

# INSTRUCTIONS TO THE APPLICANT FOR THE PREPARATION OF A TECHNICAL FILE

for a product for which an application for granting / modification the Slovenian Technical Approval (STS) has been made

## 1. Introduction

The Slovenian National Building and Civil Engineering Institute (ZAG) as an Approval Body (OTS) has prepared these instructions for the applicant who submitted an application for granting / modification the Slovenian Technical Approval (STS), and has then determined with a verification procedure that the prescribed conditions for beginning work on this application have been met.

**Technical file:** is the applicant's technical documentation which it submits to the approval body. It should contain all information about the applicant, about the product and individual base materials used in its production, including information about their suppliers. The intended use of the product should be clearly defined. Besides the above, it also contains information about key production stages and about the existing state of the control of the production. Also included in the documentation are instructions for users (building designers, construction work contractors) for designing and installing the product.

The technical file can also contain information about the requirements from the design documents for the facility in which the product shall be installed and which the product must comply with. It should also contain all the required drawings, sketches, details, connections and joints and lists relating to the product.

The technical file can also contain evidence of already performed product tests and/or calculations.

The attached technical file is the basis for preparing the work programme at the beginning of the procedure for preparing / modification the STS.

## 2. Information for the Tehnical File

When preparing the technical file for this construction product, the applicant shall require the following documents or supporting documents or information or data (hereinafter: the Information):

a) General Information about the Manufacturer:
<ul style="list-style-type: none"> <li>- name, address,</li> <li>- phone, , e-mail,</li> <li>- contact person,</li> <li>- production plant(s),</li> <li>- any holders of concessions in Slovenia or abroad,</li> <li>- the manufacturer's authorisation to the Applicant <b>submitting</b> the application.</li> </ul>

### Note 1:

The above information **refers to the Applicant** submitting the application for granting/extending the STS, who is in most cases also the manufacturer of the construction product concerned. If this is not the case, this must be declared by indicating the manufacturer and the location of the production plant(s) where the component(s) of the construction product(s) are being manufactured. In this case, the Applicant must also submit **the manufacturer's written authorisation** which should state that they shall provide the Applicant and us with all the required information about their product and, if necessary, in accordance with the submitted application allow a visit to their production plant for the requirements of granting/extending the STS..

Such information is also required when the concerned construction product is composed of several parts that could each individually also constitute a separate construction product. In this case, the application

for granting the STS shall refer to the kit of products which is being placed on the market or brought into use as such.

**Note 2:**

It is generally not required to attach for the second time the required information about the relevant product and its envisaged use that was already provided with the application. But in all cases, the information should **match** the information that was previously provided in the application for granting / modification the STS.

**b) General Information about the Product**

- trade name,
- product type,
- technical description,
- intended use of the product and its declared essential characteristics/quality.

**Note 3:**

When **describing the product**, the STS Applicant provides the technical information about the construction product or the kit of products. They should indicate the type, form, size, materials from which the product is made, components, etc. If suitable, they should also state the limitations (e.g. what the product is not).

**Note 4:**

When **specifying the intended use** of the construction product or kit, the STS Applicant generally provides the following information:

- the type(s) and part(s) of construction works (buildings, infrastructure) in which the product or kit shall be installed or used;
- the method of installation, assembly, application or construction of the product or kit in the facility;
- other information about the use of the product or kit where it is suitable (e.g. climate conditions and similar);
- "category of use" of the product or kit if this is suitable according to the conditions on the market.

**Note 5:**

The construction product can be marketed to act independently as an individual product or a material or a **kit of products** of at least two individual components, which on their own can also constitute separate construction products. This can apply if the construction product-component:

- is manufactured by the manufacturer of the kit (namely, the STS Applicant themselves) themselves; or
- is manufactured by another manufacturer with whom the manufacturer of kit (namely, the STS Applicant themselves) has made an agreement; or
- is bought by the manufacturer of the kit (namely, the STS Applicant themselves) on the free market; or
- is bought by the buyer of the kit - often the contractor - on the free market.

**Note 6:**

The STS Applicant for the product or kit shall take full responsibility that the product or kit and their products-components are in accordance with **the awarded STS for the entire period of validity**.

