon a previous written Contractor's approval.

8. The COV suspend or withdrawn the certificate, if will be find out:

- the manufacturer has not removed nonconformity of the product or of the FPC within specified period,
- the parameters of the essential product characteristics according to the results of planned tests are not in conformity with the parameters in the Declaration of Performance; or the results of the type test,
- the FPC does not consistently ensure the required level of production control;
- the manufacturer has changed the production technology or changed the raw materials, semi-finished products or components used, which have such a significant influence on the parameters or product characteristics that a new certification is required,
- the manufacturer has not allowed to the COV or its subcontractor to carry out audit/continuous surveillance or planned tests,
- the manufacturer requests to withdraw the certificate.

In the event of appeals to decision of withdrawing/suspending is the manufacturer entitled to apply the Ministry of Transport and Construction of the Slovak Republic/ Slovak office of standards, metrology and testing of the Slovak Republic for the reviewing process and decision of COV within 10 days from the day of the act. Reproduction of this document is permitted only in full. Reproduction of its part is permitted only with permission of the COV.

B/ Changes affecting certification:

Manufacturer duties (or his authorized representative):

Notice the COV without any delay modifications in design or in raw materials in manufacture/construction phase within performance of verification of product that might affect the result of verification. The data in documents shall indicate their validity and effectuality.

Notify the COV of any change in property, structure or management, requiring an alteration in the issued certificate within the term of its validity. The data in documents shall indicate their validity and effectuality.

COV duties:

At changing of certification requirements due to changes in legislation, technical specification, etc., the COV informs stakeholders in about the changes being prepared by written notification (by registered letter or email) or within continuous surveillances/audits.

Procedure for announcing the changes affecting certification:

- 1. The certificate holder shall inform the COV about changes that could affect the certification process in writing or by e-mail. The application / notification is submitted by applicant/client on a form "Change notification" which is available on www.vud.sk.
- 2. If the certificate holder inform the COV about changes that could affect certification process, the COV shall consider the impact of this change and decide on the appropriate action.
- 3. In the event that these changes do not have an affect on the issued certificate the COV shall notify the certificate holder in writing (on paper, e-mail).
- 4. In the event that in the product design, in ownership, in structure or in management is change detected of the certificate holder, or finding other information indicating that the product no longer corresponds to the requirements of certification scheme, the COV ask in writing the certificate holder to remedy the deficiencies within a specified time period commensurate with the seriousness of the identified deficiencies.
- 5. If the certificate holder provides confirmation that within set time limit he has accepted the changes, the COV will subsequently make changes to the certification documentation for the product in question
- 6. If the certificate holder informs the COV that he is not able to accept the changes within the set time limit, or if the conditions do not allow to do so, the certificate expires and the COV subsequently takes measures specified in the certification scheme, necessary modifications of formal certification documents, publicly available information in order to ensure that it does not provide any indication that the product is still certified.

C/ Procedure at complaints and appeals

- 1. Upon receipt of a formal complaint of a client to procedure of the COV or receiving of an appeal, the Head of COV or an authorized employee shall confirm whether the complaint or appeal concerns the certification activities for which he is responsible and, if so, will deal with them.
- 2. Complaints / appeals against the COV on the basis of the Head of COV or an authorized employee are registered in the book of Complaints and Appeals.
- 3. The processing of the decision on reasonable complaint / appeal must be carry out, review and approved by persons who have not been involved in the certification activities related to the complaint / appeal. Employees who have been employed at the client or have provided consultations for the client shall not be involved in the review or approval of the complaint / appeal within 2 years from the end of the employment or the provision of consultations.
- 4. Period for answer related to the complaint/appeal shall be up to 30 days from the date of receipt of the complaint/appeal to the COV, if is not agreed with the client (complainant / the person to appeal) another term.

- 5. The Head of COV or authorized employee who had not been involved in solving of certification activities shall decide whether the complaint/appeal is reasonable or not reasonable and after that send the decision in stated term to the client.
- 6. If the complaint / appeal is not reasonable the client is informed in writing (on paper, e-mail).
- 7. If the complaint / appeal is reasonable, the COV Head or an authorized employee who had not been involved in solving of certification activities in cooperation with the Quality Manager, shall analyze the causes of the complaint / appeal and the appropriate corrective and preventive action shall be taken and the actions are checked by the COV Head / DSCal Director. About the verification of corrective and preventive action is made report Protocol on verifying of complaint/appeal. The protocol is sent in writing to the client by employee authorized to act behalf of the COV in stated term in accordance with a relevant act.

