

## Personal Protective Equipment Regulation Application Evaluation and Agreement Procedure

### A) DOCUMENT APPROVALS

No	Definition	Action	Approved By	Date
1	Document approved	Approval	Nurgül Çınar	10.04.2025
2	Translation approved	Approval	Songül Ağar	09.04.2025

### B) REVISION HISTORY

No	Definition	Reason	Approval Date	Release Date
7	The notification of application rejections to CIRCA has been added. The English version has been added.	Review & addition of the English version.	10.04.2025	10.04.2025

## 5. Purpose and Scope

The purpose of this procedure is to describe the procedures for receiving and evaluating applications from clients requesting certification in accordance with (EU) 2016/425 Personal Protective Equipment Regulation, preparing the offer-agreement, sending to the client, carrying out activities before conformity assessment.

## 6. Definitions

**Offer:** It is a document that contains the service request, the terms and prices of the service, and becomes a contract when signed mutually between SZUTEST and the prospective client.

**Application Fee:** The fee is charged by SZUTEST for the evaluation of the application and the preparations to be done before the conformity assessment activity.

**Inspection Fee:** The fee is charged for conformity assessment activities (inspection, document review, etc.) to be carried out on site or in the test laboratory on inspection-based modules.

**Audit Fee:** The fee is charged for conformity assessment activities (audit and document review) to be performed in quality system-based modules.

**Surveillance Fee:** The fee is charged for surveillance audits carried out during the validity period of the document within the scope of conformity assessment activities to be carried out in quality system-based modules.

**Company:** The applicant is a natural person or legal entity.

**Relevant Regulation:** 2016/425/EU Personal Protective Equipment Regulation

## 7. Responsibilities

The Technical Manager, Department Manager and Unit Manager are responsible for the implementation of this procedure.

## 8. Method

### 8.1. Application Assessment

All communication channels are open for receiving applications. Applications can be made electronically (fax, e-mail or through [www.szutest.com.tr](http://www.szutest.com.tr)), in person and by telephone, but the preliminary application made by telephone is processed after confirmation in writing.

Regardless of the source from which the applications come, they are evaluated by the Technical Manager after confirmation is received with the FR.PPE.01 Certification Application Form (2016/425/AB).

This evaluation is the control for completely filled of the FR.PPE.01 Certification Application Form (2016/425/EU) and the control of the compliance of the application scope with both SZUTEST and the relevant regulation.

Then, the following official documents are requested from the candidate client depending on the scope of the certification.

- Copy of trade registry gazette (If not available, copy of Chamber Activity Certificate)
- Tax board
- Signature circular
- Technical documentation regarding the product
- The technical file must contain an assessment and adequate analysis of the risk(s) and be prepared in accordance with the applicable requirements of the PPE Regulation.

The technical file must contain the following elements:

- A general description of the product
- Product design and manufacturing drawings
- The product's pictures, diagrams and definitions and explanations necessary to understand its operation.
- Instructions for use and care
- A list of harmonised standards that are fully or partially applied and a description of the solutions used to meet the essential requirements of the Regulation in cases where such standards are not applied,
- Test reports made by the company for the product and the raw materials of the product.
- Technical documentation on the approved type and a copy of the EU type examination certificate (for Modules C2 and D)
- Manufacturer's address and title, and if applied by an authorized representative also name and address
- A written declaration showing that the same application has not been made to another notified body,
- All information about the projected product category
- Quality system related documents (for Module D)

Application evaluation is carried out by qualified Technical Manager in the relevant field in accordance with PR.PPE.03 Qualification Procedure.

This evaluation is carried out to verify,

- The information in the application form and the documents submitted with the application,
- Whether the product is within the scope of the regulation
- Whether the product is within the scope of the applied standard
- Whether the product is categorized in accordance with the regulation
- Whether the application is within the scope of Szutest
- The suitability of SZUTEST for the relevant activity.

- Whether the product categorization is appropriate.

TL.PPE.10 Category Determination Instruction is used for product categorization.

If the manufacturer and the applicant organization are different from each other, approval of Annex 1 of the FR.PPE.01 Certification Application Form (2016/425/EU) is requested.

If the manufacturer and the applicant organization are different from each other, there must be a detailed contract between the organizations, defining all the issues, in addition to the FR.PPE.01 Certification Application Form (2016/425/EU) – Annex 1. The following minimum requirements are sought in this contract:

- Information on work to be done
- Responsibilities of the parties (commercial&technical)
- Which methods will be used to do the work
- Contract period

In case of an application that is evaluated as unsuitable, the client is notified in writing (e-mail etc.).

Application rejection reasons may be one or more of the following:

- Not within the scope of SZUTEST authority
- The applicant not possessing legal entity status.
- Unreliable business history
- Geographical location is not suitable (state of emergency)
- Working with the applicant would be contrary to the principle of impartiality.
- The applicant is involved in illegal activities
- The company has a history of repeated non-conformities
- No more than 30 days have passed since the document cancellation by SZUTEST
- The applicant already has an application to another approved body for the same product group

The maximum response time to the applicant is 5 working days.

The other notified bodies operating under the same harmonized legislation shall be informed via CIRCA by the Technical Manager within 30 days, if applicable, regarding the application rejections.

For applications from Russia and Belarus (e.g. countries), before the application is approved, the companies in question are checked to see if they are under embargo through the OFFICE OF FOREIGN ASSETS CONTROL Specially Designated Nationals and Blocked Persons List document. If the company name and/or product is not on the list, the application will be rejected.