*For a kit of products, this means that when initially defining the kit, they should also specify which of the four options relating to individual products-components from the previous note they have chosen. The STS granted for the kit shall accordingly specify all required elements for the kit as well as for each individual product-component of the kit (the system of assessing and verifying the constancy of performance, the manufacturer's tasks, the tasks of the certification body - if required, marking).*

*The holder of the STS **cannot transfer this responsibility** onto any other manufacturer of an individual part*

**Note 7:**

*In the event that a certain **product-component** from the kit already has suitable supporting documents about the characteristics (declaration of performance) and any required **markings** (e.g. CE mark obtained based on hEN or ETA), the manufacturer of the kit can use it in its kit without additional tests only, if the supporting documents testify to it complying with all the required characteristics/properties of the kit of products. It namely often transpired that an individual product, especially those supported by a standard, are too narrowly specified in terms of all their possible uses. In this case, the kit manufacturer shall have to together with the manufacturer of the product-component carry out additional tests and/or calculations and enable us in the process of a technical assessment to evaluate the adequacy of the entire kit for the intended use.*

**Note 8:**

*In some cases, to properly technically assess a construction product's or a kit's intended use it is also necessary to define its additional "accompanying" products or materials which are required for the installation of the kit into the facility. They are not a part of the relevant product or kit (being put on the market), but are required for testing, calculations and assessment of the product or a kit. In this case, it is called a **fictitious kit**.*

**Note 9:**

*When preparing the technical file or specifying its content, the following information, that describes the relevant product or kit and its intended use, might be required. The information will be used in the technical assessment to determine the adequacy of the product for its intended use. The **information** may consist of, for example:*

- sketches, designs, drawings or images (the most suitable, if it serves the technical assessment);
- any reports on already performed calculations, tests and similar assessments, including supporting documents about characteristics and production or quality control;
- information about the production process and used materials (own and any supplier's),
- information about own production plant(s);
- information about the relationship(s) with any suppliers of an individual product (or products) or materials(s), namely components for the kit of products;
- additional information that can be used for technical assessment.

**Note 10:**

*We ask the Applicant to include in the provided information for their product or kit, as well as for its component parts, also the information that constitutes their or a partner's **trade secret**. This information will be used exclusively for the procedure of preparing or making the technical assessment. This information shall not be disclosed in the granted STS. We shall keep such information along with other information in our technical documentation. Access to this documentation shall only be given to a body chosen by the Applicant which shall take part in the procedure of evaluating and verifying constancy of performance (for the requirements of performing testing, control and certification tasks) and, at a request,*

to the suitable inspection body (for controlling the process of placing the product on the market and into service).

**Note 11:**

If all prescribed conditions are met, the STS shall be granted **in Slovenian**. At the Applicant's request and expenses, the granted STS can be translated into other languages and also labelled as such.

Information required for preparing the technical file must generally be prepared or made **in Slovenian**. If the information is prepared in a non-Slovenian language(s), it shall be suitable without a need for a translation, if we decide so during the procedure for processing the application and preparing the STS. Otherwise, the Applicant shall have to prepare a suitable translation of such information into Slovenian.

**c) Other Information about the Product**

- technical information (in more detail - see Note 9) about individual product characteristics;
- a list of technical specifications used for identifying and discovering information about individual product characteristics;
- other information that might be of use for the technical assessment.

**Note 12:**

In general, such information is information required for evaluating the product's or kit's adequacy for the intended use which was not provided or was not required to be provided when submitting the application for the STS.

**d) Information about Product's Base Materials or Components of a Kit**

- general information (item 2);
- list of used components in the product or kit;
- list of used technical specifications
- technical information (Note 9) about the characteristics of an individual component of the product or kit for the purposes of identifying them.

**Note 13:**

If the product's or kit's manufacturer for **a certain component of a product** (namely base material) or **a kit** (namely the product-component) selects **several suppliers** and the component affects the characteristic(s) of the product or the kit which is used to assess the its adequacy for the intended use, the required information should be provided for each of them separately. We make the final assessment about the scope and significance of the effect.

**Note 14:**

**Information** which might already be in use for identifying the supplied base materials of the product or the components of the kit must be matched in terms of the type, composition and similar of an individual material or component and the significance it has in the product or the kit.

**Note 15:**

It is the OTS's right to assess the adequacy of the selected and provided information about the identification of the base materials of the product or components of the kit and their supporting documents. If such information or supporting documents do not ensure clear identification, even for any later intentions of the holder of the STS to change or replace an individual base material of the product or a component of the kit with a new one, at the beginning of the procedure for preparing the STS the OTS shall demand **additional identification tests** and support documents.