In the event of appeals to decision of withdrawing/suspending is the manufacturer entitled to apply the Ministry of Transport and Construction of the Slovak Republic/ Slovak office of standards, metrology and testing of the Slovak Republic/ or in accordance with relevant legislative provisions for the reviewing process and decision of COV within 10 days from the day of the act.

D/ Particulars of the application for assessment / verification of the product parameters / for conformity assessment by the DeBo:

1. Name of the manufacturer / applicant, identification data of the manufacturer / applicant

Data are given according to the valid business register. If the manufacturer is represented by the applicant (importer, distributor, authorized representative), the applicant submits to the COV a verified authorization of the manufacturer.

2. Trade name and its types

The name of the product and its types, complementary material shall be indicated in accordance with the name under which the product will be placed on the market (product label, conformity mark).

3. Place of production

The address of the place of production shall be stated even if it is identical with the registered office of the manufacturer.

4. SK/Module/Area code

SK – is determined in accordance with Regulation No. 162/2013 Coll. (e.g. 0514, 1606, ...) – Construction products in accordance with the Act.

Module – is determined in accordance with relevant TSI and in accordance with the Commission Decision No. 2010/713/EU (e.g.: CB, CD, SB, SD, CH...) - Interoperability

Area code – is determined in accordance with Regulation No. 305/2011 (e.g. 12, 22, ...) – Construction products in accordance with the Regulation.

5. Characteristics of the product and purpose of its use

The manufacturer / applicant shall determine the precise definition of the intended use of the product and determine its variants (types).

6. List of related standards and regulations

The related standards according to which the COV shall perform the conformity assessment / verification and the regulations, technical specifications, manufacturer's factory standards according to which the manufacturer declares the product characteristics shall be provided.

7. Drawing of the product and variants (types)

From the drawing documentation shall be evident the structural design and material composition of the product. The drawings shall meet the requirements of the technical documentation and be legible.

8. Technological process of production

Short description of the technological process of production, or subcontracts in the production process.

9. Other documentation

Reports, test reports, calculations, procedures, technical sheets, safety data sheets, product labels, FPC regulations, declaration, etc. These documents shall be submitted in the original or copy. The copy shall include a written declaration by the manufacturer that it is identical to the original. The declaration shall be accompanied by the date and signature of the manufacturer.

10. Authorization to use results of test reports of another manufacturer

The authorization shall be provided to the manufacturer by the owner of the test report in order to show the agreement of his results to the applicant. The authorization must be submitted in the original, containing the identification data of both parties and the purpose for which it was provided.

11. Authorization of the manufacturer for assessment verification

An authorization is provided by the manufacturer to the applicant for the process of assessment/verification of the product according to the valid legislation in the Slovak Republic. The authorization must be submitted in the original, must contain the identification data of both parties and the purpose for which it was provided.

12. Certificate of quality management system (QMS)

A valid certificate of QMS not older than a year is submitted with the latest audit report, or confirmation from the certification company that issued certificate is valid and maintained and the certificate meets the requirements of standard under which the certificate was issued.

13.Extract of business register

Valid extract of business register is being submitted.

14. Providing confidential information

The COV will only disclose confidential information about customers or stakeholders to authorities that are bound by confidentiality under relevant Acts/Regulations.

15.Language of output documents of assessment/verification

The manufacturer (or authorized representative) shall specify in the application (TL COV 20 / TL COV 26/TL COV 200) in which language the output certification documents (Certificate and Reports) shall be drawn up. You can choose from Slovak, Czech (if applicable) or English.

If the manufacturer (or authorized representative) requests output documents in a language other as mentioned above, the COV may issue certification documents, but only on the basis of an officially certified translation that will serve to issue the certification documents.

16.Communication language with customer

The personnel of COV communicate with customers in Slovak (Czech) or English language.

E/ Certification fees

Information on certification fees and other fees related to the services of the COV is available on request at the Head of COV, Division Director and COV personnel.

Note:

Where the applicant submits applications separately for several variants (types) of a product, the documentation covering all types is sufficient to be submitted in one copy (with one application). The manufacturer shall indicate the reference at the relevant point of the application.

Žilina, 22.07.2021

Bc. Ľubomír Vlasko Head of COV