First of all, the links to follow are as follows:

Lists for individuals, companies, etc.:

<https://home.treasury.gov/policy-issues/financial-sanctions/specially-designated-nationals-and-blocked-persons-list-sdn-human-readable-lists>

Lists for countries and products:

<https://www.sanctionsmap.eu/#/main>

## 8.2. Preparation of the Offer and Sending it to the Client

FR.PPE.02 Product Certification Service Agreement (2016/425/EU) is prepared by technical experts for companies whose application review has been completed and accepted. Information on which subcontractor laboratory will have the tests performed by SZUTEST is specified in the contract. Once the conformity assessment process has started, any changes that may be required in the contract are implemented by reaching an agreement with the client. A copy of the technical file is requested from the client depending on the scope to be documented. The price policy in Article 8.4 is taken as basis for the prices to be given in the contract.

Offers must include at least the following information;

- Commercial information of the prospective client (title, authorized person name, address, telephone numbers, tax office and tax number, e-mail address)
- Commercial and contact information of SZUTEST
- Scope of conformity assessment
- SZUTEST's obligations
- Obligations of the prospective client
- Preliminary preparations to be made by the customer before the review
- Fees
- Offer validity period
- Privacy commitment

After the prospective client approves the prepared offer, it becomes a contract and the relevant project is recorded via the App.Szu software.

## 8.3. Project opening

After the offer approved by the client becomes a contract, the work file is opened by the Technical Manager.

All relevant documents are placed in the created work file. The company name, the name of the service to be provided and the file number are written on the file according to the TL.11 Project Tracking and File Archiving Instruction and tracking is ensured.

## 8.4. Price Policy

EXPLANATION	PRICING (VAT must be added)
Application evaluation (Respiratory Protective Equipment)	150 Euro - 700 Euro
Application evaluation (Protective Clothing)	150 Euro - 900 Euro
Application evaluation (Face and eye protection equipment)	150 Euro - 500 Euro
Application evaluation (Foot and Leg Protective Equipment)	150 Euro - 500 Euro
Application evaluation (Equipment Providing Hand and Arm Protection)	150 Euro - 500 Euro
Application evaluation (Hearing Protective Equipment)	150 Euro - 500 Euro
Application evaluation (Head Protective Equipment)	150 Euro - 500 Euro
Application evaluation (Protective Equipment Against Falls from Heights)	150 Euro - 900 Euro
Application evaluation (Floating Equipment)	150 Euro - 500 Euro
Fee for evaluation of test reports if tests are provided by the client (Respiratory Protective Equipment)	350 Euro - 600 Euro
Fee for evaluation of test reports if tests are provided by the client (Protective Clothing)	350 Euro - 1200 Euro
Fee for evaluation of test reports if tests are provided by the client (Face and eye protection equipment)	350 Euro - 600 Euro
Fee for evaluation of test reports if tests are provided by the client (Foot and Leg Protective Equipment)	350 Euro - 750 Euro
Fee for evaluation of test reports if tests are provided by the client (Equipment Providing Hand and Arm Protection)	350 Euro - 600 Euro
Fee for evaluation of test reports if tests are provided by the client (Hearing Protective Equipment)	350 Euro - 900 Euro
Fee for evaluation of test reports if tests are provided by the client (Head Protective Equipment)	350 Euro - 600 Euro
Fee for evaluation of test reports if tests are provided by the client (Protective Equipment Against Falls from Heights)	350 Euro - 1200 Euro
Fee for evaluation of test reports if tests are provided by the client (Floating Equipment)	350 Euro - 1200 Euro
Module B	<b>500 Euro</b> - Technical documentation review man/day fee (number of man/day is determined by the number of products applied for)
	<b>1200 Euro</b> - Certification Fee
Module C2	<b>350 Euro</b> - Audit man/day fee
	Certificate Issuance Fee
	For 1-3 Products ( <b>1200 Euro</b> +VAT)
	For 4-7 Products ( <b>1100 Euro</b> + VAT)
	For 7-10 Products ( <b>1000 Euro</b> + VAT)
Module D	For 11 and more Products ( <b>900 Euro</b> + VAT)
	Initial certification <b>2000 Euro</b>
	Surveillance audits every year <b>1500 Euro</b>
Audit man/Day Fee	<b>350 Euro</b>
Requests for changes to the document and request for English documents	<b>150 Euro</b>
Document revision due to model addition	<b>400 Euro</b>
Certificate Usage Fee	<b>500 Euro</b>
Note 1: These fees do not include the audit team's transportation, accommodation, etc.	
Note 2: For applications regarding certification, the required amount of advance payment is received.	
Note 3: In case of using a subcontractor laboratory, the current prices received from the laboratory and the test fees may vary.	
Note 4: SZUTEST reserves the right to re-evaluate the fee at certain rates, subject to customer approval.	
Note 5: Euro offers are converted to TL at the contract stage based on the central bank selling rate of that day.	
Note 6: Application fees and test report evaluation fees vary depending on product model, color, size, type (for protective clothing).	

An 8% discount may be applied upon the written request of the applicant.

If the company has more than one campus within the scope of certification, each campus will be audited separately, but the application fee will be charged only once. For Module B+C2 or Module B+D applications, the application review fee is charged once.