**e) Information about the Design and Use of the Product**

- information about planning the use of the product, namely the instructions for design;
- information about the procedures for using the product, namely instructions for preparing, transporting, storing, installing, final treatment, use and maintenance;
- information about any conditions the contractors performing work must meet when installing the product into the facility;
- other information that might be of use for the technical assessment.

**Note 16:**

*If reasonable depending on the type and nature of the product or the kit, the Applicant's or manufacturer's task is to determine a method for planning (**designing**) and using (**installation**) their product or kit. This means that the adequacy of the product or kit for its intended use is assessed based on the product or kit that was designed and installed according to the procedure specified by its manufacturer.*

**f) Information about Key Parts of the Manufacturing Process**

- description of the most important parts of the manufacturing process of the product or the components of the kit;
- a list of technical specifications used when carrying out the most important parts of the manufacturing process of the product or the components of the kit.

**Note 17:**

*The description of the key parts of the manufacturing process of the relevant product or individual components of a kit and, if reasonable also the kit itself, must be such that it allows determining the suitable methods, manners and places for implementing the production control system which shall prove and maintain the compatibility of the product or the kit with the requirements from the granted STS.*

**g) Information about the Factory production control (FPC) of the Product or Individual Components of the Kit and the Kit Itself**

- description of the Factory production control(FPC);
- designation of FPC performers, with responsibilities and tasks;
- list of internal organisational regulations/documents and resources supporting the FPC;
- the method of enforcing these regulations/documents in practice, namely for every individual;
- part of production that directly or indirectly affects the goals of the FPC;
- procedure(s) for handling non-compliant products;
- procedure(s) for implementing corrective and preventive measures;
- how the product traceability is ensured in individual stages of production and after their shipping;
- how training of personnel involved in the FPC is arranged;
- specifications, certification and take-over inspections and procedures for each of the product's base materials or components of the kit, with a scope and effect they have on the product or the entire kit, during their production as well as at the end of production, while stating/adding:
  - references to the used technical specification or internal regulation/document;
  - used take-over criteria;
  - used frequency of identification or measuring;
  - examples from existing documentation/records for managing the FPC,
- description of the system for calibrating all laboratory and other equipment that is used for implementing the FPC, while providing:
  - list of such equipment;

- used methods;
- used frequency of identification or measuring;
- procedures for preparing records and results

**Note 18:**

The Applicant must state the information about **any (non-)existing control of production** of their product or individual components of their kit and, if reasonable, the kit itself. Together with other information, the information on such a state will serve as a basis for preparing a comprehensive production control system which will be specified in the granted STS. It will define the tasks the Applicant or the manufacturer will have to perform for their own control of the product or the kit and its components. The adequacy of the implementation of this system will, if necessary, be checked within the defined scope and frequency by the body which is involved in the assessment and verification of constancy of performance and which the Applicant, at the time already be the holder of the STS, chose between the designated authorities.

**Note 19:**

The below **list of the main areas** of each **system** or the **organisation of the quality management** (QMS) can be helpful in determining the suitable information about the control of the production of the relevant product or kit and its components which will be needed as part of the procedure for preparing the STS for assessing the adequacy of any existing production control. Therefore the Applicant will have to answer and support their answers with documents all our questions from the questionnaire relating to QMS for the following areas:

1. general organisation of QMS;
2. work and take-over documentation;
3. production:
  - 3.1. means;
  - 3.2. input materials or products;
  - 3.3. process management and validation;
  - 3.4. managing non-compliant products;
  - 3.5. preserving products;
4. information for the market and from the market;
5. corrective measures;
6. preventive measures;
7. conclusions.

**Note 20:**

In the event the **information or supporting documents** provided in the technical file are **incorrect**, we shall inform the Applicant of this and call on them to replace such information and documents with new or correct ones.

**Note 21:**

Work on preparing everything related to the preparation of STS **is based on information** the Applicant first provides in their application for granting the STS and later submits in **the technical file**. Only then is it possible to begin preparing the STS based on a **contract** with the OTS.

**Note 22:**

*It is **prohibited to amend the information** the Applicant provided in the application or technical file, or to in any other way effect its amendment. If the Applicant nonetheless due to any reason wishes to amend the information or change the procedures that in any way effects the amendment of the provided information, they should consult the OTS. We shall assess what the effect such an amendment shall have on the already performed work of preparing the STS and the prepared programme of required testing. If the effect is such that a need arose to change the programme of work and testing required for the technical assessment, the amendment shall be implemented within the applicable provisions of the contract.*